COGENTIX MEDICAL INC /DE/

FORM 10-K
(Annual Report)

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

FORM 10-K

(Mark one)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2017.

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-20970

COGENTIX MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3430173**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5420 Feltl Road **Minnetonka, Minnesota**	**55343**
(Address of principal executive offices)	(Zip Code)

(952) 426-6140
(Registrant's telephone number, including area code)

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

Common Stock, $.01 par value	**The NASDAQ Capital Market**
(Title of class)	(Name of Exchange on which registered)

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 (§229.405 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting stock and nonvoting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of June 30, 2017 was $25,010,958.

As of March 20, 2018, the registrant had 60,905,666 shares of common stock outstanding.

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This annual report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created by those sections. For more information, see "Part I. Item 1. Business — Cautionary Note Regarding Forward-Looking Statements."

As used in this report, the terms "Cogentix," "Cogentix Medical," the "Company," "we," "us," "our" and similar references refer to Cogentix Medical, Inc. (formerly known as Vision-Sciences, Inc.) and our consolidated subsidiaries, and the term "common stock" refers to our common stock, par value $0.01 per share. References to "VSCI," "Vision-Sciences" or "Vision" generally refer to Vision-Sciences, Inc. and its consolidated subsidiaries prior to the consummation of the merger of Uroplasty, Inc. with and into Vision's wholly-owned merger subsidiary ("Merger Sub") on March 31, 2015 (the "Merger"), and sometimes also are used as references to our current, ongoing operations related to the historical VSCI that continue following the Merger. References to "UPI" or "Uroplasty" generally refer to Uroplasty, Inc., and its consolidated subsidiaries prior to the consummation of the Merger, and sometimes are also used as reference to our current ongoing operations related to the historical UPI that continue following the Merger and sometimes also are used as reference to our current, ongoing operations related to the historical Uroplasty that continue following the Merger.

This report contains the following trademarks, trade names and service marks of ours: PrimeSight ™ , Vision-Sciences®, EndoSheath®, Slide-On®, EndoWipe®, The Vision System®, and Urgent® for our neuromodulation product, Macroplastique® for our urological tissue bulking product, VOX® for our otolaryngology tissue bulking products, PTQ® for our colorectal tissue bulking product and Uroplasty® for Uroplasty LLC, one of our subsidiaries . This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

PART I

ITEM 1. BUSINESS

Overview of the Company

Cogentix Medical is a global medical device company headquartered in Minnetonka, Minnesota, with additional operations in New York, Massachusetts, The Netherlands and the United Kingdom. We design, develop, manufacture and market a robust line of high performance fiberoptic and video endoscopy products under the PrimeSight ™ brand that are used across multiple surgical specialties in diagnostic and treatment procedures, with our focus being on the Urology market. We also offer the Urgent ® PC Neuromodulation System, a device that delivers percutaneous tibial nerve stimulation ("PTNS"), for the office-based treatment of overactive bladder ("OAB"). OAB is a chronic condition that affects approximately 40 million adults in the U.S. The symptoms include urinary urgency, frequency and urge incontinence. We also offer Macroplastique ® Implants, an injectable urethral bulking agent for the treatment of adult female stress urinary incontinence that is primarily due to intrinsic sphincter deficiency. Outside the U.S., we market additional bulking agents: PTQ ® for the treatment of fecal incontinence and VOX ® for vocal cord augmentation.

The PrimeSight flexible endoscopes are used in conjunction with the proprietary sterile, single-use microbial barrier known as the EndoSheath ® Protective Barrier. Because the EndoSheath Protective Barrier is placed over the patient contact area of the scope, it eliminates the need for high-level disinfection between cases. This allows a scope to be ready in substantially less time than with conventional reprocessing. Key advantages to the PrimeSight Endoscopes when used with the EndoSheath Protective Barrier are reduction in costs and time associated with traditional reprocessing, increased practice productivity and patient throughput. In addition, the Protective Barrier isolates the endoscope from patient contact and protects the endoscope controls from contamination. The PrimeSight Endoscopy line also includes rigid endoscopes and highly portable peripherals such as the video system and stroboscopy unit.

We target the urology, urogynecology and gynecology market space for our PrimeSight Endoscopy line. We manufacture, market and sell our cystoscopy systems and EndoSheath protective barriers to urologists, urogynecologists and gynecologists.

We also manufacture, market, and sell our: (i) bronchoscopy systems (an endoscope that allows detailed viewing of the lungs) and EndoSheath Protective Barrier to intensivists, pulmonologists, thoracic surgeons, and other airway-related physicians, (ii) transnasal esophagoscopy ("TNE") systems and EndoSheath Protective Barrier to general surgeons, primarily bariatric and gastroesophageal reflux disease ("GERD") surgeons, and (iii) ear, nose and throat ("ENT") endoscopy systems to ENT physicians and speech pathologists.

Our Urgent ® PC Neuromodulation System ("Urgent PC System") is a U.S. Food and Drug Administration (the "FDA") cleared, minimally invasive nerve stimulation device designed for office-based treatment of OAB and the associated symptoms of urge incontinence, urinary urgency and urinary frequency. Using a small-gauge needle electrode inserted above the ankle, our Urgent PC System delivers electrical impulses to the tibial nerve that affects the sacral nerve plexus, a control center for pelvic floor and bladder function. Components of our Urgent PC System include a 34-gauge needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapy session, the physician or other qualified health care provider inserts the needle electrode above the ankle and connects the electrode to the stimulator. Typically, a patient undergoes a course of 12 consecutive weekly treatments, and, subsequently, a personal treatment plan of single treatments at a lesser frequency to sustain the therapeutic effect. We believe physicians prefer our Urgent PC System because it offers effective therapies for patients that can be administered in an office setting and provides the physicians with a profitable revenue stream. We believe patients prefer the Urgent PC System to pharmaceutical treatment options or surgeries because it is a minimally invasive treatment alternative that does not have the side effects associated with pharmaceutical treatment options or the adverse events associated with surgeries.

Macroplastique ® ("Macroplastique") is an injectable, urethral bulking agent for the treatment of adult female stress urinary incontinence primarily resulting from intrinsic sphincter deficiency. It is designed to restore the patient's urinary continence immediately following treatment. Macroplastique is a soft-textured, permanent implant injected, under endoscopic visualization, around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone elastomer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

Overview of Strategy for Calendar Year 2018 and Beyond

Our strategy for calendar year 2018 and beyond is to continue to leverage our assets to generate organic growth and to expand our product portfolio through acquisition or otherwise. In July 2017 we entered into an exclusive license with Promepla, a Monaco-based medical device manufacturer, to launch an Endo-Urology product line in the U.S. under the Cogentix brand. We launched this product line in January 2018. We currently have a distribution platform that includes 54 direct sales representatives in the U.S., with 51 sales representatives serving the Urology, Urogynecology and Gynecology market and three sales representatives serving the non-Urology markets of Airway Management and Industrial markets. Internationally, we have 16 direct sales representatives in various geographies and a network of distributor relationships. We believe this sales force has the capacity to add more products to their existing portfolio, and a key element of our strategy is to continue to leverage this distribution platform to generate revenue growth. We plan to expand our product portfolio through merger, acquisition, licensing or distribution opportunities. We believe that there are underperforming yet innovative assets available that we can add to our portfolio and grow at double digit rates. Examples of such assets include orphaned technologies within larger organizations, new technologies ready for commercialization with which our existing distribution platform can penetrate the market quickly, and existing products that are not meeting their potential due to undersized sales forces within their current company.

Our sales team's primary focus continues to be on the sale of our PrimeSight urology portfolio, our Urgent PC System, and our Endourology product line. We will emphasize the "always ready, always sterile" attribute of our PrimeSight systems utilizing the EndoSheath Protective Barrier, as well as their ability to enable physicians to safely and cost-effectively treat more patients in less time, thereby providing physicians with flexibility to better manage increased patient demand. We will continue to focus on generating greater patient and physician awareness of our Urgent PC system and on training physicians in the proper use and clinical benefits of our Urgent PC System for overactive bladder. We do not expect to see significant growth in our Macroplastique business because we believe it is a small, mature market that is competitively penetrated.

Pending Acquisition of the Company by Laborie

Our strategy for calendar year 2018 and beyond is premised on the Company's continued operation as a stand-alone entity, under the management of the current executive officers and the oversight of the current board of directors. The Company's strategy may change significantly in the event of our acquisition by Laborie Medical Technologies ULC, a global developer, manufacturer and marketer of medical technology and consumables used in gastrointestinal procedures and for the diagnosis and treatment of pelvic health in the Urology, Gynecology and Colorectal fields ("Laborie"). On March 11, 2018, the Company entered into an Agreement and Plan of Merger, under which Laborie will acquire all of the outstanding shares of our common stock for a total consideration of approximately $239 million (the "Merger Agreement"). Under the terms of the Merger Agreement, Laborie (through its wholly-owned subsidiaries LM US Parent, Inc. ("Parent") and Camden Merger Sub, Inc. ("Merger Sub")) has commenced a tender offer for all of the outstanding shares of our common stock for $3.85 per Share, net to the seller in cash , without interest and less any applicable withholding taxes (the "Offer"). Subject to the terms and conditions of the Merger Agreement, following the consummation of the Offer, Merger Sub will merge with and into the Company, and the Company will become a wholly-owned subsidiary of Parent (the "Merger").

Closing of the transaction is subject to certain conditions, including the tender of outstanding shares of our common stock that r epresent one share more than one half of all shares outstanding immediately prior to the time Merger Sub, for the first time, irrevocably accepts for payment shares validly tendered and not withdrawn pursuant to the Offer (the "Offer Acceptance Time") . Accelmed Growth Partners LP and Mr. Lewis Pell, who collectively beneficially own approximately 59.4% of outstanding shares of our common stock, have entered into Tender and Support Agreements in favor of Parent and Merger Sub, pursuant to which those stockholders, among other things, agreed to tender all shares beneficially owned by them to Merger Sub. T he Company currently anticipates the transaction will close in the first half of the second quarter of 2018.

Our Markets

Urology

Within the Urology market, we developed unique products for urology with our PrimeSight fiber and video cystoscopes, both utilizing the EndoSheath Protective Barrier. Our cystoscopes consist of two components: (i) a reusable flexible endoscope incorporating our proprietary design, and (ii) a proprietary, sterile, single-use EndoSheath Protective Barrier.

Our PrimeSight line includes our advanced digital, video-based flexible cystoscopes, a CCD-based video imaging endoscopy system, which features an integrated built-in LED light source and operates with our all-in-one PrimeSight video processor or DPU. We also market and distribute a fiber optic cystoscope.

Our Urgent PC System is an FDA-cleared, minimally-invasive, neuromodulation system that delivers PTNS for office-based treatment of OAB and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Macroplastique is an injectable, urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency ("ISD").

Airway Management and Industrial Markets

We develop unique products for the ENT, pulmonology/critical care and bariatric/gastrointestinal ("GI") specialties. We manufacture and market fiber and video laryngoscopes, which we refer to as ENT scopes. Our fiber and video ENT scopes can be used with or without the EndoSheath Protective Barrier, as they do not feature any working channels and are diagnostic only. We market and sell products for pulmonology using our fiber and video bronchoscopes. Our bronchoscopes utilize our EndoSheath Protective Barrier and are inserted through the mouth or nose and into the lower airway, providing visualization of the lungs and the ability to perform a variety of diagnostic and therapeutic procedures. We had also developed a digital, video-based flexible TNE endoscope, which utilizes our EndoSheath Protective Barrier. Our TNE system provides visualization of the esophageal anatomy via a sedation-free transnasal approach. Each of our video airway management scopes is a CCD-based video imaging endoscopy system, which includes an integrated built-in LED light source and operates with our all-in-one DPU.

Through our wholly-owned subsidiary, Machida Incorporated ("Machida"), we design, manufacture and sell borescopes to a variety of users, primarily in the aircraft engine manufacturing and aircraft engine maintenance industries. A borescope is an instrument that uses optical fibers or a small camera for the visual inspection of narrow cavities. Our borescopes are used to inspect aircraft engines, cast parts and ground turbines, among other items. Machida's quality line of borescopes includes a number of advanced standard features normally found only in custom designed instruments. We were the first to offer a flexible borescope with a grinding attachment, allowing users to "blend" or smooth small cracks in turbine blades of jet engines without disassembling the engine, saving our customers a significant amount of expense and time.

Our Products

We market the following products:

- PrimeSight Endoscopes (i.e., cystoscopes, laryngoscopes, transnasal esophagoscopes and bronchoscopes for medical use; and borescopes for industrial use) and Digital Processing Units ("DPUs");
- EndoSheath Protective Barrier;
- Urgent PC System;
- Macroplastique;
- Licensed products, including a full suite of endourological devices such as ureteral access sheaths, gravity irrigation lines and nitinol guide wires that are complementary to our urology product portfolio; and
- Other products and applications.

PrimeSight Endoscopes and PrimeSight Digital Processing Units for Medical Use

The PrimeSight Endoscopy family of products will encompass our state-of-the-art endoscopes, processors, accessories, as well as the endoscope-associated EndoSheath and EndoWipe products.

We have developed two visualization platforms for flexible endoscopy: fiber optic (4000 Series) and video (5000 Series and 7000 Series). Our 4000 Series fiberscopes contain advanced fiber optic imaging systems with high quality functional aspects, such as small diameter endoscopes and portability options, through the use of a battery-powered light source. Our lightweight, advanced, digital video-based endoscopes facilitate diagnostic and therapeutic procedures. Our small diameter video endoscopes contain a high resolution, tiny charge-coupled device ("CCD") camera at the tip of the scope, offering a sharp, vibrant, full screen image. The 7000 Series and 5000 Series video endoscopes also feature pioneering functional aspects, including the elimination of an external light source, the inclusion of an integrated light emitting diode ("LED"), industry leading small diameter sizes and robust durability.

Our 7000 Series and 5000 Series of PrimeSight video endoscopes are utilized with our multi-functional video processor or DPU. Unlike conventional video endoscopy "towers," we have integrated key peripherals into a single all-in-one unit, providing a more cost-effective design that allows for maximum portability in various health care settings. Our DPU provides high quality imaging along with workflow efficiency features and plug-and-play simplicity in operation. Users can easily capture video and images during various endoscopic procedures to patient files for future viewing. Our LCD provides full screen presentation with no truncation (framing) of image, commonly seen in other endoscope manufacturer's products. Along with our EndoSheath Protective Barrier, our DPU contributes significantly to portability by allowing bedside procedures where space is limited. Our DPU is also easily transported from facility to facility allowing physicians to perform video endoscopy even in the remotest locations. Our DPU includes a simplified user interface, programmable user preference controls, expanded on-screen notifications, and easy-to-maintain patient lists, all of which allow end-users to improve productivity and workflow by customizing the operation of the system to the day-to-day needs of the practice. Additionally, the system incorporates a "one-touch" integrated keyboard to ensure quick activation of functions, including full control of video playback options, such as frame-by-frame review or historical image comparison, both of which are ideal for patient progress review.

In the U.S., we sell our endoscopes and sheaths through our direct sales force. Internationally, our endoscopes and sheaths are sold primarily by distributors.

EndoSheath Protective Barrier

We have developed the EndoSheath Protective Barrier for use with our proprietary PrimeSight Endoscopes. The protective barrier is made with materials using our proprietary process that makes the barrier material lubricious (smooth), allowing the health care practitioner to easily install the disposable onto the endoscope. In addition, our protective barrier technology has an optically clear window that fits securely over the endoscope tip, providing a clear image. Once installed, the protective barrier offers complete isolation between the endoscope and the patient. After the procedure is completed, the barrier easily slides off and is removed from the endoscope and discarded.

Our EndoSheath Protective Barrier offers various-size working channels, unlike conventional flexible endoscopes, which have the working channel inside the endoscope itself, allowing our users to customize the scope to the procedure (e.g., diagnostic cystoscopy, which requires a small working channel, or therapeutic cystoscopy, which requires a larger working channel). This enables us to provide procedure-specific EndoSheath Protective Barrier without requiring physicians to purchase a new endoscope for a different procedure.

Within the Urology market, we offer urologists two EndoSheath Protective Barrier models for each of our fiber and video cystoscopes: a diagnostic model with a 1.5mm working channel size that provides enhanced patient comfort, and a therapeutic model with a 2.1mm working channel size that provides the same capabilities as conventional cystoscopes. Our protective barrier installs easily onto the cystoscope; it includes a covering for the endoscope and a working channel, which may be used for irrigation, suction and therapeutic tool delivery as well as an additional covering for the control body (handle), where the physician operates the cystoscope. The protective barrier is the only component that comes into contact with the patient and is discarded after each procedure.

Within the Airway Management market, we market and distribute two EndoSheath Protective Barrier models for our video TNE endoscope: a diagnostic model with a 1.5mm working channel size, and a therapeutic model with a 2.1mm working channel size. This unique feature of our EndoSheath Protective Barrier design provides gastroenterologists, ENT physicians, bariatric surgeons and others with two choices: a diagnostic model with a smaller overall diameter (due to a smaller working channel) for patient comfort, and a therapeutic model with a larger working channel, providing the same capabilities as conventional endoscopes.

Within the Pulmonology market, we market and distribute four EndoSheath Protective Barrier models for video and fiber bronchoscopy: a 1.5mm working channel, a 2.1mm working channel, a 2.8mm working channel (currently available outside of the U.S. only), and one without a working channel. We are currently seeking clearance to market the 2.8mm channel model in the U.S. The multiple sizes are necessary due to various procedures that are performed by pulmonologists and airway management physicians. Depending on the type of procedure being performed, a pulmonologist or airway management physician may use a very small diameter model, with or without a working channel, or a larger diameter model with a working channel.

In November 2015, the ECRI Institute (a nonprofit organization dedicated to bringing the discipline of applied scientific research to discovering which medical procedures, devices, drugs, and processes are best to improve patient care) listed inadequate reprocessing of flexible endoscopes and the potential for cross-contamination and patient infection as the number one most dangerous hazard on its list of the top-ten health technology hazards for 2016 and 2017. The use of our PrimeSight Endoscopy systems with the EndoSheath Protective Barrier allows health care providers to perform a simplified and efficacious reprocessing routine after their use of endoscopes, avoiding the elaborate – and sometimes inadequate - high level disinfection/sterilization routines required by the FDA for conventional endoscopes. The FDA requires that all conventional flexible endoscopes be reprocessed according to FDA-cleared manufacturers' instruction for use, whether they are used in hospitals, clinics or office settings. With our protective barrier, we are able to prevent the endoscope from coming into contact with the patient and organic material during the procedure, reducing the steps needed to reprocess flexible endoscopes from approximately 27 to three, thereby saving time, lowering costs and reducing the complexity of the process.

This design of our "always ready, always sterile" system, provides a multitude of benefits to health care practitioners, such as redefining health care economics by lowering per procedure costs through less capital equipment investment, less service and maintenance costs of capital equipment, less required use of toxic chemicals, increased patient scheduling flexibility and procedure volume, improved practice efficiency, and the capacity to reallocate unproductive labor resources from reprocessing activities to more productive tasks of patient care and throughput.

Urgent PC Systems

Our Urgent PC System is an FDA-cleared, minimally-invasive, neuromodulation system that delivers PTNS for office-based treatment of OAB and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence. For each 30-minute office-based therapy session, the physician or other qualified health care provider inserts the small-gauge needle electrode above the ankle and connects the electrode to the stimulator. Typically, a patient undergoes a course of 12 consecutive weekly treatments, and, subsequently, a personal treatment plan of single treatments at a lesser frequency to sustain the therapeutic effect.

For individuals with overactive bladder symptoms, the nervous system control for bladder filling and urinary voiding is incompetent. For OAB patients, signals to indicate a full bladder are sent early and frequently, triggers to allow the bladder to relax for filling are ineffective, and nervous controls of the urethral sphincter to keep the bladder closed until an appropriate time are inadequate. An individual with OAB may exhibit one or all of the symptoms that characterize overactive bladder: urinary urgency (i.e., the strong, compelling need to urinate), urinary frequency (i.e., repetitive need to void) and urge incontinence (i.e., involuntary loss of urine associated with an abrupt, strong desire to urinate).

When patients seek treatment for OAB, physicians normally start with conservative therapies such as biofeedback and behavioral modification (e.g., bladder training, scheduled voiding techniques and pelvic floor training). When, as is often the case, these therapies are not entirely successful, the next treatment of choice is drug therapy. If, as is the case with a majority of the patients, the drug therapy is ineffective or cannot be tolerated by the patient, the physicians suggest other treatments. For those patients, we believe our minimally invasive Urgent PC System treatments offer an alternative to the more invasive treatments such as surgery, implantation of a sacral nerve stimulation device, or injection of OnabotulinumtoxinA, a prescription drug marketed under the name of Botox, into the bladder.

Macroplastique

Macroplastique is an injectable, urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency ("ISD"). Urinary incontinence is defined as the involuntary loss of urine and is the result of either bladder or urethral dysfunction.

In 2007, the U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases reported that, depending on the definition of urinary incontinence used, 5% to 50% of the U.S. adult population suffers from some form of urinary incontinence. Per the American Urological Association, there are three types of urinary incontinence:

- *Stress Urinary Incontinence* — Stress urinary incontinence ("SUI") refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. SUI, the most common form of urinary incontinence among women, is estimated to affect almost 30 million women over the age of 18 in the U.S. (Hampel et al., 1997 and 2000 U.S. census data). SUI is caused by urethral hypermobility and/or ISD. Urethral hypermobility – abnormal movement of the bladder neck and urethra – can occur when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change can result from pregnancy, childbirth or age-related tissue deterioration. SUI can also be caused by ISD, or the inability of the urinary sphincteric mechanism to function properly. ISD can be due to congenital or age-related sphincter weakness or can result from damage to the sphincteric mechanism following pelvic trauma, surgery, neurologic diseases or radiation therapy.

- *Urge Incontinence* — Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate. Urge incontinence often occurs when neurologic problems cause the bladder to contract and empty with little or no warning, and is part of the overactive bladder syndrome .

- *Overflow Incontinence* — Overflow incontinence is associated with an over-distention of the bladder. This can be the result of an under-active bladder or an obstruction in the bladder or urethra.

Macroplastique is an injectable, urethral bulking agent that is designed to restore the patient's urinary continence immediately following treatment. Macroplastique is a soft-textured, permanent implant injected, under endoscopic visualization, around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone elastomer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

We have sold Macroplastique for urological indications in over 40 countries outside the United States since 1991. We began marketing Macroplastique in the United States in 2007.

Other Products and Applications

We also provide and market the following additional products and applications:

Macroplastique ® for Vesicoureteral Reflux . Outside the U.S., we market our Macroplastique products for treatment of vesicoureteral reflux - the abnormal backflow of urine from the bladder into the ureters or kidneys that is most prevalent in infants and children whose ureters did not fully develop. In this application, a bolus of the elastomer implant is injected around the orifice or valve where the ureter enters the bladder.

PTQ ® Implants . We also market our silicone elastomer implants under the name PTQ ® Implants outside of the U.S. as a minimally invasive product to address fecal incontinence (sometimes referred to as bowel incontinence). Our PTQ Implants offer minimally-invasive, soft-textured permanent implant for treatment of fecal incontinence. PTQ is implanted circumferentially into the submucosa of the anal canal, creating a "bulking" and supportive effect around the anal sphincter. PTQ is CE marked and currently sold outside the United States in various international markets.

Urgent PC for Fecal Incontinence . Our Urgent PC System is CE marked and sold outside of the United States for the treatment of fecal incontinence .

VOX ® Implants . In addition to urological applications, we market our silicone elastomer bulking material outside the United States to help improve speech and swallowing function in patients with unilateral vocal cord paralysis. The implants are sold for vocal cord rehabilitation applications under the trade name VOX ® Implants.

Licensed Products . In The Netherlands and United Kingdom only, we distribute certain wound care products in accordance with a distributor agreement. Under the terms of the distributor agreement, we are not obligated to purchase any minimum level of wound care products. We sell a variety of products to urologists through our U.K. facility. We also have an exclusive license to distribute a full suite of endourological devices in the United States, including ureteral access sheaths, gravity irrigation lines and nitinol guide wires that are complementary to our urology product portfolio.

Sales, Distribution and Marketing

Medical Products

The end users of our PrimeSight Endoscopy systems for medical use and related products primarily consist of urologists, pulmonologists, thoracic surgeons, gastroenterologists, bariatric surgeons, and ENT doctors in medical clinics, physicians' private offices, ambulatory surgical centers, and hospitals. Other physicians may also use our medical devices performing procedures in alternate settings. The end users of our Urgent PC System and Macroplastique products are primarily urologists, urogynecologists and gynecologists with significant office-based and outpatient surgery-based patient volume.

We market and distribute these medical products worldwide. In the U.S., we sell our products through a direct sales force. Outside the U.S., we sell our products through a combination of a direct sales force and a network of distributor organizations. Most of our distributors outside the U.S. also market and distribute products of other companies.

In the United States, we have a sales organization that consists of 54 direct field sales representatives, seven Regional Sales Directors, and a marketing organization to market our products directly to our customers. Of our 54 direct sales representatives, 51 specialize in the urology market and three specialize in the airway management and other markets.

Outside of the United States, we sell our Urgent PC System and Macroplastique products primarily through a direct sales organization in the United Kingdom, The Netherlands, Switzerland, Ireland, Belgium, Finland, Sweden and Denmark, and in all other markets primarily through distributors. Each of our distributors has a territory-specific distribution agreement, including requirements they may not sell products that compete directly with ours. Our PrimeSight Endoscopy systems and products are sold internationally primarily through national distributors. On July 26, 2017, we announced that we had acquired Genesis Medical ("the Genesis acquisition") based in London, United Kingdom. Genesis sells and markets a variety of products to urologists within the United Kingdom and has been the exclusive U.K. distributor of PrimeSight endoscopy systems since 2013.

We use clinical studies and worldwide scientific community awareness programs to demonstrate the safety and efficacy of our products. Publications of clinical data in peer-reviewed journals and presentations at professional society meetings by clinical researchers increase the scientific community's awareness of our products, including patient indications, treatment technique and expected outcomes. We provide a range of activities designed to support physicians in their clinical research.

Borescopes for Industrial Use

Our borescopes are sold directly by our subsidiary, Machida, and through a global network of independent sales representatives.

We regularly evaluate the effectiveness of all of our sales channels and may change them if we believe a different method would be more appropriate.

Third-Party Reimbursement

In the United States as well as in foreign countries, sales of our medical products depend in significant part on the availability of reimbursement from third-party payers. In the United States, third-party payers consist of government programs such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

1. coding, which ensures uniform descriptions of procedures, diagnoses and medical products;

2. coverage, which is the payer's policy describing the clinical circumstances under which the payer will pay for a given treatment; and

3. payment processes and amounts.

Whether a particular procedure qualifies for third-party reimbursement depends upon factors such as the safety and effectiveness of the procedure. Reimbursement may be denied if the medical device used was experimental or was used for a non-approved indication. We believe, based upon our knowledge and experience of third-party reimbursement practices and advice from consultants in this area, that third-party reimbursement is available for most procedures that utilize our products.

PrimeSight Endoscopes

Third-party payers use a variety of mechanisms to determine reimbursement amounts for procedures such as endoscopies. In most cases, payment is based upon amounts determined by the Centers for Medicare & Medicaid Services ("CMS"), a governmental agency under the U.S. Department of Health and Human Services. As part of its responsibilities, CMS assigns relative value units ("RVUs") to over 10,000 physician services. An RVU for a specific procedure is comprised of values for work, practice expense and malpractice insurance, and when multiplied by a conversion factor, represents a dollar value for a specific procedure.

CMS has multiple fee schedules to accommodate payment to the hospital, the ambulatory surgery center, and the physician. Physician services are reimbursed based on where the service is performed. If the physician performs the service in his or her office and the office bears the burden of overhead costs, the physician is reimbursed based on non-facility RVUs to accommodate the overhead costs. If the physician performs the service in a hospital or the ambulatory surgery center, the payment to the physician is lower, reflecting the physician work and malpractice expenses, but without the overhead since the facility bears that financial burden.

We believe that the number of procedures performed in non-facility settings will increase. As these procedures move to non-facility settings, physicians will have to contend with the cost and effort required to reprocess conventional endoscopes. We believe our PrimeSight Endoscopy portfolio will provide an economically beneficial alternative to the use of conventional endoscopes based upon the provider not having to purchase multiple endoscopes or expensive disinfecting equipment and supplies, and not having to spend his or her valuable time cleaning endoscopes. We believe that with over 100 million people in the U.S. over the age of 50, the number of endoscopic procedures that physicians will perform will increase. Our EndoSheath technology, combined with the resource-based system for setting values for physician services, represents a sound economic solution for physicians to perform diagnostic and therapeutic procedures in their offices.

EndoSheath Protective Barrier

Most third-party payers do not reimburse health-care providers separately for the cost of our sterile, single-use EndoSheath Protective Barrier products.

Urgent PC System

Sales of our Urgent PC System are significantly influenced by the availability of third-party reimbursement for PTNS treatments. Effective January 2011, the American Medical Association granted a Category 1 Current Procedural Terminology ("CPT") code for PTNS treatments.

As of November 2017, all regional Medicare carriers, with approximately 59 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers insuring approximately 163 million lives provide coverage for PTNS treatments.

Outside of the U.S., our Urgent PC System treatments are reimbursed under an available reimbursement code in The Netherlands. In other countries in Europe, there are no specific reimbursement codes for Urgent PC System treatments, and generally reimbursement is from fund-holder trusts or global hospital budgets.

Macroplastique

We believe there are appropriate CPT codes available to describe the use of Macroplastique to treat adult female stress urinary incontinence due to intrinsic sphincter deficiency in the United States. Outside of the United States, government managed health care systems and private insurance control reimbursement for devices and procedures. Reimbursement systems in international markets vary significantly by country. In the European Union, reimbursement decision-making is neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government. Reimbursement for Macroplastique has been successful in multiple international markets where hospitals and physicians have budgets approved by fund-holder trusts or global hospital budgets.

Manufacturing and Suppliers

We have FDA-registered manufacturing facilities in Minnetonka, MN, Westborough, MA and Orangeburg, NY where we manufacture all of our tissue bulking products, Endosheath products and PrimeSight products, respectively. Our facilities use dedicated heating, cooling, ventilation and high efficiency particulate air filtration systems to provide cleanroom and other controlled working environments when required. Our trained technicians perform all critical manufacturing processes in qualified environments according to validated written procedures. We use qualified vendors to sterilize our products using validated methods.

PrimeSight Endoscopes

We manufacture our flexible endoscopes for medical and industrial use at our facility in Orangeburg, NY, using purchased components and subassemblies as well as certain proprietary components we or our subcontractors produce. Some purchased components and subassemblies are available from more than one supplier. For most of our purchases, we have no long-term agreements with our vendors or suppliers, and we purchase our components and supplies on a purchase order basis. For certain critical components, we have long-term supply arrangements with third parties.

EndoSheath Protective Barrier

We currently manufacture our EndoSheath disposable barriers at our facility in Westborough, Massachusetts using raw materials, molded parts, and components purchased from independent vendors, some of which are manufactured to our specifications. We also design and build our own production machines and tools.

Most components we purchase are available from multiple sources, with the exception of certain key components that are supplied to us by key suppliers, with whom we have long-term supply arrangements, but no long-term supply agreements. We purchase our components and supplies on a purchase order basis and seek to maintain adequate inventory levels of such components to prevent supply disruptions. We contract with third parties for the sterilization of all of our EndoSheath disposables.

Urgent PC System

We subcontract the manufacturing of both the stimulator and lead set components of our Urgent PC System. Each component is manufactured by a single-source supplier meeting our quality and other requirements. Although we believe our sources of supply could be replaced if necessary without undue disruption, it is possible that the process of qualifying new suppliers could cause an interruption in our ability to manufacture our products, which could have a negative impact on sales.

Macroplastique

Macroplastique and its related products VOX and PTQ are manufactured in the Minnetonka, MN facility using raw materials, molded parts and proprietary process methods. The accessory products, including sterile needles and an administration device, are contract manufactured. The bulking agent is manufactured in onsite cleanroom facilities. Due to the nature of the materials used and the regulatory obligations for the product, two key materials are provided by qualified single source suppliers. We believe that the sources of the key materials could be replaced with minimal disruption to manufacturing; however, it is possible that the process of qualifying a new vendor or equivalent material could cause an interruption that could negatively impact sales.

Competition

PrimeSight Endoscopy and EndoSheath Protective Barrier (Flexible Endoscopes and Disposables)

We believe that the primary competitive factors in the medical device market for flexible endoscopes include safety and effectiveness, the optical quality of product offerings, product reliability, price, physician familiarity with the manufacturer and its products, ease of use and third-party reimbursement policies.

Our ability to compete is directly affected by several factors, such as our sales and marketing capabilities, our product development and innovation capabilities, our ability to obtain required regulatory clearances, our ability to protect the proprietary technology which our products are based upon, our manufacturing skills and our ability to attract and retain skilled employees.

We believe our proprietary PrimeSight Endoscopes and EndoSheath platform currently provides us with a competitive advantage over our competition. Currently, most of our competitors sell endoscopes that require elaborate and time-consuming reprocessing procedures. Some newer competitors sell disposable endoscopes that sacrifice optical quality and functional performance in favor of single-use safety. Our unique platform provides the safety of a sterile, single use device as well as the performance of a high-quality reusable device.

Our current and future medical endoscopes face global competition, primarily from companies such as Olympus, Pentax, and Karl Storz. Some of our competitors and some potential competitors may have greater financial resources, experience, sales and marketing personnel and capabilities, research and development, and manufacturing personnel and capabilities than we do. In addition, any company that is able to significantly redesign conventional flexible endoscopes to simplify or significantly improve their reprocessing, may result in competition for our products.

In our industrial markets, we believe that our over 35-year history of product effectiveness, ease of use, product reliability and competitive pricing are the principal competitive factors contributing to our success. Among our competitors are Olympus, Lenox, and Karl Storz Industrial.

Urgent PC System

We believe our Urgent PC System offers a minimally invasive, office-based treatment alternative in the continuum of care for OAB patients. Conservative therapies such as dietary restrictions, pelvic floor exercises, bladder retraining, biofeedback, and anticholinergic drugs usually precede our Urgent PC System treatments. Anticholinergic medications that could be seen as competing with PTNS include Detrol ® and Toviaz ® (both by Pfizer Inc.); Ditropan ® (Johnson & Johnson); Enablex ® (Novartis AG); Sanctura ® (Allergan, Inc.) and Vesicare ® (GlaxoSmithKline plc). These medications treat symptoms of OAB, some by preventing unwanted bladder contractions and others by tightening the bladder or urethra muscles or by relaxing bladder muscles. We believe our Urgent PC System normally is prescribed after these drugs are used but discontinued because they were ineffective or had unwanted side effects. In the case of anticholinergic medications, the side effects often include dry eyes, dry mouth, constipation, cognitive changes and blurred vision.

Allergan, Inc. began to commercialize Botulinum toxin A (Botox ®) for OAB treatments in calendar 2013, and this treatment is a direct competitor for our Urgent PC System following unsuccessful drug therapy. In this procedure, Botox is injected into the bladder wall, often with approximately twenty individual injection sites, to numb and mask the symptoms of urgency and frequency.

Medtronic's InterStim ® neuromodulation device, which stimulates the sacral nerve, requires surgical implantation of a lead near the patient's spine in addition to a battery powered stimulator in the buttocks. In contrast, our Urgent PC System allows minimally invasive stimulation of the sacral nerve plexus via a small needle electrode in the ankle in an office-based setting without any surgical intervention. Medtronic formally launched a competing PTNS technology in 2016, the NURO ™ system. Other companies may also enter the U.S. market with neuromodulation or other products for the treatment of OAB.

Macroplastique

Injectable urethral bulking agents for stress urinary incontinence competing directly with Macroplastique in the United States include: Durasphere ® manufactured by Carbon Medical Technologies, Inc. and distributed by Coloplast Corp; and Coaptite ® manufactured by Merz Aesthetics, Inc. and distributed by Boston Scientific Corporation. We believe Macroplastique competes effectively against these products because it will not degrade, resorb or migrate, has no special preparation or storage requirements, and is safe and effective for treating adult female stress urinary incontinence.

Outside of the United States, Deflux ® (manufactured by Q-Med AB, a wholly owned subsidiary of Galderma S.A., and distributed by Salix Pharmaceuticals, Ltd.) and Bulkamid ® (manufactured by Contura, Inc., Denmark and distributed by SEP Pharma) compete with Macroplastique for vesicoureteral reflux and SUI, respectively.

Government Regulation

The testing, manufacturing, promotion, marketing and distribution of our medical products in the United States, Canada, Europe and other parts of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and other analogous agencies. Unlike our medical products, the manufacturing of our Machida industrial scopes is not subject to direct government regulation.

United States

Our products are regulated in the United States as medical devices by the FDA under the Food, Drug and Cosmetic Act ("FDC Act"). Noncompliance with applicable requirements can result in, among other things:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, or total or partial suspension of production;
- denial of requests for 510(k) clearance or pre-market approval of new products;
- withdrawal of existing approvals; and
- criminal prosecution.

Depending on the degree of risk posed by the medical device and the extent of controls needed to ensure safety and effectiveness, there are two pathways for FDA marketing clearance of medical devices. For devices deemed by FDA to pose relatively less risk (Class I or Class II devices), manufacturers, in most instances, must submit a pre-market notification requesting permission for commercial distribution, known as 510(k) clearance. Devices deemed by FDA to pose the greatest risk (Class III devices), such as life-sustaining, life-supporting or implantable devices, or a device deemed not to be substantially equivalent to a previously cleared 510(k) device, require the submission of a pre-market approval (PMA) application. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

Our PrimeSight flexible endoscopes and accessory products have been classified by the FDA as Class II devices and EndoSheath Protective Barrier products have been classified by the FDA as Class II sterile devices. We have received FDA clearance for all of our endoscopes and accessory products that require clearance with the exception of the bronchoscope 2.8mm EndoSheath model, for which we are currently seeking FDA clearance. We expect that we will be required to file 510(k) Pre-market Notifications for each additional endoscope that we develop in the future.

In October 2005, our initial version of the Urgent PC System received 510(k) clearance for sale within the United States. In July 2006, our second generation Urgent PC System received 510(k) clearance for sale within the United States.

In October 2006, we received FDA pre-market approval for the use of Macroplastique to treat female stress urinary incontinence in the United States. As part of the FDA-approval process, we are conducting a customary post-market study.

After a device is placed on the market, numerous regulatory requirements apply. These include:

- Quality System Regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the 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 such malfunction were to recur; and
- notices of correction or removal, and recall regulations.

The FDC Act requires that medical devices be manufactured in accordance with FDA’s current Quality System Regulations, which require, among other things, that we:

- regulate our design and manufacturing processes and control them by the use of written procedures;
- investigate any deficiencies in our manufacturing process or in the products we produce;
- keep detailed records and maintain a corrective and preventative action plan; and
- allow the FDA to inspect our manufacturing facilities on a periodic basis to monitor our compliance with Quality System Regulations.

European Union, Canada and Other Regions

The European Union has adopted rules that require that medical products receive the right to affix the CE mark, which stands for Conformité Européene. The CE mark demonstrates adherence to quality standards and compliance with relevant European medical device directives. Products that bear the CE mark can be imported to, sold or distributed within the European Union.

We have received CE certification from Underwriters Laboratories UK for conformity with the European Union Medical Devices Directive allowing us to CE mark our endoscopes and accessory product lines currently sold in Europe.

Our initial version of the Urgent PC System received CE marking in November 2005. Our second generation Urgent PC System received CE mark approval and approval from the Canadian Therapeutic Products Directorate of Health in June 2006.

We received the CE mark approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for VOX in 2000 for vocal cord rehabilitation and; for PTQ in 2002 for the treatment of fecal incontinence.

Under the Canadian Medical Devices Regulations, all medical devices are classified into four classes, Class I being the lowest risk class and Class IV being the highest risk. Class I devices include among others, devices that make only non-invasive contact with the patient. Classes II, III and IV include devices of increasingly higher risk as determined by such factors as degree of invasiveness and the potential consequences to the patient if the device fails or malfunctions. Our current endoscopes and accessory products sold in Canada generally fall into Classes I and II. All Class II, III and IV medical devices must have a valid Medical Device License issued by the Therapeutic Products Directorate of Health Canada before they may be sold in Canada (Class I non-sterile devices require only an establishment license, which we have obtained and maintain on an annual basis). We have obtained applicable Medical Device Licenses in Canada for all of our currently marketed endoscopes and accessory products.

Quality Standards

In August 2005, the quality system certification at our facility in Natick, Massachusetts was updated to establish conformance with International Organization for Standardization ("ISO") 13485: 2003 and continued conformance with Medical Devices Directive ("MDD") 93/42/EEC and the Canadian Medical Device Regulations ("CMDR"). In September 2015, we completed a facility transfer from Natick, Massachusetts to Westborough, Massachusetts. All regulatory and quality standards have been met, allowing ongoing operations for domestic and international distribution.

In April 2007, our facility in Orangeburg, New York successfully completed an expansion audit and we were awarded ISO 13485 certification for this location. This certification allowed us to start shipping scopes from our facility in Orangeburg, New York, in addition to shipments from our facility in Natick, Massachusetts. The Westborough and Orangeburg facilities are registered with the FDA as medical device manufacturers. As a result, these facilities are subject to the FDA's Quality System Regulations, which regulate the design, manufacturing, testing, quality control, and documentation procedures. We are also required to comply with the FDA's labeling requirements, as well as its information reporting regulations.

Our manufacturing facility in Minnetonka, Minnesota and our manufacturing processes at that facility have been inspected and certified in compliance with ISO 13485, applicable European medical device directives and Canadian Medical Device Requirements.

The export of medical devices is also subject to regulation in certain instances. Our compliance with these various regulatory requirements is monitored through periodic inspections by the FDA and audits by independent authorities to maintain our ISO 13485, Canadian Medical Device Requirements and European medical device directives status. We routinely update our systems to comply with changes to applicable regulations such as the recent changes to the European medical device directives, as amended by 2007/47/EC.

In addition to the three-year ISO certification audits, we undergo annual surveillance audits to confirm that we are properly maintaining our quality system. This quality system has been developed in accordance with the ISO to ensure that companies are aware of the standards of quality to which their products will be held worldwide.

Patents, Trademarks and Licenses

We seek to establish and protect our proprietary technology using a combination of patents, trademarks, copyrights, trade secrets, and nondisclosure and non-competition agreements. We file patent applications for patentable technologies we consider important to the development of our business based on an analysis of the cost of obtaining a patent, the likely scope of protection, and the relative benefits of patent protection compared to trade secret protection, among other considerations.

As of March 2018, we hold 24 U.S. patents, and we have three U.S. patent applications pending. In addition, we have 72 foreign patents granted and have two foreign patent applications pending. The issued and granted patents will expire on various dates in the years 2018 through 2031. These patents relate to electro-nerve stimulation; soft-tissue bulking materials, processes and applications; disposable sheaths for endoscopes; endoscopic designs and features; and reusable flexible endoscopes, as well as other various products, endoscopy and non-endoscopy related.

While we believe that our patents adequately protect our technologies, there can be no assurance that any of our issued patents are of sufficient scope or strength to provide meaningful protection and that any of our pending patent applications will result in patents being issued to us. In addition, there can be no assurance that any of our current or future patents will not be challenged, narrowed, invalidated or circumvented by others, or that our patents will provide us with any competitive advantage. Any legal proceedings to maintain, defend or enforce our patent rights could be lengthy and costly, with no guarantee of success. Third parties could also hold patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available to us on reasonable terms, or if at all.

We also seek to protect our trade secrets by requiring employees, consultants, and other parties to sign confidentiality agreements and noncompetition agreements, and by limiting access by outside parties to our confidential information. There can be no assurance that these measures will prevent any unauthorized disclosure or use of our confidential information or that others will not be able to independently develop such information.

In the U.S. and throughout the European Union, we have registered “Cogentix Medical” as our Company name, and Uroplasty® for Uroplasty LLC, one of our subsidiaries. We have registered “Urgent” for our neuromodulation product, “Macroplastique” for our urological tissue bulking products, “VOX” for our otolaryngology tissue bulking products, and “PTQ” for our colorectal tissue bulking products. We own the U.S.-registered trademarks PrimeSight ™ , Vision Sciences ® , EndoSheath ® , Slide-On ® , EndoWipe ® and The Vision System ® .

Research and Development

We have research and development projects and activities to develop, enhance and evaluate potential new products for which we incur costs for regulatory submissions, regulatory compliance and clinical research. Our expenditures for clinical research include studies for new applications or indications for existing products, post-approval regulatory compliance and marketing and reimbursement approval by third-party payers. Our expenditures for research and development totaled approximately $4.7 million for the fiscal year ended December 31, 2017 and $4.7 million for the fiscal year ended December 31, 2016.

Product Liability

The medical device industry is subject to substantial litigation. The nature of our products exposes us to significant product liability risks. We currently carry a worldwide product liability insurance policy that covers up to $10 million in liability. We believe that such coverage amount is appropriate, given our business, products, past sales levels and our anticipated sales levels. However, we cannot assure that our existing insurance coverage limits are adequate to protect us from liabilities we might incur. Product liability insurance is expensive to obtain and maintain, and may not be available to us in the future on terms that are acceptable to us, if at all. We evaluate the adequacy of our coverage periodically to determine if adjustments should be made. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any product recall. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products and our ability to generate revenues.

Compliance with Environmental Laws

Our operations are regulated under various federal, state, and local laws governing the environment, including laws governing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the clean-up of contaminated sites. We have infrastructure in place to ensure that our operations are in compliance with all applicable environmental regulations. Our compliance with applicable environmental requirements for calendar year 2017 and the calendar year 2016 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During 2017 and 2016, none of our customers individually accounted for 10% or more of our net sales.

Backlog

We did not have significant backlog at the end of 2017 or 2016.

Employees

As of December 31, 2017, we had 208 employees, of which 207 were full-time and one was part time. No employee was subject to a collective bargaining agreement. We believe we maintain good relations with our employees.

Executive Officers

Certain information concerning our executive officers is set forth below. No family relationships exist among any of our directors and executive officers.

Darin Hammers , age 53, has served as Cogentix's President and Chief Executive Officer since May 2016, and he was appointed to the Board of Directors in July 2016 when he transitioned from interim to permanent President and Chief Executive Officer. Previously Mr. Hammers was Chief Operating Office starting in January 2016, and prior to that was Senior Vice President of Global Sales & Marketing starting in August 2013. Mr. Hammers joined Cogentix's predecessor company Uroplasty as Vice President of Global Sales in January 2013. Mr. Hammers' experience includes over 27 years of increasing leadership roles in medical device sales and marketing. Prior to joining Uroplasty, Mr. Hammers was Vice President of Sales for Bard Medical Division of C.R. Bard based in Covington, GA, focused on Urology care products. Prior to that, Mr. Hammers spent more than 12 years with Boston Scientific in various sales leadership positions in the Urology/Gynecology areas.

Brett Reynolds , age 49, has served as Cogentix's Senior Vice President, Chief Financial Officer and Corporate Secretary since June 2016. Mr. Reynolds previously served in the same role from March 2015 to January 2016, and before the Merger, he served in the same roles for Cogentix's predecessor company Uroplasty from 2013 until 2015. Mr. Reynolds' experience spans more than 25 years in finance and operations. He was the Chief Financial Officer of Synovis Life Technologies, a publicly traded medical device manufacturer, from 2005 to 2012. Following the sale of Synovis to Baxter International in 2012, Mr. Reynolds served as Site Leader of the former Synovis operations until 2013. Prior to Synovis, Mr. Reynolds served in executive financial positions at Chiquita Processed Foods, LLC, Imation Corp. and Deloitte & Touche LLP.

Chris Arnold , age 50, has served as Cogentix's Vice President, Global Sales since August 2016. Mr. Arnold previously served as Vice President, U.S. Sales since joining Cogentix's predecessor company Uroplasty in January 2015. Mr. Arnold has over 21 years of sales and executive leadership roles in the medical device industry, including Executive Director of Global Sales for Greatbatch Medical's Cardiac, Neurovascular and Vascular Division, Region Vice President for Smith and Nephew Orthopaedics, and over 14 years with Boston Scientific, including in the role of Director of Sales for the Urology/Gynecology Division.

Incorporation and Current Subsidiaries

We are incorporated as a Delaware corporation, and are the successor of operations originally begun in 1987. We have two domestic subsidiaries, Machida Incorporated, a Delaware corporation, and Uroplasty, LLC, a Delaware limited liability company. We also have two international subsidiaries, Uroplasty BV Incorporated, a Dutch corporation, and Uroplasty LTD Incorporated, a UK corporation. Uroplasty LTD has one subsidiary, Genesis Medical Holdings Limited. Genesis Medical Holdings has two subsidiaries, Genesis Medical Limited and Genesis Medical (Sales) Limited.

Available Information

Our principal executive offices are located at 5420 Feltl Road, Minnetonka, Minnesota 55343. Our telephone number at this address is (952) 426-6140. Our website is located at www.cogentixmedical.com . The information contained on our website or connected to our website is not incorporated by reference into and should not be considered part of this report.

You can access, free of charge, our filings with the Securities and Exchange Commission, including our annual report on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any other amendments to those reports, at our website or at the Securities and Exchange Commission's website at www.sec.gov .

Cautionary Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on its Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our business, operating results and financial condition. We have identified some of these forward-looking statements with words like "believe," "may," "could," "would," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" and "continue," the negative of these words, other words and terms of similar meaning and the use of future dates. These forward-looking statements may be contained in this section, the notes to our financial statements and elsewhere in this report, including under the heading " *Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* ." Our forward-looking statements generally relate to:

- Our future revenues, future operating expenses, anticipated use of cash and whether and how long our existing cash and cash equivalents and investments will be sufficient to fund our operations;
- the market size and market acceptance of our products;
- the status of our product development programs;
- the timing, costs and benefits associated with our restructuring plan; and
- the effect of new accounting pronouncements and future health care, tax and other legislation.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading " *Part I. Item 1A. Risk Factors* " below. We caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading " *Part I. Item 1A. Risk Factors* " below, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading " *Part I. Item 1A. Risk Factors* ." The risks and uncertainties described under the heading " *Item 1A. Risk Factors* " below are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our operating results or financial condition, may emerge from time to time. We assume no obligation to update our forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-Q and current reports on Form 8-K that we file with or furnish to the Securities and Exchange Commission.

ITEM 1A. RISK FACTORS

Our operations are subject to a number of risks and uncertainties that may affect our financial results, our accounting, and the accuracy of the statements we make in this Form 10-K. For example, we make statements about our belief in the efficacy of our product, the impact of regulatory and reimbursement approvals on our products and revenues, the attributes of our products versus those of our competitors, the adequacy of our resources, including cash, available to us, and other matters all of which represent our expectations or beliefs about future events. Our actual results may vary from these expectations because of a number of factors that affect our business, the most important of which include the following:

Risks Related to the Pending Acquisition of the Company by Laborie

Laborie's obligation to consummate the Merger is subject to certain conditions, which if not satisfied may prevent, delay or jeopardize the consummation of the Merger, result in additional expenditures of money and resources, and/or reduce the anticipated benefits of the Merger.

Laborie's obligation to consummate the Merger is subject to certain closing conditions. These closing conditions include, among others, the following: (i) the Company's stockholders shall have validly tendered and not validly withdrawn in the Offer the number of Shares which, when added to the Shares then owned by Merger Sub, would represent one Share more than one half of all Shares outstanding immediately prior to the Offer Acceptance Time ; (ii) the absence of a Company Material Adverse Effect (as defined in the Merger Agreement); (iii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended; and (iv) those other conditions set forth in Annex I to the Merger Agreement.

We cannot predict whether and when these conditions will be satisfied, and no assurance can be given that required closing conditions will be satisfied. In the event that the Merger is not consummated, we will have spent considerable time and resources, and incurred substantial costs, including costs related to the Merger, many of which must be paid even if the Merger are not completed. If the Merger is not consummated, our reputation in our industry and in the investment community could be damaged and, as a result, the market price of our common stock could decline.

The Merger Agreement contains provisions that restrict our ability to pursue alternatives to the Merger and, in specified circumstances, could require us to pay a termination fee of $8.365 million.

Pursuant to the Merger Agreement, we are restricted, subject to certain exceptions, from directly or indirectly, soliciting, initiating, knowingly encouraging or knowingly facilitating the submission or an announcement of any competing proposal or the making of any inquiry, offer or proposal that would reasonably be expected to lead to any competing proposal from another person. Furthermore, in connection with the termination of the Merger Agreement under certain specified circumstances related to a change in the recommendation of the Company Board or the entry into an agreement for a superior proposal, the Company may be required to pay a termination fee of $8,365,000, which is equal to 3.5% of the aggregate equity value represented by the transaction. These provisions could discourage a third party that may have an interest in acquiring all or a significant part of our business from considering or proposing that acquisition, even if such third party were prepared to enter into a transaction that would be more favorable to us and our stockholders than the Merger. These provisions also might result in a potential third-party acquirer proposing to pay a lower price to our stockholders than it might otherwise have proposed to pay because of the added expense of the $8.365 million termination fee that may become payable in certain circumstances.

If the Merger Agreement is terminated and we determine to seek another business combination, we may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the proposed Merger.

Failure to complete the Merger within the expected time frame, or at all, could adversely affect our stock price, financial results and our future business and operations.

In the event that the Merger is not completed or delayed our business may be harmed because:

- matters related to the proposed Merger may require substantial commitments of time and resources thereby diverting management's and our employees' attention from our day-to-day business, including servicing existing customers, attracting new customers and developing new products and strategies;
- our relationships with customers, distributors, collaborative partners, suppliers and patients may be harmed as a result of the proposed Merger and result in uncertainties with respect to our products, employees and business;
- our financial performance may be negatively impacted by disruptions in our sales and marketing, research and development, and other business activities;
- we may fail to retain key employees who have sought and obtained different employment in anticipation of the Merger being completed;
- we have agreed to restrict certain of our activities pending the consummation of the Merger that may negatively affect our ability to execute on our business strategies and attain our financial goals; and
- certain significant costs related to the proposed Merger, such as legal, advisor and accounting fees and other expenses, are payable by us whether or not the proposed Merger are completed, including a termination fee under certain circumstances.

If the Merger is not consummated, the market price of our common stock may decline to the extent that the current market price of our common stock reflects a positive market assumption that the Merger will be completed. Our stock price may also fluctuate significantly based on announcements by Laborie and other third parties or us regarding the Merger, or based on market perceptions of the likelihood of us completing the Merger. Such announcements may lead to perceptions in the market that the Merger may not be completed, which could cause our stock price to fluctuate or decline. In addition, if the Merger Agreement is terminated our stock price could decline significantly.

Any of these events could harm our results of operations and financial condition and could cause a decline in the price of our common stock, particularly if the Merger is not completed.

While the Merger is pending, we will be subject to business uncertainties that could adversely affect our business.

Uncertainty about the effect of the Merger on employees, customers and suppliers may have an adverse effect on our business. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Merger is consummated and for a period of time thereafter, and could cause customers, suppliers and others who deal with us to seek to change their existing business relationships with us. In addition, the Merger Agreement restricts us from taking specified actions until the Merger occurs without the consent of Laborie. These restrictions may prevent us from pursuing attractive business opportunities that may arise prior to the completion of the Merger. In addition, the Merger could expose us or members of our board of directors to litigation. Any such legal proceedings could delay or prevent the Merger from becoming effective within the agreed upon timeframe or at all. If closing of the Merger is delayed or does not occur, it could have a material adverse effect on our business.

Risks Related to Our Ongoing Business

Our future results will suffer if we do not effectively manage our expanded operations.

We anticipate that the size of our business will increase significantly beyond the current size. Our future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. There are no assurances that we will be successful or that we will realize the expected operating efficiencies, cost savings and other benefit currently anticipated from the future mergers and acquisitions.

If goodwill or other intangible assets that we have on our balance sheet become impaired, we could be required to take significant charges against earnings.

We have recorded a significant amount of goodwill and other intangible assets. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of our goodwill and other indefinitely-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

We may obtain additional financing, which may not be available on favorable terms at the time it is needed and which could reduce our operational and strategic flexibility.

We may obtain additional financing in 2018. We would seek to acquire that through additional equity and/or debt financing arrangements, which may or may not be available on favorable terms at such time. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

We have historically incurred losses and may never reach profitability.

We have incurred net losses in each of the last five fiscal years, including the calendar year ended December 31, 2017. As of December 31, 2017, we had an accumulated deficit of approximately $82 million primarily because of costs relating to the development, including seeking regulatory approvals, and commercialization of our products. We expect our operating expenses relating to sales and marketing activities along with product development and clinical trials will continue to increase during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have generated in prior years. We may never achieve these objectives or otherwise become profitable.

The size and resources of our competitors may render it difficult for us to successfully compete in the marketplace.

Our products compete against similar medical devices and other treatment methods, including drugs. Many of our competitors, which include some of the largest medical products and pharmaceutical companies in the world, have significantly greater financial, research and development, manufacturing and marketing resources than we have. Our competitors could use and have used these resources to develop and/or acquire products that may be safer, more effective, less invasive, less expensive or more readily accepted than our products. Their products could make our technology and products obsolete or noncompetitive. Our competitors could also devote greater resources to the marketing and sale of their products and adopt more aggressive pricing policies than we can. For example, Medtronic's InterStim ® neuromodulation device competes with our Urgent PC System, and in 2016 they formally launched an additional PTNS technology, the Nuro ™ system.

Our ability to compete effectively depends upon our ability to distinguish our brand and our products from our competitors' brands and their products and to obtain adequate reimbursement for procedures performed using our products. Factors affecting our competitive position include:

- ability to sell products tailored to meet the needs of our customers and patients;
- sales, marketing, and distribution capabilities;
- product performance and design;
- quality of customer support;
- product pricing;
- product safety;
- success and timing of new product development and introductions; and
- intellectual property protection.

Our stock price may fluctuate and be volatile.

The trading price of our common stock may be subject to significant fluctuations due to the following factors, among others:

- actual or anticipated variations in operating results;
- conditions or trends in the medical device market;
- announcements of new or acquired products or technologies by us or our competitors;
- announcements by us or our competitors of significant customer wins or losses, gains or losses of distributors;
- technological innovations, new products or services;
- the success of our efforts to acquire or license additional products;
- additions or departures of key personnel;
- actual or expected sales of a large number of shares of our common stock;
- availability of sources of capital;
- adverse litigation;
- unfavorable legislative or regulatory decisions;
- developments in U.S. or international reimbursement systems;
- variations in interest rates;
- general market and economic conditions;
- availability of components on acceptable terms;
- availability of distributor arrangements on favorable terms; and
- changes in accounting standards, policies, guidance or interpretations.

In addition, the stock market in general, the Nasdaq Capital Market, and the market for shares of novel technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of life science companies have been unusually volatile in recent years, and such volatility may continue for the foreseeable future. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In addition, this volatility and the low level of market liquidity for our common stock could adversely affect an investor's ability to sell shares of our common stock and the market price for such shares, at any given time.

In the past, companies that have experienced volatility in the market price of their stock have been the targets of securities class action litigation. We may become the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management attention, which could seriously harm our business.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our common stock.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

We expect to acquire new products or technologies, and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, products, technologies or employees, we may fail to realize expected benefits or harm our existing business.

Our success will depend, in part, on our ability to expand our product offerings and grow our business in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may seek to do so through the licensing or acquisition of complementary businesses, products or technologies rather than through internal development. The identification of suitable license or acquisition candidates and obtaining adequate financing can be difficult, time consuming and costly, and we may not be able to successfully complete identified acquisitions. Products and technologies that we license or acquire may require additional development prior to sale, including clinical testing and approval by the FDA and other regulatory bodies, and we may encounter difficulties or delays in completing the development or receiving the necessary approvals. We may find that the product or technology cannot be manufactured economically or commercialized successfully. We may not be able to acquire or license the right to products on terms that we find acceptable, if at all.

Furthermore, even if we successfully complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products or technologies into our operations, and the process of integration could be expensive and time consuming, and may strain our resources. Consequently, we may not achieve anticipated benefits of the acquisitions, which could harm our existing business. In addition, future acquisitions could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results or cause a reduction in the price of our common stock.

Product liability claims could adversely affect our business and results of operations.

The manufacture and sale of our products expose us to significant risk of product liability claims, which may have a negative impact on our business. Any defects or risks that we have not yet identified with our products may give rise to product liability claims. Our existing worldwide product liability insurance coverage of up to $10 million in liability may be inadequate to protect us from liabilities we may incur. We may also not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim (or series of claims) would be brought against us for uninsured liabilities or in excess of our insurance coverage, and ultimately it is determined that we are liable, our business could suffer. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, or other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of any of our products would likely be costly, would be uninsured and could also result in increased product liability claims. Further, while we train our physician customers in the proper use of our products, we cannot be certain that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may occur and this could give rise to product liability claims against us.

Product quality problems could lead to reduced revenue, gross margins and net income.

We produce highly complex video-based endoscope products that incorporate sophisticated technology, including hardware and software. Software typically contains bugs that can unexpectedly interfere with operations. Our quality assurance testing programs may not be adequate to detect all defects, either ones in individual products or ones that could affect numerous shipments, which might interfere with customer satisfaction, reduce sales opportunities, increase warranty repairs, or reduce gross margins. In the past, we have had to replace certain components and provide remediation in response to defects or bugs in our products. There can be no assurance that such a remediation, depending on the products involved, would not have a material impact on our revenue, margins, and net income. An inability to cure a product defect could result in the failure of a product line, a product recall, temporary or permanent withdrawal of a product from a market, damage to our reputation, inventory costs or product reengineering expenses, any of which could have a material adverse impact on our revenue, margins, and net income.

We expect gross margins to vary over time, and our level of product gross margins may not be sustainable.

The current levels of our product gross margins may not be sustainable and may continue to be adversely affected by numerous factors, including:

- obsolescence of components or products due to sales trends and new product introductions;
- our inability to reduce supply and production costs;
- increases in material or labor costs;
- changes in shipment volume;
- loss of cost savings due to changes in component pricing, including the impact of foreign exchange rates for components purchased overseas;
- changes in distribution channels; and
- increased warranty costs.

The use and acceptance of certain of our products depend heavily upon the availability of third-party reimbursement for the procedures in which our products are used.

In the U.S., healthcare providers that purchase medical devices, including our products, generally rely on third-party payers, including Medicare, Medicaid, private health insurance carriers and managed care organizations, to reimburse all or part of the cost and fees associated with the procedures performed using these devices. The commercial success of our products will depend on the ability of healthcare providers to obtain adequate reimbursement from third-party payers for the procedures in which our products are used. Third-party payers are more frequently challenging the coverage and pricing of medical products and procedures.

Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate to justify the use of our products. In addition, third-party payers may deny reimbursement if they determine that the device used in a treatment was not cost-effective or was used for a non-approved indication, particularly if there is not a published Current Procedural Terminology, or CPT, code for reimbursement. For example, in 2009, the American Medical Association advised the medical community that the previously recommended Category 1 CPT code for percutaneous tibial nerve stimulation, or PTNS, treatments should be replaced with an unlisted code. As a result, many third-party insurers delayed or denied reimbursement for PTNS treatments, significantly impacting the sales of our Urgent PC System, until a new code was introduced effective in January 2011.

Reimbursement and healthcare payment systems in international markets vary significantly by country, with some countries offering government-sponsored healthcare or private insurance, or both. In many countries where there is government-sponsored healthcare reimbursement, decisions are made by individual hospitals with the government setting an upper limit of reimbursement. In most foreign countries, there are also insurance systems that may offer payments for alternative procedures. We cannot be certain that we, or in countries in which we work with our distributors, those distributors, will successfully and cost-effectively manage all of these payment systems.

All third-party reimbursement programs, whether government-funded or commercially insured, inside the U.S. or outside, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefit, second opinions, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of programs can potentially limit the amount that healthcare providers may be willing to pay for medical devices and could have a material adverse effect on our financial position and results of operations.

We cannot predict how quickly or how broadly the market will accept our products.

In addition to the availability of third-party reimbursement, market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefit, and cost-effectiveness of our products compared to products or treatment options of our competitors. We cannot assure you that we will be successful in educating the marketplace about the benefit of our products. If we fail to convince health care providers to use our products versus competing products, then demand for our products would suffer, which would cause a decline in our revenue and profitability. Similarly, if we fail to maintain our working relationships with health care providers, many of our products may not be developed and marketed in line with the needs and expectations of the providers who use and support our products, which could cause a decline in our revenue and profitability. We rely on these providers to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products.

We may not have the resources to successfully market our products, which would adversely affect our business and results of operations.

The marketing of our products requires a significant amount of time and expense in order to identify the physicians who would use our products and to train a sales force that is large enough to interact with the targeted physicians. The ease and predictability of third-party reimbursement significantly impacts the success of our marketing activities. We may not have adequate resources to market our products successfully against larger competitors who have more resources than we do. If we cannot market our products successfully, our business and results of operations would be adversely affected.

If we are not able to attract, retain and motivate our sales force and expand our distribution channels, our sales and revenues will suffer.

In the U.S., we have a sales organization consisting primarily of direct sales representatives, and a marketing organization to market our products directly and support our distributor organizations. We expect to expand our sales and marketing organization, as needed, to support our growth. We have and will continue to incur significant additional expenses to support this organization. We cannot be certain that our sales organization will be able to generate sales of our urology and endoscopy products at levels that justify our expense, or even if we can, that we will be able to recruit, train, motivate or retain qualified sales and marketing personnel.

A significant portion of our revenue outside of the United States is through a network of independent distributors. Our ability to increase product sales in foreign markets will largely depend on our ability to develop and maintain relationships with our distributors and on their ability to successfully market and sell our products. We may not be able to retain distributors who are willing to commit the necessary resources to marketing and selling our products to the level of our expectations. Failure to maintain or expand our distribution channels or to recruit, retain and motivate qualified personnel could have a material adverse effect on our product sales and revenues.

In addition, we have a limited ability to direct or influence the activities of our third-party, independent distributors. Our distributors could take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and brand:

- sell products that compete with our products in breach of their non-competition agreements with us;
- fail to adequately promote our products; or
- fail to provide proper service to our end users.

If we are unable to adequately manage our distribution network, or if our distributors fail to meet their obligations under their agreements with us, our corporate image among end users of our products could be damaged, resulting in a failure to meet our sales goals. In addition, foreign governments have increased their anti-bribery efforts in the healthcare sector to reduce improper payments received by hospital administrators and doctors in connection with the purchase of pharmaceutical products and medical devices. We are subject to the regulations of the Foreign Corrupt Practices Act and are required to monitor our activities associated with our foreign sales. To our knowledge, none of our distributors engages in corrupt practices. However, our distributors may violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products, which would adversely affect our corporate image and business.

Our distributors may not obtain regulatory approvals on a timely basis, if at all.

We often rely on our distributors in countries outside the U.S. in seeking regulatory approval to market our products in particular countries. To the extent we do so, we are dependent on persons outside of our direct control to make regulatory submissions and secure approvals, and we do not, and will not, have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our sales from our international operations and our results of operations may be adversely affected.

If we cannot attract and retain key personnel and members of our senior management team, we may not be able to manage and operate successfully, and we may not be able to meet our strategic objectives.

Our future success depends, in large part, upon our ability to attract, retain and motivate members of our senior management team and key managerial, scientific, sales and technical personnel. We are highly dependent on our senior management team, and any unanticipated loss or interruption of their services could significantly reduce our ability to meet our strategic objectives because, given the intense competition for senior management and other key personnel, it may not be possible for us to find appropriate replacement personnel should the need arise. The loss of a member of our senior management or our professional staff would require the remaining senior executive officers to divert immediate and substantial attention to seeking a replacement. There is no guarantee that we will be successful in retaining our current personnel or in hiring or retaining qualified personnel in the future. Loss of key personnel or the inability to hire or retain qualified personnel in the future could have a material adverse effect on our ability to operate successfully. Further, our inability, if any, to enforce non-compete arrangements related to key personnel who have left the company could have a material adverse effect on our business.

If third parties claim that our products infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain and costly. We face the risk of claims that our products have infringed on third parties' intellectual property rights. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming for us to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, in which agreements may not be available on terms acceptable to us, or at all;
- divert the attention of our management; or
- result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

In addition, new patents obtained by our competitors could threaten our products' continued life in the market even after it has already been introduced.

If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively.

Our success depends in part on our ability to protect the proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. Our patents and patent applications, if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us.

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality and noncompetition agreements with our current key employees and with other parties to whom we have divulged trade secrets. However, these agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event competitors discover or independently develop similar proprietary information.

Efforts on our part to enforce any of our proprietary rights could be time-consuming and expensive, which could adversely affect our business and prospects and divert our management's attention.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we use our networks to collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, personally identifiable information of our customers and employees, and data relating to patients who use our products. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to our customers, damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our operating margins, revenues and competitive position.

The loss or interruption of materials from any of our key suppliers could delay the manufacture of our products, which would limit our ability to generate sales and revenues.

We currently purchase several key materials used in our products from single source suppliers, including the finished products for our Urgent PC System. If one of these suppliers delayed or curtailed shipments to us, our ability to manufacture and deliver product would be impaired, our sales would decline or be curtailed for that product, and we would be forced to quickly locate an alternative source of supply. We cannot be sure that acceptable alternative arrangements could be made on a timely basis. Further, our reliance on such suppliers and the cost and difficulty we would encounter in qualifying an alternative subjects us to increased risk of price increases by single source suppliers. Additionally, the qualification of materials and processes as a result of a supplier change could be deemed as unacceptable to regulatory authorities and cause delays and increased costs due to additional test requirements. A significant interruption in the supply of materials, for any reason, could delay the manufacture and sale of our products, which would limit our ability to generate revenues.

Certain components for our fiber-based endoscopes and video-based endoscopes are generally only available from one source. Our inability to obtain any of these parts could delay or prevent us from making and selling products, which would have a material adverse effect on our future financial condition and results of operations.

Our borescopes are assembled using components and subassemblies purchased from independent vendors. While most components and subassemblies are currently available from more than one supplier, certain critical components are currently purchased only from limited key suppliers with which we do not have long or short-term contracts. Our failure to obtain a sufficient quantity of such components on favorable terms could materially adversely affect the sales in our industrial business.

Our medical products and manufacturing practices are subject to regulation by the FDA and by other state and foreign regulatory agencies.

Our medical products are subject to extensive regulation in the U.S. and in the foreign countries where we do business. There can be no assurance that the required regulatory clearances will be obtained, and those obtained may include significant limitations on the uses of the product in question. In addition, changes in existing regulations or the adoption of new regulations could make our regulatory compliance more difficult in the future. The failure to obtain required regulatory clearances or to comply with applicable regulations may result in fines, delays, suspensions of clearances, seizures, recalls of products, operating restrictions or criminal prosecutions, and could have a material adverse effect on our operations.

We face significant uncertainty in the industry due to government healthcare reform.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, as amended, (the "Affordable Care Act") as well as any future healthcare reform legislation, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax from 2016 through 2019, if it is reinstated, it may adversely affect our sales and the cost of goods sold.

Though all bills to repeal the Affordable Care Act were defeated in Congress in 2017, actions have been taken that create uncertainty around its implementation, and that may continue to adversely impact enrollment and insurer participation in the health insurance exchanges established by the Affordable Care Act, while increasing premiums on the exchanges. President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Furthermore, the administration terminated payments of cost-sharing subsidies to insurers participating on the exchanges, and terminated subsidies used to help individuals with co-payments and deductibles, which has increased premiums on the health insurance exchanges and terminated payments. The enrollment period in 2018 was reduced by half, to 45 days, and funding was reduced for advertising and other resources supporting the 2018 enrollment period.

We expect that continuing uncertainty around the Affordable Care Act, together with additional state and federal healthcare reform measures, could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payers are willing to pay. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

If we are not able to maintain sufficient quality controls, regulatory approvals of our products by the European Union, Canada, the FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.

The FDA, European Union, Canada or other related authorities could stop or delay approval of production of products if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA's Quality System Regulations impose extensive testing, control, documentation and other quality assurance requirements. Canada and the European Union also impose requirements on quality systems of manufacturers, who are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure or delays in obtaining the right to label our products with the CE mark, which demonstrates adherence to quality standards and compliance with relevant European medical device directives, would impair our ability to import, sell and distribute our products within the European Union. Further, our suppliers are also subject to these regulatory requirements. Failure by any of our suppliers or us to comply with these requirements could prevent us from obtaining or retaining approval and marketing of our products.

We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have been active in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from 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 federal False Claims Act, 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. Various states have also enacted laws modeled after the federal False Claims Act.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

We derive a significant portion of our sales from outside of the U.S., so foreign exchange rate fluctuations could adversely affect our operating results, and we are subject to other risks of international operations.

We derived approximately 27% of our net sales in the calendar year ended December 31, 2017 from customers and operations in international markets. Because costs and prices of our products or components in overseas countries are affected by foreign exchange rate fluctuations, they may have an adverse effect our business, operating results and financial condition.

Currently, we do not have any foreign exchange forward contracts and we do not hedge anticipated foreign currency cash flows.

The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to a number of additional risks, including:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy export licensing requirements;

- local political and economic instability;
- difficulties in recruiting and maintaining distributors and staff in remote locations, including sales people;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- foreign taxation compliance and penalties;
- deemed repatriation of foreign revenue and resulting U.S. federal income taxation;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; and
- difficulties in enforcing or defending intellectual property rights.

Additionally, on June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, which is commonly referred to as "Brexit". Subsequent to the referendum, on March 29, 2017, the United Kingdom triggered the two-year process of leaving the European Union, and the British government has begun negotiating the terms of the United Kingdom's future relationship with the European Union. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on the movement of people of money, and on imports and exports between the United Kingdom and European Union countries and increased regulatory complexities. In addition to the factors listed above, any regulatory changes that arise as a result of Brexit may adversely affect our operations and financial results.

Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results.

We are required to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefit. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. We either operate or plan to operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, and we utilize a number of distributors for whose actions we could be held liable under the FCPA and other anticorruption laws. We inform our personnel, distributors and agents of the requirements of the FCPA and other anticorruption laws, including, but not limited to their reporting requirements. We also have developed and will continue to develop and implement systems for formalizing contracting processes, performing due diligence on personnel, distributors and agents and improving our recordkeeping and auditing practices regarding these regulations. However, there is no guarantee that our personnel, distributors or agents have not or will not engage in conduct undetected by our processes and for which we might be held responsible under the FCPA or other anticorruption laws.

If our personnel, distributors or agents are found to have engaged in practices in violation of the FCPA or other anticorruption laws, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions. During the past few years, the SEC has increased its enforcement of violations of the FCPA against companies, including several medical device companies. Although we do not believe we are currently a target, any investigation of any potential violations of the FCPA or other anticorruption laws by U.S. or foreign authorities could have an adverse impact on our business, financial condition and operating results.

Certain foreign companies, including some of our competitors, are not subject to prohibitions as strict as those under the FCPA or, even if subjected to strict prohibitions, such prohibitions may be laxly enforced in practice. If our competitors engage in corruption, extortion, bribery, pay-offs, theft or other fraudulent practices, they may receive preferential treatment from personnel of some companies, giving our competitors an advantage in securing business, or from government officials, who might give them priority in obtaining new licenses, which would put us at a competitive disadvantage.

Federal income tax reform could have unforeseen effects on our financial condition and results of operations.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act ("TCJA") was signed into law. U.S. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted. The Tax Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective for tax years starting after December 31, 2017, implementing a hybrid territorial tax system, repealing AMT and making pre-2018 credits refundable, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. As a result, we recorded tax expense of $3.31million in the fourth quarter as a result of revaluation of the deferred tax assets due to the corporate tax rate change from 35% to 21% starting in 2018. All but $70,000 of this was directly offset by a change in the valuation allowance. The Company has $68,000 of AMT credit carryforwards that are expected to be fully utilized due to the credit now being refundable under the TCJA. The company calculated a deemed repatriation income amount due to the change to a territorial tax system under the TCJA. This income can be fully offset with NOLs. The corresponding deferred tax liability associated with it was reversed. The amounts incorporate assumptions made based upon the Company's current interpretation of the Tax Act and may change as the Company receives additional clarification and implementation guidance.

Our controlling stockholders exercise voting control over the Company and have the ability to elect or remove from office all of our directors.

On November 3, 2016, pursuant to the Purchase Agreement, we issued 16,129,033 shares of our common stock to Accelmed Growth Partners, L.P. in exchange for $25.0 million. At the same time, we also converted the outstanding principal amount, approximately $28.5 million, and accrued interest, approximately $1.0 million, on our promissory notes held by Lewis C. Pell into 17,688,423 shares of our common stock.

As a result of the transactions described above, Mr. Pell and Accelmed own or control a majority of our outstanding common stock as of December 31, 2017. In connection with the transaction, Accelmed and Mr. Pell entered into the Voting Agreement. Pursuant to the terms of the Voting Agreement, Mr. Pell and Accelmed have agreed to vote their shares of our common stock for the other party’s nominees to the board of directors. Under the Voting Agreement, each of Mr. Pell and Accelmed are entitled to nominate two directors, with the remaining seats to be filled by nominees that are mutually agreed upon by Mr. Pell and Accelmed in accordance with the terms of the Voting Agreement.

The Purchase Agreement provides that so long as Accelmed holds no less than 20% of the Company’s issued and outstanding shares of common stock, that the Company shall not dissolve the Company, engage in a business combination that is subject to a stockholder vote, change the size of the board of directors, incur new indebtedness in excess of $10.0 million or amend the capitalization of the Company, without the prior approval of the directors nominated by Accelmed pursuant to the Voting Agreement.

As such, Accelmed and Mr. Pell exercise significant control over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of the Company or forcing management to change our operating strategies in ways that are not supported by stockholders other than the controlling stockholders.

We are not subject to certain listing standards that normally apply to companies whose shares are quoted on Nasdaq.

The Voting Agreement is intended, in part, to qualify the Company as a "Controlled Company" under Nasdaq Rule 5615(2), which permits the Company to utilize the controlled company exemption to the independent director requirements of Nasdaq Listing Rule 5605. A Controlled Company is not required to have a majority of its board of directors comprised of independent directors. Director nominees are not required to be selected or recommended for the board's selection by a majority of independent directors or a nomination committee comprised solely of independent directors, nor do the Nasdaq listing standards require a Controlled Company to certify the adoption of a formal written charter or board resolution, as applicable, addressing the nominations process. A Controlled Company is also exempt from Nasdaq's requirements regarding the determination of officer compensation by a majority of the independent directors or a compensation committee comprised solely of independent directors. Although we currently comply with certain of the Nasdaq listing standards that do not apply to Controlled Companies, our compliance is voluntary, and there can be no assurance that we will continue to comply with these standards in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease an 18,258 square-foot office, warehouse and manufacturing facility in Minnetonka, Minnesota for our corporate headquarters pursuant to a lease agreement with DCII-5400-5510 Feltl Road, LLC expiring in June 2019. At the Minnetonka facility, we manufacture Macroplastique and warehouse and ship Urgent PC and Macroplastique.

We lease a 20,500 square-foot office, warehouse and manufacturing facility in Orangeburg, New York pursuant to a lease agreement with GHP Office Realty, LLC that expires in February 2019. At the Orangeburg facility, we manufacture our advanced line of endoscopy-based medical products, including our flexible fiber and video endoscopes, for a variety of specialties and markets and industrial borescopes to a variety of users, primarily in the aircraft engine manufacturing and aircraft engine maintenance industries.

We lease an approximately 24,400 square foot office, warehouse and manufacturing facility in Westborough, Massachusetts, pursuant to a lease agreement with Glenborough Flanders Park, LLC that expires in December 2025. We manufacture our EndoSheath products at this location.

We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands. At this facility, we maintain our European headquarters and warehouse.

We lease an approximately 1,800 square-foot office and warehouse space in London, United Kingdom, pursuant to a lease agreement with Mr. and Mrs. Penberthy that expires in December 2021. At the London facility, we warehouse and ship our PrimeSight and EndoSheath products for the UK market.

We believe that these facilities are suitable and adequate for our operations for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any material active legal actions. However, from time to time, we may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Market Information

Our common stock is listed on the Nasdaq Capital Market under the symbol "CGNT."

The following table sets forth the high and low closing sales prices for our common stock for the year ended December 31, 2017 and for the year ended December 31, 2016, as reported on the Nasdaq Capital Market.

Year ended December 31, 2017	Low	High
First Quarter	$ 1.72	$ 2.21
Second Quarter	$ 1.60	$ 1.95
Third Quarter	$ 1.62	$ 2.94
Fourth Quarter	$ 2.60	$ 3.15

Year ended December 31, 2016	Low	High
First Quarter	$ 0.95	$ 1.35
Second Quarter	$ 0.71	$ 1.14
Third Quarter	$ 0.96	$ 1.99
Fourth Quarter	$ 1.37	$ 2.99

As of March 20, 2018, we had approximately 99 holders of record of our common stock. Registered ownership includes nominees who may hold securities on behalf of multiple beneficial owners. We have never declared or paid cash dividends on our common stock. We currently intend to retain all future earnings, if any, for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans.

The following table provides particular information regarding our equity compensation plans as of December 31, 2017.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Security Holders (1)	2,545,963	$ 2.72	139,738

(1) Consists of options outstanding under the Cogentix Medical, Inc. 2015 Omnibus Incentive Plan, the Uroplasty 2006 Amended Stock and Incentive Plan, as amended, the Vision-Sciences, Inc. 2000 Plan, the Vision-Sciences, Inc. 2003 Director Option Plan, and the Vision-Sciences, Inc. 2007 Stock Incentive Plan

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Upon exercise of stock options or vesting of restricted stock, employees can request the Company to withhold shares to pay the resulting income tax withholdings of the employee. These transactions constitute stock repurchases and are the only stock repurchases engaged in by the Company. Information regarding the Company's stock repurchases during the year ended December 31, 2017 is as follows:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2017 – March 31, 2017	-	-	-	-
April 1, 2017 – June 30, 2017	10,261	$ 1.71	-	-
July 1, 2017 – September 30, 2017	-	-	-	-
October 1, 2017 – December 31, 2017	-	-	-	-
Total	10,261	$ 1.71	-	-

ITEM 6. SELECTED FINANCIAL DATA

Summary Statement of Operations Data (in thousands except per share data)

Not required to be disclosed.

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

You should read this discussion of our financial condition and results of operations in conjunction with, and we qualify our discussion in its entirety by, the Consolidated Financial Statements and notes thereto included elsewhere within this report, the material contained under Part 1, Item 1. "Description of Business" and Part I, Item 1A. "Risk Factors" of this report, and the cautionary disclosure about forward-looking statements at the front of Part I of this report.

Overview

Cogentix Medical is a global medical device company. We design, develop, manufacture and market innovative proprietary technologies primarily serving the urology and related markets. The Urgent ® PC Neuromodulation System is an FDA-cleared device that delivers percutaneous tibial nerve stimulation ("PTNS") for the office-based treatment of overactive bladder ("OAB"). The FDA-cleared PrimeSight ™ Endoscopy Systems utilizing the EndoSheath Protective Barrier combine state-of-the-art endoscopic technology with a sterile, disposable microbial barrier, providing practitioners and healthcare facilities with a solution to meet the growing need for safe, efficient and cost-effective flexible endoscopy. We also offer Macroplastique ® a urethral bulking agent for the treatment of stress urinary incontinence. Outside the U.S., the company markets additional bulking agents: PTQ ® for the treatment of fecal incontinence and the VOX ® for vocal cord augmentation. In July 2017, we acquired Genesis Medical LTD ("the Genesis acquisition"), a privately held U.K. company that distributes a variety of products to urologists.

Our strategic direction for calendar year 2018 and beyond is premised on the Company's continued operation as a stand-alone entity, under the management of the current executive officers and the oversight of the current board of directors. The Company's strategy may change significantly in the event of our acquisition by Laborie Medical Technologies ULC. See "Item 1. Business – Recent Developments" for more information on this pending transaction.

Results of Operations

Twelve-months ended December 31, 2017 compared to twelve-months ended December 31, 2016

Net Sales . Consolidated net sales of $56,316,000 in the current period represented a $4,465,000 increase, or 8.6%, over net sales of $51,851,000 in the prior period. The increase is primarily due to a $4,565,000 increase in revenue from the Urology product lines, which is comprised of the PrimeSight, Urgent PC, Macroplastique and other urology products, and is offset by a $100,000 net decrease in revenue from the Airway Management and Industrial product lines.

Consolidated net sales for PrimeSight urology technology of $19,041,000 in the current period represented a $4,025,000 increase, or 26.8%, over net sales of $15,016,000 in the prior period. The increase is due to our sales force becoming more proficient in selling this technology as well the fact that our PrimeSight technology platform meets the needs of our medical customers for always ready, always sterile flexible endoscopy solutions. Our urology PrimeSight products have been clinically proven to reduce the risk of cross contamination associated with the reuse or reprocessing of difficult to clean conventional endoscopes and they also reduce the typical 45-minute reprocessing time to less than 10 minutes, allowing for greater patient throughput, increased physician productivity and ultimately economic benefit for our customers.

Consolidated net sales of our Urgent PC System of $21,355,000 in the current period represented a $118,000 increase, or 0.6%, when compared to net sales of $21,237,000 in the prior period. U.S. unit growth was offset by a 3% decline in average selling price. U.S. unit growth was due primarily to sales execution and increased penetration in existing accounts. Our sales team has effectively demonstrated the clinical efficacy and value proposition of Urgent PC to our physician customers resulting in the increased sales. The sales team continues to place a strong emphasis on servicing existing accounts and increasing utilization within existing accounts. The decrease in average selling price is primarily due to the continued sales efforts of a large competitor who entered the PTNS space in the first quarter of 2016. Average selling prices have been substantially consistent over the past four quarters.

Consolidated net sales of our Macroplastique product of $7,140,000 in the current period represented a $247,000 decrease, or 3.3%, from net sales of $7,387,000 in the prior period. Macroplastique serves a small market, and the focus of our sales force has been on growing our PrimeSight and Urgent PC products.

Consolidated net sales of other urology products of $1,778,000 in the current period represented a $669,000 increase, or 60.3%, over net sales of $1,109,000 in the prior period. The increase is due primarily to non-PrimeSight revenue from the Genesis acquisition.

Consolidated net sales of our non-urology products (Airway Management and Industrial Boroscopes) of $7,002,000 in the current period represented a $100,000 decrease, or 1.4%, from net sales of $7,102,000 in the prior period. The decrease is primarily due to our increased focus on Urology products.

Consolidated net sales to customers in the U.S. of $40,888,000 in the current period represented an increase of $1,374,000, or 3.5%, over net sales of $39,514,000 in the prior period.

Consolidated net sales to customers outside the U.S. of $15,428,000 in the current period represented an increase of $3,091,000, or 25.1%, over net sales of $12,337,000 in the prior period.

Gross Profit : Gross profit was $37,444,000 (66.5% of net sales) in the current period versus $35,603,000 (68.7% of net sales) in the prior period. The change in gross profit percentage is attributed primarily to product mix, as revenue from our PrimeSight products were a higher proportion of total sales in the current period as compared to the prior period, and our PrimeSight products have a lower profit percentage than our Urgent PC and Macroplastique products.

General and Administrative Expenses ("G&A") : G&A expenses of $8,294,000 in the current period increased $1,516,000 from $6,778,000 in the prior period. The increase in expenses is primarily attributed to an increase of $646,000 in share based compensation expense and approximately $383,000 of business development costs as well as inclusion of approximately $286,000 for the operating costs of Genesis.

R *esearch and Development Expenses ("R&D")* : R&D expenses of $4,742,000 in the current period increased $41,000 from $4,702,000 in the prior period. The increase is attributed to ongoing enhancements to our PrimeSight product line.

Selling and Marketing Expenses ("S&M") : S&M expenses of $22,907,000 in the current period increased $1,594,000 from $21,313,000 in the prior period. The increase is attributed primarily to the expansion of the U.S. sales force as well as the addition of five sales personnel from the Genesis acquisition and is partially offset by a $388,000 refund from the IRS related to medical device taxes paid in 2013 - 2015.

Amortization of Intangibles : Amortization of intangibles was $2,390,000 in the current period compared to $2,363,000 in the prior period.

One-Time-Costs - Proxy Settlement Costs : One-time costs in the prior period related to the proxy contest settlement between the Company and Mr. Lewis Pell and related litigation in connection with the 2016 Annual Meeting. These fees included $758,000 of professional fees (primarily legal) and $1,500,000 of severance costs for the Company's former CEO. There were no similar costs in the current period.

Other Income (Expense) : Other income (expense) includes interest income, interest expense, foreign currency exchange and other non-operating costs when incurred. Net other income was $272,000 in the current period compared to net other expense of $20,139,000 in the prior period. Other income in the current period is primarily interest income from our investments. Other expense in the prior year is primarily due to cash debt conversion expense of $18.8 million as a result of the conversion of $29.5 million (face value) of convertible debt – related party that was converted into equity in the fourth quarter of 2016.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (functional currencies of our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between us and our foreign subsidiaries. We recorded foreign currency exchange gains of $48,000 in the current period.

Income Tax Expense : We recorded income tax expense of $137,000 in the current period. Income tax expense is attributed to our foreign subsidiaries and to the payment of minimum state taxes in the U.S. We cannot use our U.S. net operating loss carry forwards to offset taxable income in foreign jurisdictions. Our actual income tax expense differs from the statutory federal income tax benefit largely due to the recording of valuation allowances in both periods presented.

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was signed into federal law, which among other changes, reduces the federal corporate income tax rate from 35% to 21%; provides for a deduction for capital expenditures; limits executive compensation, net interest and net operating loss ("NOL") deductions; requires capitalization and amortization of research and development expenditures; initiates the migration from a worldwide to a territorial tax regime; introduces a tax on deferred foreign earnings (a deemed repatriation); and provides a deduction for foreign-derived intangible income. We expect the new tax law will have the following impacts:

- the deferred tax asset on our balance sheet was reduced by approximately $3.3 million of December 31, 2017;
- the impact to the company of the tax on deferred foreign earnings is immaterial
- the rate at which our NOL carry forwards will be utilized will be unchanged

The Company will continue to analyze the TCJA to assess the full effects on the Company's business strategy and financial results. For additional discussion of the impact of the Tax Cuts and Jobs Act on our accounting policies, see the section entitled "Critical Accounting Policies – Income Taxes."

Non-GAAP Financial Measures

The following tables reconcile our operating loss calculated in accordance with accounting principles generally accepted in the U.S. ("GAAP") to non-GAAP financial measures that exclude non-cash charges for share-based compensation, and depreciation and amortization from gross profit, operating expenses and operating loss. The non-GAAP financial measures used by management and disclosed by us are not a substitute for, or superior to, financial measures and consolidated financial results calculated in accordance with GAAP, and you should carefully evaluate our reconciliations to non-GAAP. We may calculate our non-GAAP financial measures differently from similarly titled measures used by other companies. Therefore, our non-GAAP financial measures may not be comparable to those used by other companies. We have described the reconciliations of each of our non-GAAP financial measures described above to the most directly comparable GAAP financial measures.

We use these non-GAAP financial measures, and in particular non-GAAP operating income (loss), for internal managerial purposes and incentive compensation for senior management because we believe such measures are one important indicator of the strength and the operating performance of our business. Analysts and investors frequently ask us for this information. We believe that they use these measures to evaluate the overall operating performance of companies in our industry, including as a means of comparing period-to-period results and as a means of evaluating our results with those of other companies.

		Expense Adjustments				
	GAAP	Share-based Expense	Long-term Incentive Plan	Depreciation	Disposal of Assets	Amortization of Intangibles	Non-GAAP
Twelve-months ended December 31, 2017							
Gross Profit	$ 37,443,859	$ 22,329	$ -	$ 193,968	$ -	$ -	$ 37,660,156
% of Net sales	66.5%						66.9%
Operating Expenses:							
General & administrative	8,293,814	(1,231,667)	-	(226,939)	-	-	6,835,208
Research and development	4,742,308	(42,552)	-	(12,964)	-	-	4,686,792
Selling and marketing	22,907,468	(156,363)	-	(342,366)	(2,001)	-	22,406,738
Amortization	2,389,743	-	-	-	-	(2,389,743)	-
	38,333,333	(1,430,582)	-	(582,269)	(2,001)	(2,389,743)	33,928,738
Operating income (loss)	$ (889,474)	$ 1,452,911	$ -	$ 776,237	$ 2,001	$ 2,389,743	$ 3,731,418

		Expense Adjustments				
	GAAP	Share-based Expense	Long-term Incentive Plan	Depreciation	Disposal of Assets	Amortization of Intangibles	Non-GAAP
Twelve-months ended December 31, 2016							
Gross Profit	$ 35,603,048	$ 33,330	$ -	$ 175,696	$ -	$ -	$ 35,812,074
% of Net sales	68.7%						69.1%
Operating Expenses:							
General & administrative	6,778,010	(585,420)	74,404	(201,031)	(5,640)	-	6,060,323
Research and development	4,701,539	(23,717)	-	(2,450)	-	-	4,675,372
Selling and marketing	21,313,364	(105,652)	-	(393,500)	-	-	20,814,212
Amortization	2,363,432	-	-	-	-	(2,363,432)	-
One-time costs	2,257,654	-	-	-	-	-	2,257,654
	37,413,999	(714,789)	74,404	(596,981)	(5,640)	(2,363,432)	33,807,561
Operating income (loss)	$ (1,810,951)	$ 748,119	$ (74,404)	$ 772,677	$ 5,640	$ 2,363,432	$ 2,004,513
One-time costs	2,257,654						2,257,654
Operating income excluding one-time costs							$ 4,262,167

Liquidity and Capital Resources

Cash Flows

At December 31, 2017, our cash and cash equivalents balances totaled $20,910,000. In addition, we have short term investments totaling $6,247,000. Our net working capital as of December 31, 2017, totaled approximately $35,306,000.

For the twelve months ended December 31, 2017, cash provided by operating activities was $2,307,000, compared to cash provided by operating activities of $3,300,000 for the twelve months ended December 31, 2016. For the twelve months ended December 31, 2017, we incurred a net loss of $883,000. Significant non-cash expenses incurred in this period include depreciation and amortization expense of $3,166,000, and share based compensation of $1,453,000. Working capital changes that used cash include higher accounts receivable, lower accrued compensation, and lower accounts payable, while cash was provided as a result of lower inventories. For the twelve months ended December 31, 2016, we incurred a net loss of $22,095,000. Significant non-cash expenses incurred in the prior period include debt conversion expense of $18,841,000, depreciation and amortization expense of $3,136,000, share based compensation of $748,000 and amortization of debt discount of $941,000. Working capital changes that provided cash in the prior period include lower accounts receivable and higher accrued compensation, while cash was used as a result of inventories increasing. The prior period net loss includes nonrecurring cash expenses of $2,300,000 million attributed to legal fees and severance associated with proxy settlement costs.

During the twelve months ended December 31, 2017, cash provided by investing activities included $15,020,000 of proceeds from the maturity of available-for-sale securities, partially offset by $2,438,000 in purchases of available-for-sale securities, $2,000,000 for the investment in Vensica Medical, $857,000 for the purchase of property, plant, and equipment, and $181,000 for the Genesis acquisition. During the twelve months ended December 31, 2016, we used cash of $18,946,000 for the purchase of available-for-sale securities and $355,000 for the purchase of property, plant, and equipment.

During the twelve months ended December 31, 2016, we generated net proceeds from financing activities of $23,429,000 from the issuance of 16,129,033 shares of our common stock at a price per share of $1.55, net of related expenses, in conjunction with the closing of the securities purchase agreement dated September 7, 2016, that we entered into with Accelmed Growth Partners, L.P. (the "Accelmed Purchase Agreement"). Under the terms of the Accelmed Purchase Agreement, Accelmed agreed to purchase 16,129,033 shares of our common stock at $1.55 per share, for an aggregate price of $25,000,000. As a condition to Accelmed closing the equity investment, we agreed to convert into shares of our common stock all of the outstanding debt and accrued interest owed to Lewis C. Pell, one of our directors. On September 7, 2016, we entered into a definitive agreement with Mr. Pell (the "Pell Note Exchange Agreement") under which the debt we owed to Mr. Pell would be converted into our common stock at a price per share of $1.67 prior to closing the Accelmed Purchase Agreement. The Pell Note Exchange Agreement also provided that, simultaneously with the conversion of such debt, all outstanding warrants to purchase our common stock that are held by Mr. Pell would be cancelled.

Sources of Liquidity

In addition to our cash and investments, we have a $7,000,000 secured revolving credit facility ("Facility"), subject to eligible accounts receivable and inventory . We may obtain additional debt and/or equity financing during 2018.

Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance of our products and successfully expand our business in the U.S. We cannot guarantee that we will successfully achieve such revenue growth. If we fail to meet our projections of profitability and cash flow, or determine to use cash for matters we are not currently projecting, we may need to seek additional financing to meet our cash needs. We cannot assure you that such financing, if needed, will be available to us on acceptable terms, if at all.

The Company does not have any commitments for capital expenditures. In our normal course of business, we have commitments to purchase from various vendors finished goods and manufacturing components under issued purchase orders.

Convertible Debt – Related Party

As of December 31, 2015, we had related party convertible debt with a recorded value of $23,337,000 and a face value of $28,490,000 plus accrued interest. As a condition to the closing of the Accelmed Purchase Agreement described under the section entitled "Liquidity and Capital Resources", during the twelve months ended December 31, 2016, we converted all of the outstanding principal amount and accrued interest on the convertible debt – related party into shares of common stock at a price of $1.67. This conversion was approved by the Company's shareholders on November 3, 2016. The conversion of the convertible debt – related party was negotiated to be converted at a conversion rate that was significantly lower than the original conversion rates. The transaction was accounted for as an induced conversion and resulted in non-cash debt conversion expense of approximately $18,841,000 for the year ended December 31, 2016.

Commitments and Contingencies

Future payments under our contractual obligations as of December 31, 2017 are summarized below:

	Total	Payments Due by Period: Less Than 1 Year	1 – 3 Years	4 – 5 Years	More Than 5 Years
Operating lease commitments	$ 2,488,000	$ 817,000	$ 709,000	$ 418,000	$ 544,000

Operating lease commitments include a long-term lease with Liberty Property Limited Partnership for an 18,258 square-foot facility for our U.S. headquarters located at 5420 Feltl Road, Minnetonka, Minnesota. The lease, which had an original expiration date in April 2014, was amended in January 2014. The amended lease began on May 1, 2014, has a term of 62 months and requires average annual minimum rent payments of approximately $154,000. We lease a 20,500 square-foot office, warehouse and manufacturing facility in Orangeburg, New York pursuant to a lease agreement with GHP Office Realty, LLC. The lease, as amended, has an expiration date of February 2019. The lease requires average annual minimum rent payments of approximately $349,000. On April 2, 2015, we leased approximately 24,400 square feet in Westborough, Massachusetts pursuant to a lease agreement with Glenborough Flanders Park, LLC expiring in December 2025. The lease requires average annual minimum rent payments of approximately $134,000.

In our normal course of business, we have commitments to purchase from various vendors finished goods and manufacturing components under issued purchase orders. At December 31, 2017, the approximate future minimum purchase agreement payments in subsequent years are as follows:

2018	$ -
2019	300,000
2020	600,000
2021	900,000
2022	1,200,000
Thereafter	1,500,000
	$ 4,500,000

We have a defined benefit pension plan covering six current and twenty former employees in The Netherlands. We pay premiums to an insurance company to fund annuities for the current employees. We are responsible for funding additional annuities based on continued service and future salary increases. We closed this defined benefit plan for new employees in April 2005. As of that date, The Netherlands subsidiary established a defined contribution plan that now covers new employees. We also have a defined benefit pension plan for six former employees of our U.K. subsidiary. We closed this plan to further accrual for all employees effective December 31, 2004, and, effective March 2005, established a defined contribution plan that now covers new employees.

The following table presents the sensitivity of our funded status as of December 31, 2017, and expected 2018 pension expense to the following changes in key assumptions:

Assumption:	Increase/(Decrease) Funded Status at December 31, 2017	Increase/(Decrease) 2018 Pension Expense
Increase in discount rate by 1 percentage point	$ 191,000	$ (52,000)
Decrease in discount rate by 1 percentage point	(248,000)	64,000
Increase in estimated return on assets by 1 percentage point	n/a	(8,000)
Decrease in estimated return on assets by 1 percentage point	n/a	8,000
Increase in inflation rate by 1 percentage point	(185,000)	43,000
Decrease in inflation rate by 1 percentage point	160,000	(39,000)
Increase in compensation by 1 percentage point	(49,000)	7,000
Decrease in compensation by 1 percentage point	-	-

Regarding The Netherlands defined benefit pension plan, the market value of the assets is determined as the discounted stream of guaranteed benefit payments. Given the valuation method of the assets, the expected long-term rate of return on assets equals the discount rate. As such The Netherlands defined benefit pension plan is not included in the sensitivity analysis for the estimated return on assets, because the sensitivity on the estimated return on assets is implicitly already included in the sensitivity analysis for the discount rate.

Critical Accounting Policies

For a complete description of our critical accounting policies, see Note 1 to the Consolidated Financial Statements in Item 8 of this report. We prepare our consolidated financial statements in accordance with U.S. GAAP, which require us to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these consolidated financial statements, we have made our best estimates and judgments of certain amounts, giving due consideration to materiality. We believe that of our significant accounting policies, the following can be characterized as "critical accounting policies" and are particularly important to the portrayal of our results of operations and financial position. These critical policies may require the application of a higher level of judgment by us, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition

We recognize revenue in accordance with the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 605 (Topic 605, Revenue Recognition) . ASC 605 requires that four basic criteria must be met before revenue can be recognized:

1. persuasive evidence that an arrangement exists;

2. delivery has occurred or services were rendered;

3. the fee is fixed and determinable; and

4. collectability is reasonably assured

We recognize revenue when title passes to the customer, generally upon shipment of our products F.O.B. shipping point. Revenue for service repairs of equipment is recognized after service has been completed, and service contract revenue is recognized ratably over the term of the contract.

We include shipping and handling charges billed to customers in net sales, and include related costs incurred by us in cost of goods sold. Typically, our agreements contain no customer acceptance provisions or clauses. We sell our products to end users and to distributors. Payment terms range from prepayment to 120 days. The distributor payment terms are not contingent on the distributor selling the product to end users. Customers do not have the right to return products except for warranty claims. We offer customary product warranties.

Accounts Receivable

We grant credit to our customers in the normal course of business and, generally, do not require collateral or any other security to support amounts due. If necessary, we have an outside party assist us with performing credit and reference checks and establishing credit limits for the customer. Accounts outstanding longer than the contractual payment terms are considered past due. We carry our accounts receivable at the original invoice amount less an estimated allowance for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on the customer's financial health, and both historical and expected credit loss experience. We write off our accounts receivable when we deem them uncollectible. We record recoveries of accounts receivable previously written off when received. We are not always able to timely anticipate changes in the financial condition of our customers and if circumstances related to these customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations.

Inventories

We value inventory at net realizable value the slow moving and obsolete inventories based upon current and expected future product sales. Historically, the inventory write-offs have generally been within our expectations.

Impairment of Long-Lived Assets

Our long-lived assets consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. We use judgment to forecast future cash flows including forecasting revenues and margins, and working capital needs. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Share-Based Compensation

We account for share-based compensation costs under ASC 718, "Compensation – Stock Compensation." ASC 718 covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. We recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options and restricted shares, in our financial statements. We measure that cost based on the fair value of the equity or liability instruments issued.

Defined Benefit Pension Plans

We have a liability attributed to defined benefit pension plans we offered to certain former and current employees of our subsidiaries in the UK and The Netherlands. The liability is dependent upon numerous factors, assumptions and estimates, and the continued benefit costs we incur may be significantly affected by changes in key actuarial assumptions such as the discount rate, mortality, compensation rates, or retirement dates used to determine the projected benefit obligation. Additionally, changes made to the provisions of the plans may impact current and future benefit costs. Changes in benefit obligations associated with these factors are recognized in future years over the expected average future service of the active employees or the average remaining life expectancies of inactive employees.

Income Taxes

We recognize deferred tax assets and liabilities for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates we expect to apply to taxable income in the years in which we expect to recover or settle those temporary differences. As a result of the reduction of the federal corporate income tax rate from 35% to 21%, the deferred tax asset on our balance sheet was reduced by approximately $3,300,000 as of December 31, 2017. We recognize a valuation allowance when we determine it is more likely than not that we will not realize a portion of the deferred tax asset. We have established a valuation allowance for U.S. deferred tax assets due to the uncertainty that we will generate enough income in that taxing jurisdictions to utilize the assets with the exception of the refundable AMT credit carryforward. Therefore, we have only reflected the benefit of such deferred tax assets in the accompanying consolidated financial statements. The deferred tax asset decreased by approximately $2,758,000 in the 12 months ending December 31, 2017, and decreased by approximately $7,395,000 in the 12 months ending December 31, 2016. The valuation allowance increased by approximately $2,795,000 in the 12 months ending December 31, 2017, and decreased by approximately $7,335,000 in 12 months ending December 31, 2016.

In addition, future utilization of NOL carry forwards is subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended. This section generally relates to a 50% change in ownership of a company over a three-year period. The Tax Cuts and Jobs Act limits NOL deductions to 80% of taxable income with indefinite carry forward, with carrybacks generally eliminated. Of the $118,500,000 of NOLs for U.S. income tax purposes, $88,200,000 are expected to expire unutilized due to Section 382.

We refer you to Note 9 to the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this report for further discussion.

Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting." This ASU simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. This new standard is effective for annual periods beginning after December 15, 2016, and interim periods within that reporting period. We adopted this standard as of January 1, 2017. The adoption did not have a material impact on our consolidated financial statements. Under the new ASU we no longer account for forfeitures of restricted stock awards and stock options throughout the vesting period and instead account for them in the period in which they occur. We also recognize certain tax benefits or tax shortfalls upon a restricted-stock award vesting or stock option exercise relative to the deferred tax asset position established in the provision for income taxes line of the consolidated statements of operations instead of within the consolidated statement of shareholders' equity.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." This ASU is in response to diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows and provides guidance on eight specific cash flow classification issues. It will be effective for reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted, including adoption in an interim period. The Company adopted this standard as of January 1, 2017. The adoption did not have a material impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory (Topic 330)." Under the current guidance (i.e., ASC 330-10-352 before the ASU), an entity subsequently measures inventory at the lower of cost or market, with market defined as replacement cost, net realizable value (NRV), or NRV less a normal profit margin. An entity uses current replacement cost provided that it is not above NRV (i.e., the ceiling) or below NRV less an "approximately normal profit margin" (i.e., the floor). The new guidance requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures). The ASU will not apply to inventories that are measured by using either the last-in, first-out (LIFO) method or the retail inventory method (RIM). The amendments in ASU No. 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company adopted this standard and it had no impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". Under U.S. GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting in accordance with Subtopic 205-30 of this ASU, "Presentation of Financial Statements—Liquidation Basis of Accounting". Even when an entity's liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going concern basis of accounting, but the amendments in this ASU should be followed to determine whether to disclose information about the relevant conditions and events. The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company has evaluated the going concern considerations in this ASU. However, management does not believe that the Company has met conditions which would subject the Company's financial statements to additional disclosure.

Recently Issued Accounting Pronouncements Not Yet Adopted.

In February 2018, the Financial Accounting Standards Board ("FASB") issues ASU No. 2018-02, "Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income". The amendments in this update allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. The standard is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within these fiscal years. Early adoption is permitted. The new guidance is not expected to have a material impact on our results of operations and financial position.

In May 2017, the Financial Accounting Standards Board ("FASB") issued ASU 2017-09, "Compensation – Stock Compensation: Scope of Modification Accounting." This ASU is intended to provide guidance about which changes to the terms or conditions on a share-based payment award require an entity to apply modification accounting. This new standard is effective for annual periods beginning after December 15, 2017, and interim periods within that reporting period. The Company does not expect these amendments to have a material effect on its consolidated financial statements.

In March 2017, the FASB issued ASU 2017-08, "Receivables—Nonrefundable Fees and Other Costs: Premium Amortization on Purchased Callable Debt Securities" related to the amortization period for certain purchased callable debt securities held at a premium. The amendments shorten the amortization period for the premium to the earliest call date. The amendment is effective for interim and annual periods beginning after December 15, 2018. The Company does not expect these amendments to have a material effect on its consolidated financial statements.

In January 2017, the FASB, issued ASU No. 2017-04, "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment" which simplifies the accounting for goodwill impairment by eliminating Step 2 of the current goodwill impairment test. Goodwill impairment will now be the amount by which the reporting unit's carrying value exceeds its fair value, limited to the carrying value of the goodwill. The standard is effective for us beginning January 1, 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. The new guidance is not expected to have a material impact on our results of operations and financial position.

In August 2016, the FASB issued Accounting Standards Update ("ASU") 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." This ASU is in response to diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows and provides guidance on eight specific cash flow classification issues. It will be effective for reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted, including adoption in an interim period. We do not believe the adoption of this update will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-2, "Leases", under which lessees will recognize most leases on-balance sheet. This will generally increase reported assets and liabilities. For public entities, this ASU is effective for annual and interim periods in fiscal years beginning after December 15, 2018. ASU 2016-2 mandates a modified retrospective transition method for all entities. While the Company is still evaluating the timing and impact of the adoption of this guidance on its consolidated financial statements, it anticipates that the adoption could result in an increase in the assets and liabilities recorded on its consolidated balance sheet.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)", as amended by ASU 2015-14, "Deferral of Effective Date", which requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 sets forth a new revenue recognition model that requires identifying the contract, identifying the performance obligations, determining the transaction price, allocating the transaction price to performance obligations and recognizing the revenue upon satisfaction of performance obligations. For public entities, this ASU is effective for annual reporting periods beginning after December 15, 2017 including interim reporting periods within that reporting period. The provisions can be adopted either retrospectively to each prior reporting period presented or as a cumulative-effect adjustment as of the date of adoption. We plan to adopt this ASU effective January 1, 2018 using the cumulative-effect adjustment method. The Company has completed the assessment of this ASU on each of our revenue streams and, based on our review of contracts, we believe the impact on our consolidated financial statements is immaterial. For each of our products, revenue will still be recognized when title passes to the customer, generally upon shipment. Revenue for service repairs of equipment will continue to be recognized after service has been completed, and service contract revenue will be recognized ratably over the term of the contract. We are still evaluating the impact of the new revenue recognition standard on our disclosures due to the new qualitative and quantitative requirements under the standard.

Off-Balance Sheet Arrangements

As of December 31, 2017, we had no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company and are not required to provide the information required by this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and notes to our consolidated financial statements are contained immediately after the signature page to this report beginning on page F-1, and are incorporated herein by references. Our financial statement schedule is contained in Part IV, Item 15 of this report, and is incorporated herein by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures are defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms and that such information is accumulated and communicated to management, including our CEO and CFO, in a manner that allows timely decisions regarding required disclosure.

As of December 31, 2017, we carried out an evaluation, under the supervision and with the participation of our management, including our President and CEO (principal executive officer) and our Senior Vice President and CFO (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based upon that evaluation, each of our CEO (principal executive officer) and CFO (our principal financial officer) concluded that as of December 31, 2017, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as that term is defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in conformity with GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including principal executive officer, principal financial officer and principal accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017, based upon the framework in "2013 Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment and those criteria, management has determined that our internal control over financial reporting was effective as of December 31, 2017.

Changes in Internal Control over Financial Reporting

Based on the evaluation conducted by our management, with the participation of principal executive officer, principal financial officer and principal accounting officer, pursuant to Rules 13a-15(d) and 15d-15(d) promulgated under the Exchange Act, our management (including such officers) have concluded that there were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) that occurred since September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Directors

At the 2017 Annual Meeting, stockholders voted to declassify the board of directors effective immediately after the Meeting. As a result, directors elected at a subsequent annual meeting of stockholders would be elected to one-year terms, and until their successors are duly elected and qualified. Any director chosen as a result of a newly created directorship or to fill a vacancy on the board of directors would hold office until the next annual meeting of stockholders. The entire board of directors would stand for election at the 2018 Annual Meeting of Stockholders.

Dr. Uri Geiger , age 50, has served as a director of our company and Chairman of the Board since November 2016. Dr. Geiger is Managing Partner of Accelmed Growth Partners, L.P., a private equity investment firm he co-founded in 2009 focused on medical device companies, which as of the record date of the 2017 Annual Meeting, owned approximately 27% of the Company's outstanding common stock. Prior to founding Accelmed, Dr. Geiger served as the CEO of Exalenz Bioscience Ltd., a medical technology company, from May 2006 until December 2008. Prior to that, Dr. Geiger co-founded and was the CEO of GalayOr Networks, a developer of optical components from 2001 until 2003. Dr. Geiger was also the founding partner of Dragon Variation Fund in 2000, one of Israel's first hedge funds, which was sold to Migdal in 2007. Dr. Geiger worked on Wall Street during the 1990s, where he gained a broad understanding of and significant experience in capital markets. Dr. Geiger was formerly an adjunct professor at Tel Aviv University's Recanati School of Business where he lectured on private equity and venture capital and authored the books "Startup Companies and Venture Capital" and "From Concept to Wall Street". Dr. Geiger previously served on the board of directors of EndoChoice Holdings Inc. from January 2014 until March 2016. Dr. Geiger's years of leadership experience in both financial and business settings of the healthcare industry make him well-suited to serve as a member of the Board.

Darin Hammers , age 53, has served as the President and Chief Executive Officer of the Company since May 2016. Mr. Hammers' experience includes over 25 years of increasing leadership roles in Urology. He joined Cogentix's predecessor company Uroplasty as Vice President of Global Sales in January 2013 and was promoted to Senior Vice President of Global Sales & Marketing in August 2013. In January 2016 he was promoted to Chief Operating Officer prior to being named interim President and CEO in May 2016, and President and CEO in July 2016. Prior to joining Uroplasty, Mr. Hammers was Vice President of Sales for Bard Medical Division of C.R. Bard based in Covington, GA, focused on Urology care products. Prior to that, Mr. Hammers spent more than 12 years with Boston Scientific in various sales leadership positions in the Urology/Gynecology areas. Mr. Hammers brings to the Board of Directors of the Company substantial experience and insight in marketing and executive management of medical device companies.

Dr. James D'Orta , age 66, has been a director of our company since May 2016. He most recently served as a Director and Chief Executive Officer of ACell, a Maryland-based medical device manufacturer, from 2013 to 2015. Prior to becoming Chief Executive Officer of ACell, he served as a member of the board of directors and as chairman of the board's Corporate Governance, Nominating and Compliance Committees. Prior to ACell, Dr. D'Orta served as the Founder and CEO of Consumer Health Services, Inc. from 2005 to 2013, which provided medical support for the walk-in medical clinics in Duane Reed drugstores. Consumer Health Services was acquired by Walgreens in 2013. Mr. D'Orta formerly was an investor, medical advisor and member of the Board of Directors of Minute Clinic, the walk-in medical clinics which was sold to CVS drugstores. Earlier, he was founder and CEO of LifeLink MD, providing distribution, training and medical oversight for automated external defibrillators (AEDs), as well as public advocacy and education that helped make AEDs widely available. That company was later sold to Medtronic. Dr. D'Orta also served as a director on the board of directors of CareFirst, Inc. of BlueCross/BlueShield from 2007 to 2015. Dr. D'Orta currently serves on the board of directors of MedStar Health, Inc. Dr. D'Orta's years of leadership experience in both clinical and business settings of the healthcare industry make him well-suited to serve as a member of the Board.

Dr. Cheryl Pegus , age 53, has been a director of our company since 2013. She is currently Clinical Professor of Medicine and Population Health at NYU School of Medicine. Dr. Pegus is also the President of Caluent, LLC, a health care data analytics company and incoming Chair of the Association of Black Cardiologists. Previously, she was the Chief Medical Officer for Walgreens and served as the General Manager and Chief Medical Officer for SymCare Personalized Health Solutions, Inc., a J&J start-up company. Dr. Pegus is currently a Director of Tactile Medical (Nasdaq: TCMD), and privately held US Acute Care Solutions (USACS), a Welsh Carson portfolio company . Dr. Pegus has more than 20 years of clinical practice and industry experience that make her well-suited to serve as a member of the Board of Directors of our company.

Lewis Pell , age 74, is a co-founder of our company and has been a director since 1992. Mr. Pell served as the Chairman of the Board of Directors of the Company from 2005 to 2015. Mr. Pell also briefly served as the Company's Principal Executive Officer from June 2013 to August 2013. Prior to 2005, Mr. Pell served as Vice-Chairman of the Board of Directors since 1992. Mr. Pell is a founder or co-founder and chairman and director of several privately held medical device companies and is the chairman of Photomedex, Inc., a publicly-traded dermatology company. We believe Mr. Pell's extensive experience with Cogentix and other companies in the medical device industry, particularly his experience serving as a founder and a member of the board of directors of numerous medical device companies, and creating and developing new and emerging companies and bringing innovative medical device and technology to the marketplace, makes him well-suited to serve as a member of the Board of Directors of our company.

Mr. Kenneth Samet , age 59, has served as a director of our company since June 2016. Mr. Samet has been President, Chief Executive Officer and Director of MedStar Health, a $5 billion not-for-profit, healthcare delivery system since 2008. From 2003 to 2008, he served as President and Chief Operating Officer of MedStar Health, and prior to that, he served as Chief Operating Officer. Mr. Samet served as President of MedStar Washington Hospital Center, one of the nation's largest tertiary care hospitals, in the District of Columbia from 1990 to 2000. From the mid-1980s to 1990, Mr. Samet held a variety of leadership positions with the Medlantic Healthcare Group, which merged with Helix Health in 1998 to create MedStar Health. Mr. Samet has served as a director of Evolent Health, Inc. since 2015. Mr. Samet's years of leadership experience in large healthcare providers make him well-suited to serve as a member of the Board.

Nachum (Homi) Shamir , age 64, has served as a director of our company since November 2016. Mr. Shamir currently serves as the President, Chief Executive Officer and Director of Luminex Corporation, a publicly traded biotechnology company based in Austin, Texas, a position he has held since October 2014. Prior to joining Luminex, Mr. Shamir was the President, Chief Executive Officer and Director of Given Imaging Ltd., a developer, manufacturer and marketer of diagnostic products for the visualization and detection of disorders of the gastrointestinal tract which was acquired by Covidien PLC in early 2014. Mr. Shamir held this position from April 2006 to June 2014. Prior to joining Given Imaging, Mr. Shamir was Corporate Vice President of Eastman Kodak Company and President of Eastman Kodak´s Transaction and Industrial Solutions Group. Additionally, he served over ten years at Scitex Corporation, a manufacturer of products, systems and equipment for the graphics design, printing and publishing markets, in positions of increasing responsibility, including President and CEO from 2003 to 2004. Mr. Shamir currently serves on the board of directors of Luminex Corporation and has been serving in such position since October 2014. Mr. Shamir previously served on the board of directors of Given Imaging from April 2006 to June 2014. Mr. Shamir also served on the board of directors of Invendo Medical GmbH from June 2014 to October 2017, when the company was sold. Mr. Shamir's knowledge and executive leadership in the health care industry make him well-suited to serve as a member of the Board of Directors of our company.

Howard Zauberman , age 65, has been a director of our company since 2013. Mr. Zauberman was President and Chief Executive Officer of the Company from 2013 to March 2015. Mr. Zauberman has over 30 years of experience as a leader in the medical products industry. Prior to joining the Company, from 2005 to 2012, he was Vice President of Business Development at Henry Schein, Inc., a leading global health care distributor serving office based medical practitioners. Mr. Zauberman also served as a Special Venture Partner at Galen Partners, a health care growth equity and late stage venture capital firm, focused on technology enabled services, medical devices and specialty pharmaceuticals. Mr. Zauberman also held senior management positions at ETHICON, Inc. a Johnson & Johnson company and Pfizer, Inc. Mr. Zauberman's knowledge and executive leadership in the health care industry make him well-suited to serve as a member of the Board of Directors of our company.

Information About Director Appointments in Connection with the Pell Debt Conversion and Accelmed Investment

As a result of the Securities Purchase Agreement dated September 7, 2016 with Accelmed (the "Purchase Agreement"), and the Note Exchange Agreement dated September 7, 2016 with Mr. Pell (the "Note Exchange Agreement"), as of December 31, 2017, Mr. Pell and Accelmed owned or controlled approximately 33% and 26%, respectively, of the outstanding common stock of the Company.

In connection with the Purchase Agreement, Accelmed and Mr. Pell entered into a voting agreement (the "Voting Agreement"), whereby Mr. Pell and Accelmed have agreed to vote their shares of the Company's common stock for the other party's nominees to the Board. Under the Voting Agreement, each of Mr. Pell and Accelmed are entitled to nominate two directors, with the remaining seats to be filled by nominees that are mutually agreed upon by Mr. Pell and Accelmed in accordance with the terms of the Voting Agreement. Mr. Pell subsequently nominated himself and Howard Zauberman to the Board, and Accelmed nominated Uri Geiger and Nachum Shamir. The Voting Agreement shall continue in effect until such time as Accelmed no longer owns any of the shares of common stock that Accelmed acquired pursuant to the Purchase Agreement However, Mr. Pell may terminate the Voting Agreement at any time Accelmed and its affiliates own in the aggregate less than 50% of the purchased shares, and Accelmed may terminate the Voting Agreement at any time Mr. Pell and his affiliates own in the aggregate less than 50% of the shares of common stock issued to Mr. Pell pursuant to the Note Exchange Agreement.

The Voting Agreement is intended, in part, to qualify the Company as a "controlled company" under Nasdaq Rule 5615(c)(2), which permits the Company to utilize the controlled company exemption to the independent director requirements of Nasdaq Listing Rule 5605. Additionally, under the terms of the Purchase Agreement, the Company has agreed that principal Accelmed director shall serve as Chairman of the Board until Accelmed or its affiliates no longer own 50% of the shares purchased pursuant to the Purchase Agreement or unless otherwise agreed by Accelmed. Mr. Geiger currently serves as Chairman of the Board. The Company also amended its Bylaws to reduce the required quorum for all stockholder meetings to one-third of all issued and outstanding shares of voting stock of the Company.

Executive Officers

The executive officers of the Company are listed in Part I, Item 1 under the heading "Executive Officers."

Code of Ethics and Business Conduct

The Board of Directors adopted our Amended and Restated Code of Ethics and Business Conduct, which applies to all of our directors, executive officers, and other employees, and meets the requirements of the SEC. A copy of our Amended and Restated Code of Ethics and Business Conduct is available on the Corporate Governance section of our corporate website at *http://ir.cogentixmedical.com* . We intend to disclose any future amendments to our Amended and Restated Code of Ethics, or waivers granted to our executive officers from a provision to the Amended and Restated Code of Ethics, on our website.

Section 16(a) Beneficial Ownership Reporting Compliance [1]

Section 16(a) of the Exchange Act requires our directors and executive officers and all persons who beneficially own more than 10 percent of the outstanding shares of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Directors, executive officers and greater than 10 percent beneficial owners also are required to furnish us with copies of all Section 16(a) forms they file with the SEC. To our knowledge, based on a review of the copies of such reports and amendments to such reports furnished to us with respect to the year ended December 31, 2017, and based on written representations by our directors and executive officers, all required Section 16(a) reports under the Exchange Act, for our directors, executive officers and beneficial owners of greater than 10% of our common stock were filed on a timely basis during the year ended December 31, 2017,

Board Committees

The Board of Directors has three standing committees: Audit Committee, Compensation Committee and Governance and Nominating Committee. Each of these committees has the composition and responsibilities described below. The Board of Directors from time to time may establish other committees to facilitate the management of our company and may change the composition and the responsibilities of our existing committees. Each of our three standing committees has a charter which can be found on the on the Corporate Governance section of our corporate website at *http://ir.cogentixmedical.com* . The table below summarizes the current membership of each of our three standing board committees by our non-employee directors. None of our employee directors or non-independent directors serve as a member of any of our board committees.

Director	Audit	Compensation	Governance and Nominating
James D'Orta	√	Chair	√
Cheryl Pegus	√	√	Chair
Kenneth Samet	Chair	—	√
Nachum Shamir	—	√	—

Audit Committee

Responsibilities . The primary responsibilities of the Audit Committee include:

- overseeing our accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the Board of Directors and reporting the results or findings of its oversight activities to the Board of Directors;
- having sole authority to appoint, retain and oversee the work of our independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or or auditing matters and for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and pre-approving all audit services and permissible non-audit services to be performed for us by our independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC; and
- overseeing our system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) of a written code of ethics applicable to each of our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

[1] Pursuant to 405(a) The Company must include a paragraph regarding any directors, officers or beneficial owners of more than ten percent of any class of equity securities of the Company who failed to file form 3 and 4 (or form 5 amendments) on a timely basis. For each person must set forth the number of late reports, the number of transactions that were not reported on timely basis.

The Audit Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition and Audit Committee Financial Expert . The current members of the Audit Committee are Mr. Samet, Ms. Pegus and Mr. D'Orta. Mr. Samet is the chair of the Audit Committee.

Each current member of the Audit Committee qualifies as "independent" for purposes of membership on audit committees under the listing standards of Nasdaq and the rules and regulations of the SEC and is "financially literate" under the listing standards of Nasdaq. In addition, the Board of Directors has determined that Mr. Samet qualifies as an "audit committee financial expert" as defined by the rules and regulations of the SEC and meets the qualifications of "financial sophistication" under the listing standards of Nasdaq. These designations related to the Audit Committee members' experience and understanding with respect to certain accounting and auditing matters are disclosure requirements of the SEC and Nasdaq and do not impose upon any of them any duties, obligations or liabilities that are greater than those generally imposed on a member of the Audit Committee or of the Board of Directors.

Meetings . The Audit Committee met four times during 2017.

Compensation Committee

Responsibilities . The primary responsibilities of the Compensation Committee include:

- determining the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to our Chief Executive Officer and other executive officers;
- determining any revisions to corporate goals and objectives with respect to compensation for our chief executive officer and other executive officers and establishing and leading a process for the full Board of Directors to evaluate the performance of our Chief Executive Officer and other executive officers in light of those goals and objectives;
- administering our equity-based compensation plans, including determining specific grants of incentive awards for executive officers and other employees under our equity-based compensation plans;
- reviewing and discussing with our Chief Executive Officer and reporting periodically to the Board of Directors plans for executive officer development and corporate succession plans for the Chief Executive Officer and other key executive officers and employees; and
- establishing and leading a process for determination of the compensation applicable to the non-employee directors on the Board of Directors.

The Compensation Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition . The current members of the Compensation Committee are Mr. D'Orta, Ms. Pegus and Mr. Shamir. Mr. D'Orta is the chair of the Compensation Committee. Each of the three current members of the Compensation Committee is an "independent director" under the listing standards of Nasdaq and a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act.

Meetings . The Compensation Committee met once during 2017.

Governance and Nominating Committee

Responsibilities . The primary responsibilities of the Governance and Nominating Committee are:

- overseeing all aspects of corporate governance, including acting as an independent committee evaluating transactions between our company and significant stockholders, directors and director nominees, or executive officers;
- succession planning and identifying individuals qualified to become members of the Board of Directors;
- recommending director nominees for each annual meeting of our stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;
- being aware of best practices in corporate governance and developing and recommending to the Board of Directors a set of Corporate Governance Guidelines; and
- developing and overseeing a Board and Board committee evaluation process.

The Governance and Nominating Committee annually reviews transactions between the Company and its significant stockholders, directors and director nominees, or executive officers that are greater than $120,000. The review encompasses transactions with affiliates and immediate family members. When reviewing related party transactions, the Governance and Nominating Committee considers all relevant facts and circumstances, including:

- the commercial reasonableness of the terms;
- the benefit and perceived benefits, or lack thereof, to our company;
- opportunity costs of alternate transactions; and
- the materiality and character of the related person's interest, and the actual or apparent conflict of interest of the related person.

The Governance and Nominating Committee only approves or ratifies a related party transaction when it determines that, upon consideration of all relevant information, the transaction is in, or is not inconsistent with, the best interests of our company and stockholders. No related party transactions will be consummated without the approval or ratification of our Governance and Nominating Committee. It is our policy that directors interested in a related party transaction will recuse themselves from any vote relating to a related party transaction in which they have an interest.

The Governance and Nominating Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition . The current members of the Governance and Nominating Committee are Ms. Pegus, Mr. D'Orta and Mr. Samet. Ms. Pegus is the chair of the Governance and Nominating Committee. Each of the three current members of the Governance and Nominating Committee is an "independent director" within the meaning of the listing standards of Nasdaq.

Meetings . The Governance and Nominating Committee met once during 2017.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Equity Compensation Plans

See the information contained in Part II, Item 5 under the heading "Securities Authorized for Issuance Under Equity Compensation Plans."

ITEM 12. EXECUTIVE COMPENSATION

Compensation Philosophy and Objectives

Compensation Philosophy . The compensation we provide to our executive officers is designed both to attract and retain high quality executives to advance our business, and to provide both short-term and long-term incentives to those executives to enhance our performance. To that end, executive compensation consists of three primary elements: base salary, a short-term cash incentive opportunity under our Management Incentive Plan ("MIP"), and long-term equity incentive compensation. Although we set the level of compensation for our executives by reference to competitive compensation in a peer group of smaller, public medical device companies, we also adjust our executive compensation to attract and retain managers capable of accommodating rapid growth.

Objectives of Our Executive Compensation Program . Our compensation program for our executive officers are designed to achieve the following primary objectives:

- focus executive behavior on achievement of our annual and long-term objectives and strategy;
- provide a competitive compensation package that enables us to attract and retain, on a long-term basis, talented executives;
- provide a total compensation structure that the Compensation Committee believes is at least comparable with similarly-sized companies in the life sciences industry for which we would compete for talent and which consists of a mix of base salary, equity and cash incentives; and
- align the interests of management and stockholders by providing management with long-term incentives through equity ownership.

Accordingly, the Compensation Committee of our company also considers the following additional factors in designing our executive compensation program to further promote and achieve our compensation objectives:

- each executive's position within the company and the level of responsibility;
- the ability of the executive to affect key business initiatives;
- the executive's individual experience and qualifications;
- company and individual performance; and
- the executive's current and historical compensation levels.

Determining Executive Compensation . The Compensation Committee is responsible for establishing and administering compensation for our executive officers, including our Chief Executive Officer, and exercising oversight of compensation practices for all employees, including strategies for attracting, developing and motivating employees. Each of the members of the Compensation Committee is an "independent director" under the listing standards of Nasdaq and a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act.

The Compensation Committee of our company (i) meets as appropriate to discuss the executive compensation plan, including MIP performance measures and targets, (ii) generally retains the assistance of an independent compensation consultant every other year, and (iii) then formally establishes and approves the executive compensation plan. In fiscal 2017, the Committee engaged Arthur J. Gallagher as its independent compensation consultant, and the consultant assisted the Committee with designing Board compensation as well as assessing executive compensation.

The Compensation Committee consults with the Chief Executive Officer and other members of management in order to provide financial information and other relevant information, and specifically, to align the performance measures and targets of the annual incentive program with the proposed operating plan for the upcoming fiscal year. At the end of the fiscal year, the Chief Executive Officer participates in the Compensation Committee's discussions regarding compensation actions for the executives, including any base salary adjustments; annual incentive awards and long-term equity incentive awards, except that he will not participate in any discussions with regard to his own compensation.

In approving compensation actions for the Chief Executive Officer, the Compensation Committee considers corporate performance during the fiscal year, solicits evaluations of the Chief Executive Officer's individual performance from the other directors, and periodically considers competitive salary information gathered through comparative surveys pertaining to data specific to a peer group of public companies of comparable size and in the medical device industry. The Committee also reviews and approves the Chief Executive Officer's individual performance goals for the upcoming fiscal year.

Elements of the Executive Compensation Program in 2017

Our executive compensation program consists of three primary elements: base salary, a short-term cash incentive opportunity under our Management Incentive Plan ("MIP"), and long-term equity incentive compensation. All of our executive officers are also eligible for certain benefits offered to employees generally including: life, health, disability and dental insurance, as well as participation in our 401(k) plan.

Base Salary . Base salary is an important element of our executive compensation program as it provides executives with a fixed, regular, non-contingent earnings stream to support annual living and other expenses. The Compensation Committee's determination of the base salary of each of our named executive officers, including the Chief Executive Officer, are based on a number of factors, including the executive's experience and past performance, the level of skill and responsibility required by the executive's position and his or her qualifications for the position. As described above, the Compensation Committee also considers competitive salary information and seeks to set base salary at competitive levels in relation to the companies with which our company competes for executives.

During 2017, Mr. Hammers had a base salary of $425,000 for his role as Chief Executive Officer. Mr. Reynolds had a base salary of $300,000 for his role as Chief Financial Officer, Mr. Arnold had a base salary of $235,000 for his role as Vice President of Sales.

Short-Term Cash Incentive Compensation . In 2017, Cogentix provided its named executive officers with the opportunity to earn short-term cash incentive compensation through its Management Incentive Plan ("MIP"). The MIP is designed to provide a direct financial incentive to Cogentix's key management, including the named executive officers, for the achievement of, or surpassing, specific corporate goals.

Each named executive officer's short-term cash incentive compensation is the sum of:

- consolidated revenue versus plan revenue (75% of bonus opportunity)
- completion of a business development deal (15% of bonus opportunity)
- attainment of team member retention of at least 90% (10% of bonus opportunity)

The following table describes the short-term cash incentive opportunity for each of our named executive officers under the MIP in 2017, as a percentage of base salary.

Name	Target 2017 Incentive Opportunity as % of Base Salary	Target 2017 Bonus Opportunity
Mr. Hammers	65%	$ 276,250
Mr. Reynolds	45%	$ 135,000
Mr. Arnold	40%	$ 94,000

In 2017, revenue achievement was 101.6% of planned revenue. We also completed three business development deals – the Genesis acquisition, the equity investment in Vensica and the license agreement for Endourology. Therefore, the business development achievement was paid at 200% to plan. Finally, we achieved at least 90% for employee retention so this component was paid at 100% to plan.

Mr. Hammers, Mr. Reynolds and Mr. Arnold were paid bonuses under the MIP for 2017 in the amounts of $321,002, $156,870 and $109,228, respectively.

Long-Term Equity Incentive Compensation . In May 2017, the Compensation Committee reviewed equity compensation to our executive officers. Based upon a review of total compensation and equity compensation for the fiscal year 2017, the Compensation Committee granted restricted stock and stock options to certain members of management, including our executive officers. Effective as of May 19, 2017, 83,454 shares of restricted stock and 359,589 stock options were granted to Mr. Hammers. Mr. Reynolds received 52,457 shares of restricted stock and 226,027 stock options. Mr. Arnold received 35,765 shares of restricted stock and 154,110 stock options. The restricted stock will vest over a three-year period, with one-third vesting on each of May 19, 2018, 2019 and 2020. The options have a seven-year term and vest over a three-year period, with one-third vesting on each of May 19, 2018, 2019 and 2020. The exercise price of the stock options is $1.65, the closing stock price of the company on May 19, 2017.

Other Elements of Compensation . Executive officers also participated in various medical, dental, life, and disability benefit programs that were generally made available to all employees. Except as noted in the "Summary Compensation Table" below, we do not provide perquisites to our executive officers other than those available to all employees generally.

Employment Agreements

Cogentix has employment agreements with each of Messrs. Hammers and Reynolds. Mr. Arnold has certain severance benefits as specified in his employment offer letter.

Effective July 11, 2016, Darin Hammers was appointed as the Chief Executive Officer and President of the Company. Mr. Hammers had been serving as the interim Chief Executive Officer and President of the Company since May 24, 2016. Under the terms of his Employment Agreement dated July 11, 2016, Mr. Hammers was granted (a) an option to purchase 300,000 shares of the Company's common stock and (b) 100,000 shares of restricted stock. The option has an exercise price equal to the last sale price of the common stock as quoted on the Nasdaq on July 11, 2016, with a term of seven years, and becomes exercisable with respect to a cumulative 100,000 shares on the first, second and third anniversaries of the start date; provided Mr. Hammers remains an employee of the Company. The restricted stock will vest with respect to a cumulative one-third of the restricted shares on the first, second and third anniversaries of the start date. Mr. Hammers will be paid his base salary for 12 months and an amount equal to his last established target bonus following termination of his employment by the Company without Cause (as defined in the Employment Agreement) or by Mr. Hammers with Good Reason (as defined in the Employment Agreement). He is also entitled to a continuation of health benefits for twelve months.

Mr. Reynolds rejoined the Company as Executive Vice President, Chief Financial Officer and Corporate Secretary effective June 13, 2016. Under the terms of his Employment Agreement dated June 6, 2016, Mr. Reynolds was granted (a) an option to purchase 150,000 shares of the Company's common stock and (b) 70,000 shares of restricted stock. The option has an exercise price equal to the last sale price of the common stock as quoted on the Nasdaq on his start date, June 13, 2016, with a term of seven years, and becomes exercisable with respect to a cumulative 50,000 shares on the first, second and third anniversaries of the start date; provided Mr. Reynolds remains an employee of the Company. The restricted stock will vest with respect to a cumulative one-third of the restricted shares on the first, second and third anniversaries of the start date. Mr. Reynolds will be paid his base salary for 12 months and an amount equal to his last established target bonus following termination of his employment by the Company without Cause (as defined in the Employment Agreement) or by Mr. Reynolds with Good Reason (as defined in the Employment Agreement). He is also entitled to a continuation of health benefits for twelve months.

Mr. Arnold, under the terms of his employment offer letter, will be paid, in the event the Company terminates his employment without cause, an amount equal to his monthly base salary multiplied by the number of full years of his employment with the Company, but in no event shall post-termination payments payable to Mr. Arnold be less than six or greater than twelve months' salary.

For each named executive officer, in the event of a Change in Control, as defined in the 2015 Omnibus Plan, in which the Company is not the surviving entity and the equity awards are not assumed, vesting on all unvested options and restricted stock will accelerate. Within two years of a change in control when the Company is the surviving entity, vesting will accelerate on all unvested options and restricted stock if the executive's employment were to be terminated by the Company without Cause or Adverse Action or by him for Good Reason, as defined in the 2015 Omnibus Incentive Plan. Such a Change in Control occurred in November 2016 with the closing of the Accelmed investment. However, if acceleration would constitute a "parachute payment" (as defined in Section 280G(b)(2) of the Internal Revenue Code), then the "payments" to such Participant will be reduced (or acceleration of vesting eliminated) to the largest amount as will result in no portion of such "payments" being subject to the excise tax imposed by Section 4999 of the Internal Revenue Code.

Each named executive officer, including Messrs. Hammers, Reynolds and Arnold, has executed an Employee Confidentiality, Inventions, Non-Solicitation and Non-Compete Agreement, under which the named executive officer agreed not to disclose confidential information, to assign to our company without charge all intellectual property relating to its business which is created or conceived during the term of employment, to not encourage employees to leave employment for any reason and to not compete with us during the term of employment and for a period of twelve months thereafter.

Summary Compensation Table

The table below provides summary compensation information concerning all compensation awarded to, earned by or paid to the individuals who served as (i) our principal executive officers during the year ended December 31, 2017, and (ii) our most highly compensated executive officer who was serving at the end of December 2017, other than our principal executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($) (2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($) (3)	Total ($)
Darin Hammers President and Chief Executive Officer	2017	425,000	321,003	83,454	593,322	—	9,568	1,432,346
	2016	349,038	405,123	217,000	206,930	—	47,950	1,226,042
Brett A. Reynolds Senior Vice President, Chief Financial Officer and Corporate Secretary	2017	300,000	156,870	52,457	372,945	—	3,041	885,312
	2016	202,846	152,351	95,597	80,799	—	7,272	538,866
Chris Arnold Vice President of Sales	2017	235,000	109,228	35,765	254,282	—	798	635,073
	2016	230,269	153,336	25,750	12,553	—	7,963	429,870

(1) Amounts reported in the "Stock Awards" column represent the aggregate grant date fair value for restricted stock awards granted to each named executive officer in fiscal 2017 computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718. The grant date fair value is determined based on the fair value of our common stock at the date of the grant.

(2) Represents the aggregate grant date fair value for option awards granted to each named executive officer computed in accordance with FASB ASC Topic 718. Details of the assumptions used in valuing these awards are set forth in Note 4 to our audited financial statements.

(3) Mr. Hammers received a $40,000 moving allowance upon being named President and Chief Executive Officer in 2016. All other amounts represent 401(k) employer match.

Outstanding Equity Awards at Fiscal Year End

The table below provides information regarding unexercised stock option awards held by each of our named executive officers that remained outstanding at December 31, 2017.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of shares that have not vested (#)	Market value of shares that have not vested (1) ($)
Darin Hammers (2)	2/11/2013	$ 72,662	$ -	$ 3.62	2/10/2020	-	$ -
	8/12/2013	-	-	-	-	-	-
	4/21/2014	-	-	-	-	-	-
	4/27/2015	66,667	-	1.64	4/27/2022	16,666	52,498
	6/29/2016	33,334	-	1.03	6/29/2023	66,666	209,998
	7/11/2016	100,000	-	1.14	7/11/2023	66,666	209,998
	5/19/2017	-	359,589	1.65	5/19/2027	50,578	159,321
Brett Reynolds (2)	6/13/2016	50,000	100,000	0.88	6/13/2023	46,666	146,998
	6/29/2016	11,000	22,000	1.03	6/29/2023	22,000	69,300
	5/19/2017	-	226,027	1.65	5/19/2027	31,792	100,145
Chris Arnold (2)	4/27/2015	36,331	18,165	1.64	4/27/2022	4,844	15,259
	6/29/2016	8,334	16,666	1.03	6/29/2023	16,666	52,498
	5/19/2017	-	154,110	1.65	5/19/2027	21,676	68,279

(1) Calculated as the number of restricted stock awards that have not vested multiplied by the closing price of a share of Cogentix Medical's common stock as reported by Nasdaq on December 30, 2017 ($3.15).

(2) Restricted stock awards vest on a pro rata basis, so that one-third of the award vests on each of the first, second and third anniversaries of the grant date.

Potential Payments upon Termination or Change in Control

For a description of the payments available to our named executive officers in the event of their resignation, retirement or other termination, or in connection with a change in control of our company, see the description under the caption "Employment Agreements."

Overview of Director Compensation Program

As described in more detail under the heading " *Corporate Governance—Compensation Committee—Responsibilities* ", the Board of Directors has delegated to the Compensation Committee the responsibility, among other things, to establish and lead a process for the determination of compensation payable to our non-employee directors. The Compensation Committee makes recommendations regarding compensation payable to our non-employee directors to the entire Board of Directors, which then makes final decisions regarding such compensation.

Cash Compensation

Description	Annual Cash Retainer
Non-employee Director	$ 50,000
Board Chair	$ 25,000
Audit Committee Chair	$ 12,000
Audit Committee Member	$ 6,000
Nominating/Governance Committee Chair	$ 6,000
Nominating/Governance Committee Member	$ 2,500
Compensation Committee Chair	$ 8,000
Compensation Committee Member	$ 4,500

Mr. Geiger has waived all retainers for his service as Chair of the Board and as a non-employee director. The Company reimburses him quarterly, per the Purchase Agreement, for (i) expenses incurred in connection with his service to the Board for an amount not to exceed $32,000 annually and (ii) reasonable and documented travel expenses incurred in connection with his service to the Board.

Mr. Pell did not receive any compensation for his services as a member of the Board of Directors of our company during fiscal 2017. However, Mr. Pell received approximately $34,100 in cash as a salary for his service as an employee of our company during the fiscal year and also received secretarial support for which our company paid approximately $52,000 in cash during fiscal 2017.

Equity-Based Incentive Compensation

In addition to cash compensation, during the fiscal year ended December 31, 2017, each of our current non-employee directors received restricted stock awards for $100,000 worth of shares. The restricted stock awards vest six months from the date of the grant. Mr. Geiger waived his restricted stock award for 2017.

Director Compensation Table for 2017

The table below provides summary information concerning the compensation of each individual who served as a non-employee director of Cogentix during the year ended December 31, 2017:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1)	Option Awards ($) (2)	All Other Compensation ($) (3)	Total ($)
James D'Orta	$ 77,102	$ 100,001	$ —	$ —	$ 177,103
Uri Geiger	—	—	—	32,000	32,000
Cheryl Pegus	75,102	100,001	—	—	175,103
Kenneth Samet	76,602	100,001	—	—	176,603
Nachum Shamir	60,602	100,001	—	—	160,603
Howard Zauberman	56,102	100,001	—	25,500	181,603

(1) Amounts reported in the "Stock Awards" column represent the aggregate grant date fair value for restricted stock awards granted to each director in fiscal 2017 computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718. The grant date fair value is determined based on the fair value of our common stock at the date of the grant. As of December 31, 2017, there were no restricted stock grants outstanding.

(2) No option awards were granted to our non-employee directors during fiscal 2017. As of December 31, 2017, Mr. Zauberman and Ms. Pegus had 169,999 and 2,000 option awards outstanding, respectively.

(3) Amounts reported in the "All Other Compensation" column for Mr. Zauberman represent consulting fees for assessment of our Airway Management and Industrial product lines.

ITEM 13. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information contained under the heading "Share Ownership of Certain Beneficial Owners, Management and Directors" in the Proxy Statement is incorporated herein by reference. Further, see the information contained in Part II, Item 5 under the heading "Securities Authorized for Issuance Under Equity Compensation Plans."

ITEM 14. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Overview

The Governance and Nominating Committee reviews related party transactions and only approves or ratifies a related party transaction when it determines that, upon consideration of all relevant information, the transaction is in, or is not inconsistent with, the best interests of our company and its stockholders. Our policy with respect to transactions in which any of its directors or officers may have an interest, requires that such transaction (i) be on terms no less favorable to our company than could be obtained from unaffiliated third parties and (ii) be approved by the Governance and Nominating Committee and a majority of the uninterested, outside members of the Board of Directors. It is our policy that directors interested in a related party transaction will recuse themselves from any vote relating to a related party transaction in which they have an interest. All related party transactions in fiscal 2016 and fiscal 2017 and up to the latest practicable date before the printing of this Annual Report were approved in accordance with our policy.

Conversion of Pell Notes and Warrants

As a condition to the Accelmed investment, on September 7, 2016, we entered into the Note Exchange Agreement with Mr. Pell, under which the debt we owed to Mr. Pell was converted into our common stock at a price per share of $1.67. The Note Exchange Agreement also provided that, simultaneously with the conversion of such debt, all outstanding warrants to purchase our common stock that were held by Mr. Pell would be cancelled. We converted the outstanding principal amount, approximately $28.5 million, and accrued interest, approximately $1.0 million, on our promissory notes held by Mr. Pell into 17,688,423 shares of our common stock.

In fiscal 2016, the Board of Directors established a Special Committee of the Board, whose charter included the authority to review, evaluate, negotiate and approve the Pell debt conversion and the Accelmed investment, as well as the authority to evaluate any other conflicts of interest that could arise in connection with a potential change in control of the Company that could result from the proposed transactions. The Special Committee engaged an investment banking firm to provide a fairness opinion regarding the proposed transactions. The Special Committee recommended, and the Board approved, the transactions in September 2016, subject to stockholder approval. In November 2016, the Company's stockholders approved the transactions.

Director Independence

For a director of our company to be considered independent, the Board of Directors must affirmatively determine that the director meets the independence standards under the listing standards of Nasdaq, and the Board of Directors must affirmatively determine that the director has no material relationship with us, either directly or indirectly as a partner, stockholder or officer of an organization that has a relationship with us. The Board of Directors will consider all relevant facts and circumstances in making an independence determination, including all commercial, industrial, banking, consulting, legal, accounting, charitable, familial or other relationships any director may have with us. The Board has determined that all of the directors and director nominees, other than current directors Messrs. Hammers, Pell and Zauberman, based on their past and present employment relationships with our company, satisfy the independence standards of Nasdaq.

Because a majority of the voting power of Cogentix's outstanding common stock is owned or controlled by Lewis Pell and Accelmed, acting as a group pursuant to the Voting Agreement described under the caption "Information About Director Appointments in Connection with the Pell Debt Conversion and Accelmed Investment," the Company qualifies as a "controlled company" under Nasdaq Rule 5615(c)(2). As a result, the Company is exempt from certain Nasdaq listing requirements, including the requirements to have a majority of independent directors on the Board and fully independent Compensation and Governance and Nominating Committees. However, the Company continues to meet those requirements as of the date of this Annual Report on Form 10-K.

Beneficial Ownership

The table below sets forth information known to us regarding the beneficial ownership of our common stock as of December 31, 2017 for:

- each person our company believes beneficially holds more than 5% of the outstanding shares of our common stock based solely on our company's review of SEC filings;
- each of our directors and nominees for directors;
- each of the named executive officers named in the Summary Compensation Table under the heading *"Executive Compensation—Summary Compensation Table for Fiscal 2017* " (we collectively refer to these persons as our "named executive officers"); and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by a person includes shares subject to options held by that person that are currently exercisable or that become exercisable within 60 days of March 15, 2018. Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options currently exercisable or that become exercisable within 60 days of March 15, 2018 are outstanding for the purpose of computing the percentage of common stock owned by such person or group. However, such unissued shares of common stock described above are not deemed to be outstanding for calculating the percentage of common stock owned by any other person.

Except as otherwise indicated, the persons in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws where applicable and subject to the information contained in the notes to the table.

Name and Address of Beneficial Owner (1)	Amount and Nature of Beneficial Ownership (2)	Percent of Class
Beneficial Owners of More Than 5%		
Accelmed Growth Partners, L.P. ("Accelmed") c/o Accelmed Growth Partners Management Ltd. 6 Hachoshlim St. 6th Floor Herzliya Pituach, 46120	16,129,033	26.5%
Nantahala Capital Management LLC 19 Old Kings Highway S, Suite 200 Darien, CT 06820	3,693,853	6.0%
Named Executive Officers and Directors		
James D'Orta	159,172	0.3%
Uri Geiger	16,129,033(3)	26.5%
Darin Hammers	500,679	0.8%
Cheryl Pegus	199,472	0.3%
Lewis Pell	20,051,723	32.9%
Kenneth Samet	184,172	0.3%
Nachum Shamir	159,172	0.3%
Howard I. Zauberman	521,471	0.9%
Brett Reynolds	142,405	0.2%
Chris Arnold	80,852	0.1%
All Executive Officers and Directors as a Group	38,128,151	62.6%

(1) For Nantahala Capital Management LLC ("Nantahala"), information is contained in a Schedule 13G/A filed with the SEC on February 14, 2018 by Nantahala. The filing indicated that as of December 31, 2017, Nantahala shared voting and investment power over all of these shares with managing members Wilmot Harkey and Daniel Mack. .The business address for each of the directors and named executive officers of Cogentix is c/o Cogentix Medical, Inc., 5420 Feltl Road, Minnetonka, Minnesota 55343.

(2) Includes for the persons listed below the following shares of common stock subject to options held by such persons that are currently exercisable or become exercisable within 60 days of March 15, 2018:

Name	Shares of Common Stock Underlying Stock Options
Cheryl Pegus	2,000
Howard Zauberman	169,999
Darin Hammers	305,996
Brett Reynolds	61,000
Chris Arnold	62,830

(3) Includes shares held by Accelmed. Mr. Geiger is the controlling member and managing partner of Accelmed Growth Partners (AGP) Limited, which is the general partner of Accelmed Growth Partners (GP), L.P., which is the general partner of Accelmed, and as a result, he may be deemed to beneficially own the shares held by Accelmed. Mr. Geiger is also the controlling shareholder and managing partner of Accelmed Growth Partners Management Ltd., which has certain voting and dispositive power over the shares held by Accelmed pursuant to a management agreement.

ITEM 15. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit, Audit-Related, Tax and Other Fees

The tables below present fees for professional services rendered by Grant Thornton and its affiliates for the years ended December 31, 2017 and 2016.

	Aggregate Amount Billed	
	2017	2016
Audit Fees (1)	$ 349,922	$ 298,512
Audit Related Fees (2)	16,424	33,280
Tax Fees (3)	66,495	9,691

(1) Audit fees consisted of the audit of our annual financial statements for the years ended December 31, 2017 and 2016.

(2) Audit related fees for the current and prior year consisted of fees related to our annual 401(k) audit. Fees for 2016 also include fees related to the Accelmed Investment and Pell debt conversion.

(3) Tax fees are for work associated with our international subsidiaries.

Pre-Approval Policies and Procedures

The Audit Committee has adopted procedures pursuant to which all audit, audit-related and tax services, and all permissible non-audit services provided by our independent registered public accounting firm must be pre-approved by the Audit Committee. All services rendered by Grant Thornton during our fiscal year 2017 were permissible under applicable laws and regulations and were approved in advance by the Audit Committee in accordance with the rules adopted by the SEC in order to implement requirements of the Sarbanes-Oxley Act of 2002, other than de minimis non-audit services allowed under applicable law.

PART IV

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements:

2. Financial Statement Schedule:

Schedule I – Valuation and Qualifying Accounts

	Balance at beginning of fiscal year	Additions charged to expenses	Written off, less recoveries	Effects of foreign currency fluctuations	Balance at end of fiscal year
Allowance for doubtful accounts					
Twelve months ended December 31, 2017	$ 34,000	$ 70,000	$ (18,000)	$ 1,000	$ 87,000
Twelve months ended December 31, 2016	$ 27,000	$ 21,000	$ (14,000)	$ -	$ 34,000

	Balance at beginning of fiscal year	Additions charged against revenues	Returns written off	Effects of foreign currency fluctuations	Balance at end of fiscal year
Allowance for sales returns					
Twelve months ended December 31, 2017	$ 49,000	$ -	$ (34,000)	$ -	$ 15,000
Twelve months ended December 31, 2016	$ 41,000	$ 9,000	$ (1,000)	$ -	$ 49,000

3. Exhibits

A copy of any of the exhibits listed will be furnished at a reasonable cost, upon receipt from any person of a written request for such exhibit. Such requests should be sent to Cogentix Medical, Inc., 5420 Feltl Road, Minnetonka, Minnesota 55343 Attn: Corporate Secretary. The Exhibit Index indicates each management contact or compensatory plan or arrangement referenced as an exhibit to this report.

Exhibit No.	Exhibit	Method of Filing
*2.1	Agreement and Plan of Merger dated as of December 21, 2014 by and among Vision-Sciences, Inc., Visor Merger Sub LLC, and Uroplasty, Inc.	Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K as filed with the SEC on December 22, 2014 (File No. 000-20970)
*2.2	Agreement and Plan of Merger, dated as of March 11, 2018, by and among LM US Parent, Inc., Camden Merger Sub, Inc. and Cogentix Medical, Inc.	Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed with the SEC on March 12, 2018 (File No. 000-20970)
3.1	Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed on November 13, 2017(File No. 000-20970)
3.2	(a) Amended and Restated By-laws.	Incorporated by reference to Exhibit 3.2 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed on November 13, 2017 (File No. 000-20970)
	(b) Amendment to the Amended and Restated By-laws.	Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on March 12, 2018 (File No. 000-20970)
10.1	Common Stock Purchase Warrants of Vision-Sciences, Inc. issued to Lewis C. Pell dated November 9, 2009.	Incorporated by reference to Exhibit 10.46 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 filed with the SEC on November 12, 2009 (File No. 000-20970)
10.2	Common Stock Purchase Warrants of Vision-Sciences, Inc. issued to Lewis C. Pell dated September 30, 2011.	Incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K filed on October 4, 2011 (File No. 000-20970)
10.3	Letter Agreement dated December 21, 2014 by and between Vision-Sciences, Inc. and Lewis C. Pell regarding extension of warrants.	Incorporated by reference to Exhibit 4.4 to Current Report on Form 8-K as filed with the SEC on December 22, 2014 (File No. 000-20970)
10.4	Convertible Promissory Note issued by Vision-Sciences, Inc. issued to Lewis C. Pell dated as of September 19, 2012.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 20, 2012 (File No. 000-20970)
10.5	Additional Convertible Promissory Note issued by Vision-Sciences, Inc. to Lewis C. Pell dated September 25, 2013.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 30, 2013 (File No. 000-20970)
10.6	2014 Convertible Promissory Note issued by Vision-Sciences, Inc. to Lewis C. Pell dated June 16, 2014.	Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed with the SEC of June 17, 2014 (File No. 000-20970)
10.7	Amendment to Convertible Promissory Note dated December 21, 2014 by and between Vision-Sciences, Inc. and Lewis C. Pell.	Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K as filed with the SEC on December 22, 2014 (File No. 000-20970)
10.8	Amendment to Additional Convertible Promissory Note dated December 21, 2014 by and between Vision-Sciences, Inc. and Lewis C. Pell.	Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K as filed with the SEC on December 22, 2014 (File No. 000-20970)
10.9	Amendment to 2014 Convertible Promissory Note dated December 21, 2014 by and between Vision-Sciences, Inc. and Lewis C. Pell.	Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K as filed with the SEC on December 22, 2014 (File No. 000-20970)

Exhibit No.	Exhibit	Method of Filing
10.10	Settlement Agreement, dated May 23, 2016, by and among Cogentix Medical, Inc., Robert C. Kill, Lewis C. Pell, Howard I. Zauberman, Kevin H. Roche, Kenneth H. Paulus, James P. Stauner, and Cheryl Pegus.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on May 27, 2016 (File No. 000-20870)
10.11	Note Exchange Agreement, dated September 7, 2016, by and between Cogentix Medical, Inc. and Lewis C. Pell.	Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K as filed with the SEC on September 7, 2016 (File No. 000-20870)
10.12	Securities Purchase Agreement, dated September 7, 2016, by and between Cogentix Medical, Inc. and Accelmed Growth Partners, L.P.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on September 7, 2016 (File No. 000-20870)
10.13	Registration Rights Agreement, dated November 3, 2016, by and among Cogentix Medical, Inc., Accelmed Growth Partners, L.P. and Lewis C. Pell.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on November 3, 2016 (File No. 000-20870)
10.14	Voting Agreement, dated September 7, 2016, by and between Accelmed Growth Partners, L.P. and Lewis C. Pell.	Incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K as filed with the SEC on September 7, 2016 (File No. 000-20870)
10.15	Lease Agreement between Vision-Sciences, Inc. and 30 Ramland Road LLC dated as of March 23, 2000.	Incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K for the fiscal year ended March 31, 2000 filed with the SEC on June 29, 2000 (File No. 333-72547)
10.16	First Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of August 31, 2000.	Incorporated by reference to Exhibit 10.22 to Annual Report on Form 10-K for the fiscal year ended March 31, 2015 filed with the SEC on June 25, 2015 (File No. 000-20970)
10.17	Second Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of January 7, 2005.	Incorporated by reference to Exhibit 10.23 to Annual Report on Form 10-K for the fiscal year ended March 31, 2015 filed with the SEC on June 25, 2015 (File No. 000-20970)
10.18	Third Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of December 26, 2006.	Incorporated by reference to Exhibit 10.38 to Annual Report on Form 10-K for the fiscal year ended March 31, 2008 filed with the SEC on July 3, 2008 (File No. 000-20970)
10.19	Fourth Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of April 12, 2009.	Incorporated by reference to Exhibit 10.44 to Annual Report on Form 10-K for the fiscal year ended March 31, 2009 filed with the SEC on June 29, 2009 (File No. 000-20970)
10.20	Fifth Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of December 12, 2014.	Incorporated by reference to Exhibit 10.20 to Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2017 (File No. 000-20970)
10.21	Sixth Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of January 6, 2017.	Incorporated by reference to Exhibit 10.21 to Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2017 (File No. 000-20970)

Exhibit No.	Exhibit	Method of Filing
10.22	Loan Extension Agreement dated March 21, 2017, to the Loan Agreement, dated September 18, 2015, by and between Cogentix Medical, Inc., Machida Incorporated, Uroplasty, LLC, and Venture Bank	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on March 24, 2017 (File No. 000-20970)
10.23	Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. (formerly Uroplasty, Inc.) and Tyco Healthcare Group LP (d/b/a Covidien)	Incorporated by reference to Exhibit 10.33 to Current Report on Form 8-K filed on December 6, 2007 by Uroplasty, Inc. (File No. 001-32632)
10.24	First Amendment dated February 26, 2008, to the Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. and Tyco Healthcare Group LP (d/b/a Covidien)	Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017 (File No. 000-20970)
10.25	Second Amendment dated March 24, 2010, to the Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. and Tyco Healthcare Group LP (d/b/a Covidien)	Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017 (File No. 000-20970)
10.26	Third Amendment dated April 30, 2011, to the Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. and Tyco Healthcare Group LP (d/b/a Covidien)	Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017 (File No. 000-20970)
10.27	Fourth Amendment dated March 31, 2014, to the Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. and Covidien Sales LLC	Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017 (File No. 000-20970)
10.28	Fifth Amendment effective July 1, 2017, to the Supply Agreement, dated December 6, 2007, by and between Cogentix Medical, Inc. and Covidien Sales LLC	Incorporated by reference to Exhibit 10.8 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017 (File No. 000-20970)
**10.29	Employment Agreement between Uroplasty, Inc. and Robert C. Kill dated July 22, 2013.	Incorporated by reference to Exhibit 10.15 to Uroplasty's Annual Report on Form 10-K for the fiscal year ended March 31, 2013 (File No. 001-32632)
**10.30	First Amendment to the Employment Agreement between Uroplasty, Inc. and Robert C. Kill dated May 29, 2014.	Incorporated by reference to Exhibit 10.1 to Uroplasty's Current Report on Form 8-K as filed with the SEC on June 3, 2014 (File No. 001-32632)
**10.31	Separation and Release Agreement, dated May 23, 2016, by and among Cogentix Medical, Inc., Robert C. Kill and the other signatories thereto.	Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K as filed with the SEC on May 27, 2016 (File No. 000-20870)
**10.32	Employment Agreement, dated July 11, 2016, by and between Cogentix Medical, Inc. and Darin Hammers.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on July 12, 2016 (File No. 000-20870)

Exhibit No.	Exhibit	Method of Filing
**10.33	Employment Agreement, dated June 6, 2016, by and between Cogentix Medical, Inc. and Brett Reynolds.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on June 15, 2016 (File No. 000-20870)
10.34	Lease Agreement between Uroplasty, Inc. and Liberty Property Limited Partnership dated January 20, 2006.	Incorporated by reference to Exhibit 10.25 to Uroplasty's Current Report on Form 8-K as filed with the SEC on January 24, 2006 (File No. 001-32632)
10.35	First Amendment to Lease by and between Liberty Property Limited Partnership and Uroplasty, Inc. dated January 24, 2014.	Incorporated by reference to Exhibit 10.21 to Uroplasty's Annual Report on Form 10-K for the fiscal year ended March 31, 2014 (File No. 001-32632)
10.36	Lease Agreement between Glenborough Flanders Park, LLC and Cogentix Medical, Inc. dated as of April 2, 2015.	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K as filed with the SEC on April 3, 2015 (File No. 000-20970)
**10.37	Cogentix Medical, Inc. 2015 Omnibus Incentive Plan.	Incorporated by reference to Exhibit 4.10 to Registration Statement on Form S-8 as filed with the SEC on March 31, 2015 (File No. 333-203135)
**10.38	Uroplasty, Inc. 2002 Employee Stock Option Plan.	Incorporated by reference to the copy filed as Appendix B to Uroplasty's Definitive Proxy Statement as filed with the SEC on August 1, 2002 (File No. 000-20989)
**10.39	Uroplasty, Inc. 2006 Amended Stock and Incentive Plan.	Incorporated by reference to the copy attached as Appendix A to Uroplasty's Definitive Proxy Statement as filed with the SEC on July 25, 2008 (File No. 001-32632)
**10.40	Form of Nonqualified Stock Option Agreement under the Uroplasty, Inc. 2006 Amended Stock and Incentive Plan.	Incorporated by reference to Exhibit 10.1 to Uroplasty's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (File No. 001-32632)
**10.41	Form of Non-employee Director Nonqualified Stock Option Agreement under the Uroplasty, Inc. 2006 Amended Stock and Incentive Plan.	Incorporated by reference to Exhibit 10.2 to Uroplasty's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (File No. 001-32632)
**10.42	Form of Restricted Stock Award Agreement under the Uroplasty, Inc. 2006 Amended Stock and Incentive Plan.	Incorporated by reference to Exhibit 10.3 to Uroplasty's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (File No. 001-32632)
**10.43	Form of Non-employee Director Restricted Stock Award Agreement under the Uroplasty, Inc. 2006 Amended Stock and Incentive Plan.	Incorporated by reference to Exhibit 10.4 to Uroplasty's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (File No. 001-32632)
**10.44	Uroplasty, Inc. Performance Award Grant Notice 2006 Equity and Incentive Plan.	Incorporated by reference to Exhibit 10.2 to Uroplasty's Current Report on Form 8-K filed October 3, 2014 (File No. 001-32632)

Exhibit No.	Exhibit	Method of Filing
**10.45	Vision-Sciences, Inc. 2000 Stock Incentive Plan.	Incorporated by reference to Exhibit 10.26 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2000 filed with the SEC on June 29, 2000 (File No. 333-72547)
**10.46	Vision-Sciences, Inc. 2003 Director Option Plan, as amended.	Incorporated by reference to Exhibit 4 to the Registration Statement on Form S-8 filed with the SEC on October 10, 2008 (File No. 333-154150)
**10.47	Vision-Sciences, Inc. 2007 Stock Incentive Plan, as amended.	Incorporated by reference to the Appendix A to the Definitive Proxy Statement filed with the SEC on July 27, 2007 on Schedule 14A (File No. 000-20970)
**10.48	Restricted Stock Agreement dated November 26, 2013 between Vision-Sciences, Inc. and Howard I. Zauberman.	Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on November 27, 2013 (File No. 000-20970)
**10.49	Consulting Agreement dated March 2, 2017 between Cogentix Medical, Inc. and Howard I. Zauberman.	Incorporated by reference to Exhibit 10.42 to Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2017 (File No. 000-20970)
17.1	Letter dated May 24, 2016 from Kevin H. Roche to the Directors of Cogentix Medical, Inc.	Incorporated by reference to Exhibit 17.1 to Current Report on Form 8-K as filed with the SEC on May 27, 2016 (File No. 000-20870)
21.1	Subsidiaries of Cogentix Medical, Inc.	Filed herewith
23.1	Consent of Grant Thornton LLP, independent registered public accounting firm.	Filed herewith
31.1	Certification by the PEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
31.2	Certification by the PFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
32.1	Certification by the PEO pursuant to Section 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith
32.2	Certification by the PFO pursuant to Section 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith
101.INS	XBRL Instance	Furnished herewith ***
101.SCH	XBRL Taxonomy Extension Schema	Furnished herewith ***
101.CAL	XBRL Taxonomy Extension Calculation	Furnished herewith ***
101.DEF	XBRL Taxonomy Extension Definition	Furnished herewith ***
101.LAB	XBRL Taxonomy Extension Labels	Furnished herewith ***
101.PRE	XBRL Taxonomy Extension Presentation	Furnished herewith ***

* Certain schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. We will furnish copies of any such omitted schedules to the SEC upon request.

** Management contract or compensatory plan or arrangement filed as an exhibit to this report pursuant to Item 15(a) and 15(b) of Form 10-K.

*** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

ITEM 17. FORM 10-K SUMMARY.

None.

Table of Contents

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 30, 2018

COGENTIX MEDICAL, INC.

By /s/ Darin Hammers
Darin Hammers
President and Chief Executive Officer

In accordance with 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 / Capacity	Date
/s/ Darin Hammers Darin Hammers	President and Chief Executive Officer, (Principal Executive Officer)	March 30, 2018
/s/ Brett Reynolds Brett Reynolds	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2018
/s/ Uri Geiger Uri Geiger	Chairman of the Board of Directors	March 30, 2018
/s/ Nachum Shamir Nachum Shamir	Director	March 30, 2018
/s/ James A. D'Orta James A. D'Orta	Director	March 30, 2018
/s/ Cheryl Pegus Cheryl Pegus	Director	March 30, 2018
/s/ Lewis C. Pell Lewis C. Pell	Director	March 30, 2018
/s/ Kenneth S. Samet Kenneth S. Samet	Director	March 30, 2018
/s/ Howard I. Zauberman Howard I. Zauberman	Director	March 30, 2018

COGENTIX MEDICAL, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements
December 31, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Cogentix Medical, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Cogentix Medical, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the years then ended, and the related notes and schedules (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, 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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting 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/ GRANT THORNTON LLP

We have served as the Company's auditor since 2008.

Minneapolis, MN
March 30, 2018

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 20,909,605	$ 9,369,624
Short-term investments	6,247,265	13,573,057
Accounts receivable, net	8,275,518	6,770,838
Inventories	7,176,695	7,235,043
Other	1,075,170	571,527
Total current assets	43,684,253	37,520,089
Property, plant, and equipment, net	2,427,479	2,115,316
Goodwill	19,153,554	18,749,888
Other intangibles, net	7,362,144	9,482,578
Long-term investments	-	5,344,004
Equity method investment	1,871,360	-
Deferred tax assets and other	245,078	163,427
Total assets	$ 74,743,868	$ 73,375,302

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,983,899	$ 2,689,035
Income taxes payable	87,441	113,191
Accrued liabilities:		
Compensation	4,171,976	4,670,640
Deferred revenue	774,635	597,524
Other	1,360,743	838,272
Total current liabilities	9,378,694	8,908,662
Accrued pension liability	264,692	308,918
Deferred rent	586,296	639,019
Other	478,347	278,780
Total liabilities	10,708,029	10,135,379
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized; none issued or outstanding at December 31, 2017 and 2016, respectively	-	-
Common stock $.01 par value; 100,000,000 shares authorized, 60,905,666 and 60,436,548 shares issued and outstanding at December 31, 2017 and 2016, respectively.	609,059	604,368
Additional paid-in capital	145,982,121	144,430,381
Accumulated deficit	(81,999,901)	(81,005,654)
Accumulated other comprehensive loss	(555,440)	(789,172)
Total shareholders' equity	64,035,839	63,239,923
Total liabilities and shareholders' equity	$ 74,743,868	$ 73,375,302

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31 2017	Twelve Months Ended December 31 2016
Net sales	$ 56,316,109	$ 51,851,159
Cost of goods sold	18,872,250	16,248,111
Gross profit	37,443,859	35,603,048
Operating expenses		
General and administrative	8,293,814	6,778,010
Research and development	4,742,308	4,701,539
Selling and marketing	22,907,468	21,313,364
One-time costs	-	2,257,654
Amortization of intangibles	2,389,743	2,363,432
	38,333,333	37,413,999
Operating loss	(889,474)	(1,810,951)
Other income (expense)		
Interest income	245,678	25,455
Interest expense	(29,034)	(1,298,253)
Debt conversion expense	-	(18,841,407)
Foreign currency exchange gain (loss)	48,479	(25,022)
Other	7,365	-
	272,488	(20,139,227)
Loss before income taxes	(616,986)	(21,950,178)
Income tax expense	137,124	144,769
Equity-method investment activity, net of tax	128,640	-
Net loss	$ (882,750)	$ (22,094,947)
Basic and diluted net loss per common share	$ (0.01)	$ (0.71)
Weighted average common shares outstanding:		
Basic and diluted	59,981,534	30,903,035

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Twelve Months Ended December 31 2017	Twelve Months Ended December 31 2016
Net loss	$ (882,750)	$ (22,094,947)
Other comprehensive income, net of tax:		
Foreign currency translation adjustments	226,801	(111,515)
Unrealized gain (loss) on available-for-sale investments	17,335	(21,349)
Pension adjustments	(10,404)	220,190
Total other comprehensive income, net of tax	233,732	87,326
Comprehensive loss	$ (649,018)	$ (22,007,621)

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
Balance at December 31, 2015	26,057,327	$ 260,574	$ 76,485,650	$(58,910,707)	$ (876,498)	$ 16,959,019
Share-based compensation expense	629,994	6,300	741,819	-	-	748,119
Restricted stock exchanged for taxes	(68,229)	(682)	(56,661)	-	-	(57,343)
Conversion of related party debt and accrued interest	17,688,423	176,885	43,991,964	-	-	44,168,849
Issuance of common stock, net of expenses	16,129,033	161,291	23,267,609	-	-	23,428,900
Comprehensive loss	-	-	-	(22,094,947)	87,326	(22,007,621)
Balance at December 31, 2016	60,436,548	604,368	144,430,381	(81,005,654)	(789,172)	63,239,923
Share-based compensation expense	472,168	4,722	1,448,189	-	-	1,452,911
Proceeds from exercise of stock options, net of shares exchanged for taxes	(3,050)	(31)	(7,946)	-	-	(7,977)
Adoption of ASU 2016-09	-	-	111,497	(111,497)	-	-
Comprehensive loss	-	-	-	(882,750)	233,732	(649,018)
Balance at December 31, 2017	**60,905,666**	**$ 609,059**	**$145,982,121**	**$(81,999,901)**	**$ (555,440)**	**$ 64,035,839**

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Twelve Months ended December 31, 2017	Twelve Months ended December 31, 2016
Cash flows from operating activities:		
Net loss	$ (882,750)	$ (22,094,947)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	3,165,980	3,136,109
Debt conversion expense	-	18,841,407
Loss by equity method investee	128,640	-
Loss on disposal of equipment	1,997	5,640
Amortization of premium on marketable securities	104,757	8,003
Share-based compensation expense	1,452,911	748,119
Amortization of discount on related party debt	-	940,923
Long term incentive plan	-	(74,404)
Deferred income taxes	(80,048)	57,536
Deferred rent	(32,697)	3,777
Restricted stock exchanged for taxes	(17,690)	(57,343)
Changes in operating assets and liabilities:		
Accounts receivable	(661,770)	1,359,056
Inventories	276,090	(2,655,221)
Other current assets	(279,327)	253,553
Accounts payable	(90,320)	484,237
Interest payable	-	292,049
Accrued compensation	(768,485)	1,609,281
Accrued liabilities, other	(108,111)	270,612
Accrued pension liability	(85,270)	(116,395)
Deferred revenue	182,804	288,329
Net cash provided by operating activities	2,306,711	3,300,321
Cash flows from investing activities:		
Proceeds from maturity of available-for-sale-securities	15,020,000	-
Purchases of available-for-sale securities	(2,438,322)	(18,945,717)
Purchase of equity method investment	(2,000,000)	-
Purchases of property, plant and equipment	(856,875)	(355,145)
Acquisition of business, net of cash acquired	(181,261)	-
Net cash provided by (used in) investing activities	9,543,542	(19,300,862)
Cash flows from financing activities:		
Borrowings from line of credit	3,033,385	2,646,500
Repayments of line of credit	(3,033,385)	(2,646,500)
Payments of note payable	(47,329)	-
Payments of secured borrowings	(238,984)	-
Proceeds from exercise of stock options	9,713	-
Proceeds from sale of common stock, net	-	23,428,900
Net cash provided by (used in) financing activities	(276,600)	23,428,900
Effect of exchange rates on cash and cash equivalents	(33,672)	(35,329)
Net increase in cash and cash equivalents	11,539,981	7,393,030
Cash and cash equivalents at beginning of period	9,369,624	1,976,594
Cash and cash equivalents at end of period	$ 20,909,605	$ 9,369,624
Supplemental disclosure of cash flow information:		
Cash paid during the period for income tax	$ 284,374	$ 42,957
Cash paid during the period for interest	$ 13,845	$ 62,418
Non-cash financing activities:		
Note payable issued in conjunction with acquisition of business	$ 462,184	$ -
Non-cash debt and interest converted to equity	$ -	$ 25,327,441

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the twelve months ended December 31, 2017 and 2016

Note 1: Summary of Significant Accounting Policies

Nature of Business.

Cogentix Medical, Inc., headquartered in Minnetonka, Minnesota, with additional operations in New York, Massachusetts, The Netherlands and the United Kingdom, is a global medical device company. We design, develop, manufacture and market products for flexible endoscopy with our unique PrimeSight™ product lines featuring a streamlined visualization system and proprietary sterile disposable microbial barrier providing users with efficient and cost-effective endoscope turnover while enhancing patient safety. We also commercialize the Urgent® PC Neuromodulation System, an FDA-cleared device that delivers percutaneous tibial nerve stimulation (PTNS) for the office-based treatment of overactive bladder (OAB). OAB is a chronic condition that affects approximately 42 million U.S. adults. The symptoms include urinary urgency, frequency and urge incontinence. We also offer Macroplastique®, an injectable urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency. Outside the U.S., the Company markets additional bulking agents: PTQ ® for the treatment of fecal incontinence and VOX ® for vocal cord augmentation and vesicourethral reflux.

Change in Control.

A change in control of the Company occurred on November 3, 2016 as a result of the conversion of the Company's convertible debt – related party into equity (see Note 3) and the issuance of common shares to Accelmed Growth Partners (see Note 5). The convertible debt – related party was owed to Lewis Pell, a member of our board of directors. As a result of the transactions described above, Mr. Pell and Accelmed owned or controlled approximately 33% and 27%, respectively, of the outstanding common stock of the Company immediately subsequent to these transactions being consummated. Accelmed and Mr. Pell entered into a voting agreement pursuant to which Mr. Pell and Accelmed have agreed to vote their shares of the Company's common stock for the other party's nominees to the board of directors. Further, the securities purchase agreement with Accelmed provides it with numerous protective provisions, including prohibiting the Company, without the prior approval of the Accelmed directors, from engaging in any merger, consolidation, transfer or conversion involving the Company, incurring any new indebtedness in excess of $10,000,000, and changing the size of the Board of Directors.

The Company has elected not to apply pushdown accounting adjustments to the Company's consolidated financial statements related to the change in control as allowed by Accounting Standards Update No. 2014-17.

Basis of Presentation.

The consolidated financial statements include the accounts of Cogentix Medical, Inc. and its wholly owned subsidiaries. We have eliminated all intercompany accounts and transactions in consolidation. We have reclassified certain prior-year amounts to conform to the current year's presentation.

Revenue Recognition.

We recognize revenue in accordance with the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 605 (Topic 605, *Revenue Recognition*) . ASC 605 requires that four basic criteria must be met before revenue can be recognized:

1. persuasive evidence that an arrangement exists;
2. delivery has occurred or services were rendered;
3. the fee is fixed and determinable; and
4. collectability is reasonably assured

We recognize revenue when title passes to the customer, generally upon shipment of our products F.O.B. shipping point. Revenue for service repairs of equipment is recognized after service has been completed, and service contract revenue is recognized ratably over the term of the contract. We review our service contracts to determine if multiple element arrangements exist. A multiple element arrangement includes the sale of endoscopes and service contracts. We allocate revenue to all elements based on their stand-alone selling prices by applying the relative stand-alone selling price methodology. Revenue allocated to the endoscopes in these arrangements is recognized upon shipment. Service contract revenue is deferred and represents the allocated selling price of any deliverables of the arrangement for which the customer has provided consideration, but the revenue recognition requirements have not been satisfied.

We include shipping and handling charges billed to customers in net sales, and include related costs incurred by us in cost of goods sold. Typically, our agreements contain no customer acceptance provisions or clauses. We sell our products to end users and to distributors. Payment terms range from prepayment to 120 days. Sales to distributors are not contingent on the distributor selling the product to end users. Customers do not have the right to return products except for warranty claims. We offer customary product warranties. We present our sales in our statement of operations net of taxes, such as sales, use, value-added and certain excise taxes, collected from the customers and remitted to governmental authorities.

Use of Estimates.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires us 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. Actual results could differ from these estimates. Our significant accounting policies and estimates include revenue recognition, short- and long-term investments, accounts receivable, valuation of inventory, foreign currency translation/transactions, purchase price allocations on acquisition, the determination of recoverability of long-lived assets and liabilities and intangible assets, share-based compensation, defined benefit pension plans, and income taxes.

Advertising Expenses.

Advertising costs are expensed as incurred. Such costs incurred were approximately $360,000 and $363,000 for the twelve months ended December 31, 2017 and 2016, respectively.

Research and Development Expenses.

Costs of research, new product development, and product redesign are charged to expense as incurred.

Share-Based Compensation.

We account for share-based compensation costs under ASC 718, "Compensation – Stock Compensation". ASC 718 covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. We recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options and restricted shares, in our consolidated financial statements. We measure that cost based on the fair value of the equity or liability instruments issued. We account for forfeitures in the period in which they occur. We also recognize certain tax benefits or tax shortfalls upon a restricted-stock award vesting or stock options exercise relative to the deferred tax asset position established in the provision for income taxes line in the consolidated statement of operations.

Segment Reporting.

We operate in three markets – urology/gynecology, airway management, and industrial. Our Chief Executive Officer has been identified as our chief operating decision-maker and all significant operating decisions including the allocation of resources are based upon the analysis of the Company as three segments. This is a change from prior periods in which we reported only one segment as discrete financial information was not available for each market individually.

Defined Benefit Pension Plans.

We have a liability attributed to defined benefit pension plans we offered to certain former and current employees of our subsidiaries in the UK and The Netherlands. The liability is dependent upon numerous factors, assumptions and estimates, and the continued benefit costs we incur may be significantly affected by changes in key actuarial assumptions such as the discount rate, mortality, compensation rates, or retirement dates used to determine the projected benefit obligation. Additionally, changes made to the provisions of the plans may impact current and future benefit costs. In accordance with the provisions of ASC 715, "Compensation – Retirement Benefits", changes in benefit obligations associated with these factors may not be immediately recognized as costs in the statement of operations, but are recognized in future years over the expected average future service of the active employees or the average remaining life expectancies of inactive employees.

Disclosures About Fair Value of Financial Instruments.

Estimates of fair value for financial assets and liabilities are based on the framework established in the accounting guidance for fair value measurements. The framework defines fair value, provides guidance for measuring fair value and requires certain disclosures. The framework prioritizes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The following three broad levels of inputs may be used to measure fair value under the fair value hierarchy:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Significant unobservable inputs that cannot be corroborated by observable market data and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

If the inputs used to measure the financial assets and liabilities fall within more than one of the different levels described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The following tables show our cash and available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category recorded as cash and cash equivalents or short- or long-term investments as of December 31, 2017 and 2016:

	December 31, 2017						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-Term Investments	Long-Term Investments
Cash	$ 4,318,229	$ -	$ -	$ 4,318,229	$ 4,318,229	$ -	$ -
Level 1:							
Money market funds	16,591,376	-	-	16,591,376	16,591,376	-	-
Subtotal	16,591,376	-	-	16,591,376	16,591,376	-	-
Level 2:							
Certificates of deposit	1,440,000	-	(1,783)	1,438,217	-	1,438,217	-
Commercial paper	1,198,574	-	(362)	1,198,212	-	1,198,212	-
Corporate notes/bonds	3,612,704	-	(1,868)	3,610,836	-	3,610,836	-
U.S. government agencies	-	-	-	-	-	-	-
Subtotal	6,251,278	-	(4,013)	6,247,265	-	6,247,265	-
Total	$ 27,160,883	$ -	$ (4,013)	$ 27,156,870	$ 20,909,605	$ 6,247,265	$ -

	December 31, 2016						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-Term Investments	Long-Term Investments
Cash	$ 3,773,790	$ -	$ -	$ 3,773,790	$ 3,773,790	$ -	$ -
Level 1:							
Money market funds	3,197,958	-	-	3,197,958	3,197,958	-	-
Subtotal	3,197,958	-	-	3,197,958	3,197,958	-	-
Level 2:							
Certificates of deposit	2,160,010	2,285	-	2,162,295	-	720,031	1,442,264
Commercial paper	5,984,110	-	(4,100)	5,980,010	2,397,876	3,582,134	-
Corporate notes/bonds	9,688,957	-	(13,885)	9,675,072	-	7,273,992	2,401,080
U.S. government agencies	3,503,208	-	(5,648)	3,497,560	-	1,996,900	1,500,660
Subtotal	21,336,285	2,285	(23,633)	21,314,937	2,397,876	13,573,057	5,344,004
Total	$ 28,308,033	$ 2,285	$ (23,633)	$ 28,286,685	$ 9,369,624	$ 13,573,057	$ 5,344,004

Cash, Cash Equivalents and Marketable Securities.

We consider all cash on-hand and highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. We classify marketable securities having original maturities of more than three months when purchased and remaining maturities of one year or less as short-term investments and marketable securities with remaining maturities of more than one year as long-term investments. We further classify marketable securities as available-for-sale. We have not designated any of our marketable securities as trading securities or as held to maturity. We may sell any of our marketable securities prior to their stated maturities for strategic reasons including, but not limited to, anticipation of credit deterioration and duration management. At December 31, 2017, we did not have any long-term securities.

We consider the declines in market value of our marketable securities investment portfolio to be temporary in nature. We typically invest in highly-rated securities, and our investment policy generally limits the amount of credit exposure to any one issuer.

Cash and cash equivalents include highly liquid money market funds and debt securities with original maturities of three months or less totaling $20.1 million and $9.4 million at December 31, 2017 and 2016, respectively. Money market funds present negligible risk of changes in value due to changes in interest rates, and their cost approximates their fair market value. We maintain cash in bank accounts, which, at times, may exceed federally insured limits. We have not experienced any losses in such accounts. Cash and cash equivalents held in foreign bank accounts totaled $879,000 and $507,000 at December 31, 2017 and 2016, respectively.

Equity Investment.

ASC 323, "Investments – Equity Method and Joint Ventures," establishes accounting guidelines for an equity investment in which the Company has the ability to exercise significant influence, but does not have a controlling interest. In this situation, the equity method should be applied to an investment. Significant influence is generally considered to exist when the Company has an ownership interest in the voting stock of an entity between 20% and 50%, and other factors, such as representation on the Board of Directors, are considered in determining whether the equity method of accounting is appropriate.

Accounts Receivable.

We grant credit to our customers in the normal course of business and, generally, do not require collateral or any other security to support amounts due. If necessary, we have an outside party assist us with performing credit and reference checks and establishing credit limits for the customer. Concentration of credit risk with respect to accounts receivable relates to certain domestic and international customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, when appropriate, we obtain advance payments for our international sales. As a consequence, we believe that our accounts receivable credit risk exposure is limited. Historically we have not experienced any significant credit losses related to any individual customer or group of customers in any particular industry or geographic area.

Accounts outstanding longer than the contractual payment term, are considered past due. We carry our accounts receivable at the original invoice amount less an estimated allowance for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on the customer's financial health, and both historical and expected credit loss experience. We write off our accounts receivable when we deem them uncollectible. We record recoveries of accounts receivable previously written off when received. We are not always able to timely anticipate changes in the financial condition of our customers and if circumstances related to these customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations. The allowance for doubtful accounts was $87,000 and $34,000 at December 31, 2017 and 2016, respectively.

Inventories.

We value inventory at net realizable value the slow moving and obsolete inventories based upon current and expected future product sales. Inventories consist of approximately the following:

	December 31, 2017	December 31, 2016
Raw materials	$ 3,449,000	$ 4,483,000
Work-in-process	322,000	462,000
Finished goods	3,406,000	2,290,000
	$ 7,177,000	$ 7,235,000

Property, Plant and Equipment.

We carry property, plant and equipment, including leasehold improvements, at cost, less accumulated depreciation or fair value if acquired in a business combination, which consists of approximately the following balances:

	December 31, 2017	December 31, 2016
Land	$ 147,000	$ 129,000
Building	674,000	588,000
Leasehold improvements	1,248,000	1,240,000
Internal use software	829,000	821,000
Equipment	4,155,000	3,203,000
	$ 7,053,000	$ 5,981,000
Less accumulated depreciation and amortization	(4,626,000)	(3,866,000)
	$ 2,427,000	$ 2,115,000

We provide for depreciation using the straight-line method over useful lives of three to seven years for equipment and 40 years for the building. Certain products used as sales demonstration and service loaner equipment are transferred from inventory to machinery and equipment and are depreciated over three years. We charge maintenance and repairs to expense as incurred. We capitalize improvements and amortize them over the shorter of their estimated useful service lives or the remaining lease term. We recognized depreciation and amortization expense of approximately $777,000 and $778,000 in the years ended December 31, 2017 and 2016, respectively.

Goodwill.

Goodwill results from the Merger and from the acquisition of Genesis (as described in Note 4) and represents the excess of the purchase price over the fair value of acquired tangible assets and liabilities and identifiable intangible assets. Annually as of November 30 or if conditions indicate an additional review is necessary, the Company assesses qualitative factors to determine if it is more likely than not that the fair value of a reporting unit is less than its carrying amount and if it is necessary to perform the quantitative two-step goodwill impairment test. If the Company performs the quantitative test, it compares the carrying value of the reporting unit to an estimate of the reporting unit's fair value to identify potential impairment. The fair value of each reporting unit is estimated using a discounted cash flow model. Where available, and as appropriate, comparable market multiples are also used to corroborate the results of the discounted cash flow models. In determining the estimated future cash flow, the Company considers and applies certain estimates and judgments, including current and projected future levels of income based on management's plans, business trends, prospects and market and economic conditions and market-participant considerations. If the estimated fair value of the reporting unit is less than the carrying value, a second step is performed to determine the amount of the potential goodwill impairment. If impaired, goodwill is written down to its estimated implied fair value. We reassessed the impairment of Goodwill as of December 31, 2017 due to the change in our segment determination as described in Note 10. All of our Goodwill is associated with the medical segment and there was no impairment as of December 31, 2017.

There was no goodwill impairment loss for the years ended December 31, 2017 or 2016.

Impairment of Long-Lived Assets.

Long-lived assets consist of property, plant and equipment and finite lived intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that we may not recover the carrying amount of an asset. We measure recoverability of assets held and used from a comparison of the carrying amount of an asset to future undiscounted net cash flows we expect to generate by the asset. If we consider such assets impaired, we measure the impairment recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges for the years ended December 31, 2017 and 2016.

Product Warranty.

We warrant our products to be free from defects in material and workmanship under normal use and service for a period of twelve months after the date of sale. Under the terms of these warranties, we repair or replace products we deem defective due to material or workmanship.

The following table summarizes approximate changes in our warranty reserve:

	December 31, 2017	December 31, 2016
Warranty reserve at beginning of period	$ 127,000	$ 146,000
Warranties accrued during the period	167,000	77,000
Warranties settled during the period	(141,000)	(96,000)
Warranty reserve at end of period	$ 153,000	$ 127,000

Other Current Liabilities.

Other current liabilities consist of approximately the following:

	December 31, 2017	December 31, 2016
Sales tax and VAT payable	$ 579,000	$ 328,000
Note payable	214,000	-
Accrued legal and accounting fees	21,000	101,000
Accrued vendor payables	142,000	190,000
Other accrued expenses	405,000	219,000
	$ 1,361,000	$ 838,000

Foreign Currency Translation.

We translate all assets and liabilities of our foreign subsidiaries using period-end exchange rates. We translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders' equity. We recognize foreign currency transaction gains and losses in our consolidated statements of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates.

We recognize foreign currency transaction gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (functional currencies of our subsidiaries), as well as their effect on the dollar denominated intercompany obligations between us and our foreign subsidiaries. All intercompany balances are revolving in nature and we do not deem any portion of them to be long-term. We recognized foreign currency transaction gains (losses) of approximately $48,000 and $(26,000) in the twelve months ended December 31, 2017 and 2016, respectively.

Income Taxes.

We account for income taxes using the asset and liability method. The asset and liability method provides that deferred tax assets and liabilities be recorded based on the differences between the tax basis of assets and liabilities and their carrying amounts for financial reporting purposes. We reduce deferred tax assets by a valuation allowance, when we believe it is more likely than not that some portion or all of the deferred tax assets will not be realized.

ASC 740, "Accounting for Income Taxes", prescribes a recognition threshold and a measurement attribute for financial statement recognition of tax positions we take or expect to take in a tax return. It is management's responsibility to determine whether it is "more-likely-than-not" that a taxing authority will sustain a tax position upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position.

Under our accounting policies we recognize interest and penalties accrued on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense.

Basic and Diluted Net Loss per Share.

We calculate basic net loss per common share by dividing net loss by the weighted-average common shares outstanding, excluding outstanding shares contingently subject to forfeiture. For calculating diluted net loss per common share amounts, we add additional shares to the weighted-average common shares outstanding for the assumed exercise of stock options and vesting of restricted shares, if dilutive. Because we have had net losses, the following options and warrants outstanding and unvested restricted stock to purchase shares of our common stock were excluded from diluted net loss per common share because of their anti-dilutive effect, and therefore, basic net loss per common share equals dilutive net loss per common share:

	Number of options, warrants and unvested restricted stock	Range of exercise prices
Years ended:		
Twelve months December 31, 2017	3,022,582	$0.88 - $24.40
Twelve months December 31, 2016	2,674,000	$0.88 - $24.40

Recently Adopted Accounting Pronouncements.

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting." This ASU simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. This new standard is effective for annual periods beginning after December 15, 2016, and interim periods within that reporting period. We adopted this standard as of January 1, 2017. The adoption did not have a material impact on our consolidated financial statements. Under the new ASU we no longer account for forfeitures of restricted stock awards and stock options throughout the vesting period and instead account for them in the period in which they occur. We also recognize certain tax benefits or tax shortfalls upon a restricted-stock award vesting or stock option exercise relative to the deferred tax asset position established in the provision for income taxes line of the consolidated statements of operations instead of within the consolidated statement of shareholders' equity.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." This ASU is in response to diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows and provides guidance on eight specific cash flow classification issues. It will be effective for reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted, including adoption in an interim period. The Company adopted this standard as of January 1, 2017. The adoption did not have a material impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory (Topic 330)." Under the current guidance (i.e., ASC 330-10-352 before the ASU), an entity subsequently measures inventory at the lower of cost or market, with market defined as replacement cost, net realizable value (NRV), or NRV less a normal profit margin. An entity uses current replacement cost provided that it is not above NRV (i.e., the ceiling) or below NRV less an "approximately normal profit margin" (i.e., the floor). The new guidance requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures). The ASU will not apply to inventories that are measured by using either the last-in, first-out (LIFO) method or the retail inventory method (RIM). The amendments in ASU No. 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company adopted this standard and it had no impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". Under U.S. GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting in accordance with Subtopic 205-30 of this ASU, "Presentation of Financial Statements—Liquidation Basis of Accounting". Even when an entity's liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going concern basis of accounting, but the amendments in this ASU should be followed to determine whether to disclose information about the relevant conditions and events. The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company has evaluated the going concern considerations in this ASU. However, management does not believe that the Company has met conditions which would subject the Company's financial statements to additional disclosure.

Recently Issued Accounting Pronouncements Not Yet Adopted.

In February 2018, the Financial Accounting Standards Board ("FASB") issues ASU No. 2018-02, "Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income". The amendments in this update allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. The standard is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within these fiscal years. Early adoption is permitted. The new guidance is not expected to have a material impact on our results of operations and financial position.

In May 2017, the Financial Accounting Standards Board ("FASB") issued ASU 2017-09, "Compensation – Stock Compensation: Scope of Modification Accounting." This ASU is intended to provide guidance about which changes to the terms or conditions on a share-based payment award require an entity to apply modification accounting. This new standard is effective for annual periods beginning after December 15, 2017, and interim periods within that reporting period. The Company does not expect these amendments to have a material effect on its consolidated financial statements.

In March 2017, the FASB issued ASU 2017-08, "Receivables—Nonrefundable Fees and Other Costs: Premium Amortization on Purchased Callable Debt Securities" related to the amortization period for certain purchased callable debt securities held at a premium. The amendments shorten the amortization period for the premium to the earliest call date. The amendment is effective for interim and annual periods beginning after December 15, 2018. The Company does not expect these amendments to have a material effect on its consolidated financial statements.

In January 2017, the FASB, issued ASU No. 2017-04, "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment" which simplifies the accounting for goodwill impairment by eliminating Step 2 of the current goodwill impairment test. Goodwill impairment will now be the amount by which the reporting unit's carrying value exceeds its fair value, limited to the carrying value of the goodwill. The standard is effective for us beginning January 1, 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. The new guidance is not expected to have a material impact on our results of operations and financial position.

In August 2016, the FASB issued Accounting Standards Update ("ASU") 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." This ASU is in response to diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows and provides guidance on eight specific cash flow classification issues. It will be effective for reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted, including adoption in an interim period. We do not believe the adoption of this update will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-2, "Leases", under which lessees will recognize most leases on-balance sheet. This will generally increase reported assets and liabilities. For public entities, this ASU is effective for annual and interim periods in fiscal years beginning after December 15, 2018. ASU 2016-2 mandates a modified retrospective transition method for all entities. While the Company is still evaluating the timing and impact of the adoption of this guidance on its consolidated financial statements, it anticipates that the adoption could result in an increase in the assets and liabilities recorded on its consolidated balance sheet.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)", as amended by ASU 2015-14, "Deferral of Effective Date", which requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 sets forth a new revenue recognition model that requires identifying the contract, identifying the performance obligations, determining the transaction price, allocating the transaction price to performance obligations and recognizing the revenue upon satisfaction of performance obligations. For public entities, this ASU is effective for annual reporting periods beginning after December 15, 2017 including interim reporting periods within that reporting period. The provisions can be adopted either retrospectively to each prior reporting period presented or as a cumulative-effect adjustment as of the date of adoption. We plan to adopt this ASU effective January 1, 2018 using the cumulative-effect adjustment method. The Company has completed the assessment of this ASU on each of our revenue streams and, based on our review of contracts, we believe the impact on our consolidated financial statements will be immaterial. For each of our products, revenue will still be recognized when title passes to the customer, generally upon shipment. Revenue for service repairs of equipment will continue to be recognized after service has been completed, and service contract revenue will be recognized ratably over the term of the contract. We are still evaluating the impact of the new revenue recognition standard on our disclosures due to the new qualitative and quantitative requirements under the standard.

Note 2. Goodwill and Other Intangible Assets

Goodwill.

There was no change in the goodwill balance as of December 31, 2017 as compared to December 31, 2016 other than the addition of approximately $400,000 related to the Genesis acquisition as described in Note 4. This balance was converted to US dollars at the month end exchange rate as of December 31, 2017.

Other Intangible Assets.

Other intangible assets consisted of approximately the following at reporting dates presented below:

	December 31, 2017			December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Weighted Average Amortization period	Gross Carrying Amount	Accumulated Amortization	Weighted Average Amortization period
Developed technology	$ 6,200,000	$ 2,436,000	4.25	$ 6,200,000	$ 1,550,000	5.25
Patents & trademarks	5,653,000	5,634,000	7.25	5,653,000	5,616,000	8.25
Trademarks and trade names	190,000	84,000	7.25	190,000	75,000	8.25
Customer relationships	7,540,000	4,067,000	2.27	7,270,000	2,590,000	3.25
	19,583,000	$ 12,221,000		19,313,000	$ 9,831,000	
Accumulated amortization	12,221,000			9,831,000		
Net book value of amortizable intangible assets	$ 7,362,000		3.22	$ 9,482,000		4.23

Amortization costs were approximately $2,390,000 in the year ended December 31, 2017 and $2,363,000 in the year ended December 31, 2016.

Estimated amortization expense for all intangible assets for the five years subsequent to December 31, 2017 is as follows:

Year ending December 31,	
2018	$ 2,437,000
2019	2,431,000
2020	1,307,000
2021	894,000
2022	230,000
Thereafter	63,000
Total	$ 7,362,000

Note 3. Convertible Debt – Related Party

Prior to November 2016, the Company had convertible debt – related party payable to Mr. Lewis Pell, one of the Company's directors. In November 2016, the Company converted the outstanding principal amount (face value of $28,490,000) and accrued interest (approximately $1,000,000) payable under the convertible debt – related party into 17,688,423 shares of our common stock representing a conversion price of $1.67 per share. This conversion was approved by the Company's stockholders on November 3, 2016. The conversion of the convertible debt – related party was negotiated to be converted at a conversion rate that was significantly lower than the original conversion rates. The transaction was accounted for as an induced conversion and resulted in non-cash debt conversion expense of approximately $18,841,000 for the year ended December 31, 2016. Under purchase accounting for the Merger, the convertible promissory notes were recorded at fair value, resulting in a discount from their face value of $5,960,000. The discount was being amortized over the remaining term based on the effective interest rate method with an imputed interest rate of 4.72%, until the debt was converted.

Note 4. Business Combinations

The Company, through its wholly owned subsidiary, Uroplasty LTD, acquired 100% of the issued share capital in Genesis Medical Holdings LTD ("Genesis") and its subsidiaries effective July 25, 2017 (the "Genesis acquisition").

The Genesis acquisition has been accounted for in accordance with Accounting Standards Codification (ASC) Topic 805, "Business Combinations". The terms of the Genesis acquisition include an upfront payment equal to the estimated fair market value of the tangible net assets, approximately $280,000. The terms also include a purchase price for the ongoing business of approximately $556,000, payable at the rate of 5% of Genesis revenue on a monthly basis. In addition, if Genesis achieves revenue of approximately $4.7 million for the twelve months ended March 31, 2019, the Company will pay an additional amount of approximately $134,000. We have determined the likelihood of paying the $134,000 as probable. The note payable and the contingent consideration have been discounted to a net present value equal to approximately $618,000. All conversions between British Pounds and U.S. Dollars were computed using the July 25, 2017 exchange rate of $1.34 per £1.

Under the acquisition method of accounting, the total purchase price was allocated to the net tangible and intangible assets of Genesis based on their fair values at the effective date of the Acquisition. The final allocation is approximately as follows:

Cash and cash equivalents	$	104,373
Accounts receivable		811,034
Inventory		202,410
Property, plant and equipment		172,242
Customer relationships		268,000
Goodwill		400,870
Total assets acquired	**$**	**1,958,929**
Accounts payable	$	1,001,885
Deferred tax liability		50,920
Total liabilities assumed	**$**	**1,052,805**
Total Purchase Price	**$**	**906,124**

Cash paid to Genesis, net of cash acquired of $104,000, totaled approximately $181,000. The remaining purchase price was financed via a note payable and contingent consideration as described above.

Legal costs directly related to the acquisition of approximately $90,000 have been charged directly to operations and are included in general and administrative expense in our Consolidated Statements of Operations for the twelve months ended December 31, 2017.

The goodwill of $400,870 resulting from the acquisition is the excess if the purchase price over the fair value of the net assets acquired. The goodwill primarily reflects the value of enhancing our market opportunity and growth potential in the U.K. None of the goodwill recognized is deductible for income tax purposes as it was a stock acquisition and as such, no deferred taxes have been recorded to goodwill.

The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of the following identifiable intangible asset:

		Amount	Weighted Average Life-Years
Customer relationships	$	268,000	3

Note 5. Shareholders' Equity

Securities Purchase Agreement

On November 3, 2016, we issued 16,129,033 shares of our common stock at $1.55 per share, for aggregate gross proceeds of $25.0 million, to Accelmed Growth Partners, L.P. ("Accelmed"). This issuance of these shares was approved by our stockholders on November 3, 2016. Net proceeds totaled approximately $23,429,000 after deduction of $1,571,000 of expenses related to the issuance.

Share-based Compensation.

At December 31, 2017, the Company had one active plan, the Cogentix Medical 2015 Omnibus Incentive Plan, for share-based compensation grants ("the 2015 Plan"). Under the 2015 Plan, if we have a change in control (as defined in the 2015 Plan) and the Company is not the surviving entity, all outstanding grants, including those subject to vesting or other performance targets, fully vest immediately if they are not assumed or replaced with equivalent grants. If the Company is the surviving entity, there is no accelerated vesting of equity grants solely upon a change in control. In 2016, the Company experienced a change in control for which it was the surviving entity. Outstanding grants will vest if a participant's employment or other service with the Company is terminated, without cause or by the participant for good reason, within two years of the November 3, 2016 change in control.

Under the 2015 Plan, we reserved 2,500,000 shares of our common stock for share-based grants and 139,738 shares remain available for grant at December 31, 2017.

We grant options at the discretion of our directors. We grant option awards with an exercise price equal to the closing market price of our stock at the date of the grant. We have options outstanding to purchase 2,545,963 shares of common stock granted under the 2015 Plan or predecessor companies' plans. Options generally expire over a period ranging from seven to ten years from date of grant and vest at varying rates ranging up to three years. The options granted under the 2015 Plan generally provide for the exercise of options during a limited period following termination of employment, death or disability.

We determine the fair value of the option awards using the Black-Scholes option pricing model. We used the following weighted-average assumptions to value the options granted during the years ended December 31, 2017 and 2016, respectively:

	December 31, 2017	December 31, 2016
Expected life, in years	3.00	3.90
Risk-free interest rate	1.45%	.98%
Expected volatility	66.89%	61.86%
Expected dividend yield	0%	0%

The expected life for options granted represents the period of time we expect options to be outstanding based on historical data of option holder exercise and termination behavior for similar grants. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury rate over the expected life at the time of grant. Expected volatility is based upon historical volatility of our common stock. We estimated the forfeiture rate for stock awards to be approximately 15% for executive employees and directors and approximately 20% for non-executive employees for the year ended December 31, 2016 awards based on our historical experience. Beginning January 1, 2017, we no longer have an estimated forfeiture rate because we adopted the rules found in ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting,* and now account for forfeitures when they occur.

The following table summarizes the activity related to our stock options for the years ended December 31, 2017 and 2016, respectively:

	Number of shares	Weighted average exercise price	Weighted average grant date fair value	Aggregate intrinsic value	Weighted average remaining life in years
Balance at December 31, 2015	2,573,640	$ 4.46		-	5.24
Options granted	692,400	1.05	$ 0.49		
Options exercised	-				
Options surrendered	(1,585,050)	3.90			
Balance at December 31, 2016	1,680,990	$ 3.54		$ 752,290	6.55
Options granted	1,042,809	1.65	$ 0.74		
Options exercised	(7,211)	1.35		$ 13,001	
Options surrendered	(170,625)	4.36			
Balance at December 31, 2017	2,545,963	$ 2.72		$ 3,243,914	6.13
Options exercisable at December 31, 2017	1,031,731	$ 4.55		$ 705,799	3.39

The total fair value of stock options vested during the years ended December 31, 2017 and 2016, was approximately $223,000 and $276,000, respectively.

There were no options exercised for the year ended December 31, 2016.

We grant restricted shares at the discretion of our directors with vesting terms of six months to three years. The following table summarizes the activity related to our restricted stock for the years ended December 31, 2017 and 2016, respectively:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining life in years	Aggregate intrinsic value
Balance at December 31, 2015	686,910	$ 2.41	1.59	$ 886,114
Shares granted	937,858	1.18		
Shares vested	(324,521)	2.19		652,287
Shares surrendered	(307,699)	2.45		
Balance at December 31, 2016	992,548	$ 1.30	1.35	$ 1,995,021
Shares granted	542,541	1.67		
Shares vested	(988,097)	1.48		$ 3,112,506
Shares surrendered	(70,373)	1.56		
Balance at December 31, 2017	476,619	$ 1.32	1.93	$ 1,501,350

The aggregate intrinsic value shown above for the restricted shares represents the total pre-tax value based on the closing price of our common stock on the dates noted above.

We recognize share-based compensation expense in the statement of operations based on the fair value at the time of grant of the share-based payment over the requisite service period. We incurred a total of approximately $1,453,000 and $748,000 in share-based compensation expense for the years ended December 31, 2017 and 2016, respectively.

On December 31, 2017, we had approximately $768,000 of unrecognized share-based compensation cost, related to stock options that we expect to recognize over a weighted-average requisite service period of approximately 2.15 years. On December 31, 2016, we had approximately $344,000 of unrecognized share-based compensation cost, net of estimated forfeitures, related to stock options that we expect to recognize over a weighted-average requisite service period of approximately 2.05 years.

On December 31, 2017, we had approximately $462,000 of unrecognized share-based compensation cost, related to restricted stock that we expect to recognize over a weighted-average requisite service period of approximately 1.93 years. On December 31, 2016, we had approximately $743,000 of unrecognized share-based compensation cost, net of estimated forfeitures, related to restricted stock that we expect to recognize over a weighted-average requisite service period of approximately 1.26 years.

Note 6. Line of Credit

On September 18, 2015, we entered into a loan agreement with Venture Bank, a Minnesota banking corporation, providing us with a $7.0 million secured revolving credit facility (the "Facility"), subject to eligible accounts receivable and inventory, and secured by substantially all of our assets. The Facility was amended in March 2017. Under the amended Facility, the Facility will expire on September 18, 2018.

Under the Facility, we may borrow the lesser of: (a) the sum of (i) eighty percent (80%) of the value of eligible accounts receivable; and (ii) forty percent (40%) of the value of eligible inventory capped at the lesser of (1) $2.5 million; or (b) $7 million. As of December 31, 2017, based on eligible receivables and inventory, our total available borrowing base was $6,409,000. We did not have any borrowings under the facility as of December 31, 2017.

Loans under the Facility bear interest at a rate per annum equal to the Wall Street Journal Prime Rate plus 1.25%, provided that in no case will the interest charged be less than 5.25%. In the event that there is an event of default under the Facility, the interest rate will be increased by 6.0% for the entire period that an event of default exists. In addition, the Borrowers will pay a non-usage fee of 0.15% based on the average unused and available portion of the Facility on a monthly basis.

Note 7. Commitments and Contingencies

Operating Lease Commitments.

We lease office, warehouse, and production space under operating lease agreements, which include escalating lease payments, and lease various automobiles for our European employees. These leases expire at various times through August 2025. At December 31, 2017, the approximate future minimum lease payments in subsequent years under noncancelable operating leases with an initial term in excess of one year are as follows:

2018	$	817,000
2019		430,000
2020		279,000
2021		254,000
2022		164,000
Thereafter		544,000
	$	2,488,000

Total operating lease expenses were approximately $734,000 and $695,000 for the twelve months ended December 31, 2017 and 2016, respectively.

Minimum Purchase Agreement Commitments.

In our normal course of business, we have commitments to purchase from various vendors finished goods and manufacturing components under issued purchase orders. At December 31, 2017, the approximate future minimum purchase agreement payments in subsequent years are as follows:

2018	$ -
2019	300,000
2020	600,000
2021	900,000
2022	1,200,000
Thereafter	1,500,000
	$ 4,500,000

Employment Agreements.

We have entered into employment agreements with certain officers, the terms of which, among other things, specify a base salary subject to annual adjustments by mutual agreement of the parties, and a severance payment to the employee upon employment termination without cause. We provide for various severance amounts payable under the agreements after employment termination. Contemporaneously with the execution of their employment agreement, all of the officers executed an "Employee Confidentiality, Inventions, Non-Solicitation, and Non-Compete Agreement." This agreement prohibits the employee from disclosing confidential information, requires the employee to assign to us without charge all intellectual property relating to our business which is created or conceived during the term of employment, prohibits the employee from encouraging employees to leave our employment for any reason and prohibits competition with us during the term of employment and for a specified term thereafter.

Product Liability.

The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Any defects or risks that we have not yet identified with our products may give rise to product liability claims. Our existing $10 million of worldwide product liability insurance coverage may be inadequate to protect us from liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer.

Note 8: Savings and Retirement Plans

We sponsor various plans for eligible employees in the United States, the United Kingdom, and The Netherlands. Our retirement savings plan in the United States conforms to Section 401(k) of the Internal Revenue Code of 1986, as amended, and participation is available to substantially all employees. We may also make discretionary contributions ratably to all eligible employees. We made discretionary contributions to the U.S. plan of approximately $585,000 and $438,000 in the years ended December 31, 2017 and 2016, respectively.

Our international subsidiaries in the U.K. and The Netherlands have defined benefit retirement plans for eligible employees. These plans provide benefits based on the employee's years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. We froze the U.K. subsidiary's defined benefit plan on December 31, 2004. On March 10, 2005, we established a defined contribution plan for the U.K. subsidiary. As of April 1, 2005, we closed The Netherlands subsidiary's defined benefit retirement plan for new employees and established a defined contribution plan for them. The total contribution expense associated with the defined contribution plans in The Netherlands and the U.K. was approximately $55,000 and $38,000 for the years ended December 31, 2017 and 2016, respectively.

The amortization of actuarial gains or losses is included as a component of the annual expense for a period if, as of the beginning of the period, the cumulative net gain or loss exceeds 10% of the greater of the projected benefit obligation or plan assets. If amortization is required, the amortization is that excess divided by the expected average future service of the active employees participating in the plans or the average remaining life expectancies of inactive employees.

The Netherlands defined benefit pension plan.

The Netherlands defined benefit pension plan is funded through a guaranteed insurance contract with Zwitser Leven, an insurance company. Our contract with Zwitser Leven requires us to make annual premium payments which are sufficient to fund benefits that will satisfy the vested benefit obligation ("VBO"). Zwitser Leven does not hold separate investment assets for our contract, but rather is obligated to provide the stream of future benefits for the annual premium payments we make to the plan. We calculate the market value of the pension plan assets, held in Zwitser Leven insured assets, as the stream, based on mortality, of the earned guaranteed benefit payments discounted at a market interest rate. The benefit obligation is calculated based on the same assumptions as well. Accordingly, the impact on pension plan assets of a change in assumption for discount rate and mortality would equally offset the change in VBO.

At December 31, 2017, we project the following benefit payments in subsequent years:

2018	$ 23,000
2019	24,000
2020	24,000
2021	31,000
2022	39,000
2023 to 2027	262,000
	$ 403,000

We contributed approximately $141,000 and $125,000 in the years ended December 31, 2017 and 2016, respectively, and expect to contribute approximately $140,000 in 2018.

The following table summarizes the change in benefit obligations and the change in plan assets:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Changes in benefit obligations:		
Projected benefit obligation, beginning of period	$ 3,510,000	$ 3,665,000
Service cost	95,000	104,000
Interest cost	75,000	76,000
Benefits paid	(21,000)	(21,000)
Plan amendment	-	(658,000)
Actuarial loss (gain)	(8,000)	474,000
Foreign currency translation	498,000	(130,000)
Projected benefit obligation, end of period	$ 4,149,000	$ 3,510,000
Changes in plan assets:		
Plan assets, beginning of period	$ 3,321,000	$ 3,002,000
Contributions to plan	141,000	125,000
Management cost	(14,000)	(12,000)
Actual return on assets	47,000	357,000
Benefits paid	(21,000)	(21,000)
Foreign currency translation	472,000	(130,000)
Plan assets, end of period	$ 3,946,000	$ 3,321,000

The amount recognized in other comprehensive loss consists of:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Unrecognized net prior service benefit	$ (892,000)	$ (870,000)
Unrecognized net losses	865,000	779,000
Additional other comprehensive gain (gross of income taxes)	$ (27,000)	$ (91,000)

The projected benefit obligation, accumulated benefit obligation and the fair value of plan assets were as follows:

	December 31, 2017	December 31, 2016
Projected benefit obligation	$ 4,149,000	$ 3,510,000
Accumulated benefit obligation	4,005,000	3,376,000
Fair value of plan assets	3,946,000	3,321,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on December 31, 2017 and 2016, of $203,000 and $189,000, respectively, as accrued pension liability.

The cost of our defined benefit retirement plan includes the following components:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Gross service cost, net of employee contribution	$ 84,000	$ 99,000
Interest cost	75,000	76,000
Management cost	13,000	5,000
Expected return on assets	(74,000)	(66,000)
Amortization	(54,000)	(30,000)
Net periodic retirement cost	$ 44,000	$ 84,000

Major assumptions used in the above calculations include:

	December 31, 2017	December 31, 2016
Discount rate	2.00%	2.00%
Expected return on assets	2.00%	2.00%
Expected rate of increase in future compensation:		
General	2.5%	2.5%
Individual	0%	0%

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities. The market value of the assets is determined as the discounted stream of guaranteed benefit payments. Given the valuation method of the assets, the expected long-term rate of return on assets equals the discount rate.

The U.K. defined benefit pension plan.

As of December 31, 2017, and 2016, we held all the assets of the U.K. defined benefit pension plan in a Deposit Administration Contract with Phoenix Life Limited.

At December 31, 2017 we project the following benefit payments in subsequent years:

2018	$ 194,000
2019	-
2020	-
2021	-
2022	-
2023 to 2027	714,000
	$ 908,000

We contributed approximately $57,000 and $53,000 in the years ended December 31, 2017 and 2016, respectively, and expect to contribute approximately $61,000 in 2018.

The following table summarizes the change in benefit obligations and the change in plan assets:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Changes in benefit obligations:		
Projected benefit obligation, beginning of period	$ 736,000	$ 744,000
Service cost	4,000	4,000
Interest cost	20,000	26,000
Benefits paid	-	(96,000)
Other	(4,000)	(4,000)
Actuarial loss	34,000	197,000
Foreign currency translation	72,000	(135,000)
Projected benefit obligation, end of period	$ 862,000	$ 736,000
Changes in plan assets:		
Plan assets, beginning of period	$ 616,000	$ 775,000
Contributions to plan	57,000	53,000
Management cost	(4,000)	(4,000)
Benefits Paid	-	(96,000)
Actual return on assets	68,000	15,000
Foreign currency translation	63,000	(127,000)
Plan assets, end of period	$ 800,000	$ 616,000

The amount recognized in other comprehensive loss consists of:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Unrecognized net losses (gross of deferred taxes)	$ 225,000	$ 276,000

The projected benefit obligation, accumulated benefit obligation and the fair value plan assets were as follows:

	December 31, 2017	December 31, 2016
Projected benefit obligation	$ 862,000	$ 736,000
Accumulated benefit obligation	862,000	736,000
Fair value of plan assets	800,000	616,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets as of December 31, 2017 and 2016, of $62,000 and $120,000, respectively, as accrued pension liability.

The cost of our defined benefit retirement plan includes the following components for the years ended:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Gross service cost, net of employee contribution	$ 4,000	$ 5,000
Interest cost	20,000	26,000
Expected return on assets	(14,000)	(21,000)
Amortization	53,000	7,000
Net periodic retirement cost	$ 63,000	$ 17,000

Major assumptions used in the above calculations include:

	December 31, 2017	December 31, 2016
Discount rate	2.50%	2.70%
Expected return on assets	2.13%	2.20%

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities. The expected return on assets assumption on the investment portfolio for the defined benefit plan is based on the long-term expected returns for the assets currently in the portfolio. Management uses historic return trends of the asset portfolio combined with recent market conditions to estimate the future rate of return.

Plan Assets.

The primary objective of The Netherlands pension plan is to meet retirement income commitments to plan participants at a reasonable cost. In The Netherlands, consistent with typical practice, the pension plan is funded through a guaranteed insurance contract with Zwitser Leven, an insurance company. Zwitser Leven is responsible for the investment strategy of the insurance premiums we make. We have characterized the assets of the pension plan as an "other contract."

The primary objective of the U.K. pension plan is to meet retirement income commitments to plan participants at a reasonable cost. The objective is achieved through growth of capital and safety of funds invested. The pension plan assets are invested in a Deposit Administration Contract with Phoenix Life Limited, an insurance company, with underlying investments primarily in fixed interest U.K. government bonds.

The allocation of pension plan assets was as follows:

	December 31, 2017		December 31, 2016	
	Target Allocation	Actual Allocation	Target Allocation	Actual Allocation
Other Contract (Netherlands Plan)	100%	100%	100%	100%
Deposit Administration Contract (U.K. Plan)	100%	100%	100%	100%

We calculate the market value of the pension plan assets, held in Zwitser Leven insured assets, as the stream, based on mortality (an unobservable input), of the earned guaranteed benefit payments discounted at market interest rate. Accordingly, we have classified The Netherlands pension plan assets as Level 3 assets. The market value of the U.K. pension plan reflects the value of our contributions to the plan and the credited accrued interest at the rate specified in the Deposit Administration Contract. Accordingly, we have classified the U.K. plan assets as Level 2 assets.

The fair value of the pension plan assets by asset class is as follows:

Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2017				
Other Contract (Netherlands Plan)	$ 3,946,000	$ -	$ -	$ 3,946,000
Deposit Administration Contract (U.K. Plan)	800,000	-	800,000	-
December 31, 2016				
Other Contract (Netherlands Plan)	$ 3,321,000	$ (5,000)	$ -	$ 3,326,000
Deposit Administration Contract (U.K. Plan)	616,000	-	616,000	-

The reconciliation of beginning and ending balances for our Level 3 assets is as follows:

Other Contract (Netherlands Pension Plan Assets)	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Beginning balance	$ 3,326,000	$ 3,005,000
Loss recognized in earnings	59,000	54,000
Actuarial loss	(26,000)	291,000
Purchases	141,000	130,000
Sales	(21,000)	(21,000)
Transfers	(5,000)	(3,000)
Foreign currency translation	472,000	(130,000)
Ending balance	$ 3,946,000	$ 3,326,000

Note 9: Income Taxes

The components of income tax expense consist of the following:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Income tax provision:		
Current:		
Federal and state	$ 13,000	$ 91,000
Foreign	118,000	49,000
Deferred:		
Federal and state	-	-
Foreign	7,000	5,000
Total income tax expense	$ 138,000	$ 145,000

Actual income tax expense differs from statutory federal income tax benefit for the period presented is as follows:

	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Statutory federal income tax benefit	$ (246,000)	$ (7,462,000)
State tax benefit, net of federal taxes	13,000	(55,000)
Foreign tax	(82,000)	(39,000)
Nondeductible expenses - debt forgiveness	-	5,575,000
Nondeductible expenses – other	130,000	163,000
Subpart F Income	-	51,000
Valuation allowance (decrease)	(2,795,000)	(7,334,000)
Stock compensation shortfall (windfall)	(94,000)	96,000
Stock compensation true-up and expirations	10,000	958,000
NOL expiration and true-up	204,000	8,110,000
Deferral rate change	3,313,000	-
True-up of undistributed foreign earnings	(317,000)	-
Other	2,000	80,000
Total income tax expense	$ 138,000	$ 143,000

Deferred tax assets (liabilities) consist of approximately the following:

	December 31, 2017	December 31, 2016
Fixed assets	$ 29,000	$ (51,000)
Intangible assets	(1,806,000)	(3,479,000)
Equity method investment	33,000	-
Pension liability	69,000	76,000
Stock based compensation	446,000	535,000
Inventory	128,000	483,000
Other reserves and accruals	524,000	778,000
Deferred rent	165,000	250,000
Undistributed foreign earnings	-	(504,000)
Foreign tax credits	68,000	68,000
Credit carryforwards	88,000	72,000
Net operating losses	7,000,000	11,230,000
Customer relations intangible	(44,000)	-
	6,700,000	9,458,000
Less valuation allowance	(6,587,000)	(9,382,000)
	$ 113,000	$ 76,000

At December 31, 2017, we had U.S. net operating loss (NOL) carryforwards of approximately $117.2 million for U.S. income tax purposes before any Section 382 limitations, The NOLs expire in years 2020 through 2035. U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of NOL carryforwards is subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. Of the $117.2 million of NOLs for U.S. income tax purposes, $88.2 million are expected to expire unutilized. Of the $117.2 million of NOLs for U.S. income tax purposes, $29 million are recorded as gross deferred tax assets.

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for U.S. deferred tax assets due to the uncertainty that enough taxable income will be generated in the taxing jurisdictions to utilize the assets with the exception of the refundable AMT credit carryforward. Therefore, we have only reflected the benefit of such deferred tax assets in the accompanying consolidated financial statements. The deferred tax asset decreased by approximately $2,758,000 and $7,395,000 in the years ending December 31, 2017 and 2016, respectively. The valuation allowance increased by approximately $2,795,000 in the year ending December 31, 2017, and decreased by approximately $7,335,000 in the year ending December 31, 2016.

We reviewed all income tax positions taken or that we expect to be taken for all open years and determined that our income tax positions are appropriately stated and supported for all open years.

Under our accounting policies, we recognize interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. As of December 31, 2017, and 2016, we recorded no accrued interest or penalties related to uncertain tax positions.

We have provided for U.S. deferred income taxes as of December 31, 2017 for the undistributed earnings from our non-U.S. subsidiaries.

We are subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2017, tax years for March 31, 2015 through December 31, 2017 are subject to examination by the tax authorities. With few exceptions, as of December 31, 2017, we are no longer subject to U.S. federal or state, examinations by tax authorities for years beginning before April 1, 2014. However, all years in which a NOL could be utilized could be subject to tax examination. In addition, we are subject to examination by UK and Netherlands taxing authorities for which the fiscal years 2011-2017 and 2012-2017, respectively remain open for examination.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act ("TCJA") was signed into law. U.S. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted. The Tax Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective for tax years starting after December 31, 2017, implementing a hybrid territorial tax system, repealing AMT and making pre-2018 credits refundable, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. As a result, we recorded tax expense of $3.31M in the fourth quarter as a result of revaluation of the deferred tax assets due to the corporate tax rate change from 35% to 21% starting in 2018. The tax expense was directly offset by a change in the valuation allowance except for $70,000 that was not offset. The Company has $68,000 of AMT credit carryforwards that are expected to be fully utilized due to the credit now being refundable under the TCJA. The Company calculated a deemed repatriation income amount due to the change to a territorial tax system under the TCJA. This income can be fully offset with NOLs. The corresponding deferred tax liability associated with it was reversed. The amounts incorporate assumptions made based upon the Company's current interpretation of the Tax Act and may change as the Company receives additional clarification and implementation guidance.

Note 10: Business Segment Information

ASC 280, *"Segment Reporting,"* establishes disclosure standards for segments of a company based on management's approach to defining operating segments. Reportable segments are defined primarily by the nature of products and services, the nature of the production processes, and the type of customers for our products and services.

Prior to the fourth quarter of 2017, we disclosed only one reporting segment. Beginning in the fourth quarter of 2017, our reportable segments are disclosed as principally organized and managed as three operating segments: the urology/gynecology market, the airway management market and the industrial market. We adopted reportable segments to align with changes in how we manage our business, review operating performance and allocate resources.

In the urology/ gynecology market, the company markets a number of products through its 50+ direct sales force in the US and 10+ direct sales force in Europe in addition to the use of international distributors. The products serving this market includes endoscopy-based products (flexible fiber and video endoscopes and a proprietary sterile disposable microbial barrier known as EndoSheath technology), Urgent PC® Neuromodulation System ("Urgent PC System") a minimally-invasive, neuromodulation system that delivers percutaneous tibial nerve stimulation for office-based treatment of overactive bladder and associated symptoms; and Macroplastique® Implants ("Macroplastique"), an injectable, urethral bulking agent for the treatment of adult female stress urinary incontinence.

In the airway management market, the company markets endoscopy-based products (including flexible fiber and video endoscopes used in the practices of pulmonology, trans-nasal esophagoscopy and ENT as well as the proprietary sterile disposable microbial barrier known as EndoSheath technology for indications other than ENT).

In the industrial market, the company sells scopes and related equipment that are similar in design to those sold for medical applications into industrial markets for applications including aircraft engine inspection.

Our Chief Operating Decision Maker ("CODM") is its President and Chief Executive Officer, who utilizes discrete financial information about each segment in order to make decisions on resources allocated to each market. The Company's CODM assesses the performance of each segment and allocates resources to those segments based on revenue and operating income (loss). Operating income (loss) by segment includes items that are directly attributable to each segment, including sales and marketing functions, as well as finance, information technology, human resources, legal and related corporate infrastructure costs, along with certain benefit-related expenses. There are no unallocated expenses for the three segments. The company does not identify or allocate its assets by operating segments. Accordingly, assets are not being reported by segment because the information is not available by segment and is not reviewed in the evaluation of performance or making decisions in the allocation of resources.

Financial information regarding revenue and operating income (loss) by segment for the twelve months ended December 31, 2017 and 2016, respectively, is approximately as follows:

Segment Revenue	**December 31, 2017**	**December 31, 2016**
Urology	49,314,000	44,747,000
Airway Management	3,277,000	3,208,000
Industrial	3,725,000	3,896,000
Total	56,316,000	51,851,000

Operating Income (Loss)	**December 31, 2017**	**December 31, 2016**
Urology	281,000	(1,111,000)
Airway Management	(988,000)	(940,000)
Industrial	(182,000)	240,000
Total	(889,000)	(1,811,000)

Information regarding geographic area net sales to customers for the twelve months ended December 31, 2017 and 2016, respectively is approximately as follows:

	United States	**All Other (Foreign) Countries (1)**	**Consolidated**
Twelve months ended December 31, 2017	$ 40,888,000	$ 15,428,000	$ 56,316,000
Twelve months ended December 31, 2016	$ 39,513,000	$ 12,338,000	$ 51,851,000

(1) No other (foreign) country accounts for 10% or more of the consolidated net sales

Information regarding geographic area long-lived assets at December 31, 2017 and 2016, respectively is approximately as follows:

	United States	United Kingdom and The Netherlands	Consolidated
December 31, 2017	$ 1,793,000	$ 634,000	$ 2,427,000
December 31, 2016	$ 1,676,000	$ 439,000	$ 2,115,000

Accounting policies for the operations in the various geographic areas are the same as those described in Note 1. Sales attributed to each geographic area are net of intercompany sales and are attributed to countries based on location of customers. No single customer represents 10% or more of our consolidated net sales. Long-lived assets consist of property, plant and equipment.

Note 11. Equity Investment

ASC 323, "Investments – Equity Method and Joint Ventures," establishes accounting guidelines for an equity investment in which the Company has the ability to exercise significant influence, but does not have a controlling interest. In this situation, the equity method should be applied to an investment. Significant influence is generally considered to exist when the Company has an ownership interest in the voting stock of an entity between 20% and 50%, and other factors, such as representation on the Board of Directors, are considered in determining whether the equity method of accounting is appropriate.

On September 28, 2017, we made an equity investment in Vensica Medical ("Vensica"), a privately-held Israeli-based company developing VensiCare, an ultrasound based, needle-free drug delivery system. Our $2 million investment gave us a 20% ownership in the company and allows us to have one seat on the Vensica Medical Board of Directors along with two call options to acquire the entire company for an additional $8 million. The investment is accounted for using the equity method of accounting because the Company has significant influence, but not control, of the entity.

For the period ending December 31, 2017, our net loss in Vensica Medical was $128,640. The equity investment in Vensica is now $1,871,360.

Note 12. Subsequent Event – Pending Merger with Laborie Medical Technologies

On March 12, 2018, we entered into a definitive merger agreement ("the Agreement") with Laborie Medical Technologies ("Laborie"). Under the Agreement, Laborie will acquire all of the outstanding shares of Cogentix Medical for a total consideration of approximately $239 million. Under the terms of the Agreement, Laborie, through its wholly-owned subsidiaries LM Parent, Inc., and Camden Merger Sub, Inc. will commence a tender offer for all outstanding shares of Cogentix Medical common stock for $3.85 per share in cash. The offer of $3.85 per share in cash represents a premium of 28% over the average closing stock price of Cogentix Medical common stock over the last thirty days prior to entering into the agreement. We anticipate the transaction will close in the first half of the second quarter of 2018. Upon completion of the transaction, we will become a wholly owned subsidiary of Laborie.

Exhibit 21.1

SUBSIDIARIES OF COGENTIX MEDICAL, INC.
December 31, 2017

Subsidiary	**State or Other Jurisdiction of Incorporation**
Machida Incorporated	Delaware
Uroplasty, LLC	Delaware
Uroplasty BV	The Netherlands
Uroplasty Ltd.	United Kingdom
Genesis Medical Holdings Limited	United Kingdom
Genesis Medical Limited	United Kingdom
Genesis Medical (Sales) Limited	United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated March 30, 2018, with respect to the consolidated financial statements included in the Annual Report of Cogentix Medical, Inc. and subsidiaries on Form 10-K for the year ended December 31, 2017. We consent to the incorporation by reference of said report in the Registration Statements of Cogentix Medical, Inc. on Form S-3 (File No. 333-217385) and Form S-8 (File No. 333-203135).

/s/ Grant Thornton LLP

Minneapolis, Minnesota

March 30, 2018

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Darin Hammers, certify that:

1. I have reviewed this report on Form 10-K for the fiscal year ended December 31, 2017 of Cogentix Medical, Inc. (the "Registrant");

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

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

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

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

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

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

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

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

(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 30, 2018

By /s/ Darin Hammers
Darin Hammers
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brett Reynolds, certify that:

1. I have reviewed this report on Form 10-K for the fiscal year ended December 31, 2017 of Cogentix Medical, Inc. (the "Registrant");

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

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

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

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

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

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

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

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

(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 30, 2018

By /s/ Brett Reynolds
Brett Reynolds
Senior Vice President, Chief Financial Officer and Corporate Secretary

Exhibit 32.1

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

In connection with the Annual Report of Cogentix Medical, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Darin Hammers, the President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

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

Dated: March 30, 2018

By /s/ Darin Hammers
Darin Hammers
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Annual Report of Cogentix Medical, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brett Reynolds, Senior Vice President, Chief Financial Officer and Corporate Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

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

Dated: March 30, 2018

By /s/ Brett Reynolds
Brett Reynolds
Senior Vice President, Chief Financial Officer and Corporate Secretary