

# 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, 2016.**

**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**

(State or other jurisdiction of incorporation or organization)

**13-3430173**

(I.R.S. Employer Identification No.)

**5420 Feltl Road**

**Minnetonka, Minnesota**

(Address of principal executive offices)

**55343**

(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**

(Title of class)

**The NASDAQ Capital Market**

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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, 2016 was \$25,010,958.

As of March 17, 2017, the registrant had 60,438,959 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

*Portions of our Proxy Statement for our 2017 Annual Meeting of Stockholders (the "Proxy Statement"), are incorporated by reference in Part III.*

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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.*

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## 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. 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.

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 reprocess, 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 primarily target the urology 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<sup>®</sup> 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<sup>®</sup> (“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.

## **Recent Developments**

### ***Merger of Uroplasty and Vision-Sciences to Create Cogentix***

On December 21, 2014, Vision-Sciences entered into a merger agreement with Uroplasty, a publicly traded corporation. The Merger agreement provided for the Merger of Uroplasty with and into a newly created, wholly-owned merger subsidiary of Vision-Sciences. Following the approval of the Merger by Vision-Sciences’ and Uroplasty’s stockholders on March 30, 2015 and pursuant to the terms of the Merger agreement, on March 31, 2015, Uroplasty merged with and into Merger Sub, with the Merger Sub continuing as the surviving entity and a wholly-owned subsidiary of Vision-Sciences under the name, “Uroplasty, LLC.” Vision-Sciences changed its name to “Cogentix Medical, Inc.” immediately following the Merger and our common stock now trades on the NASDAQ Capital Market under the new symbol “CGNT.”

The Merger was accounted for as a reverse acquisition due to a number of factors including the relative voting interests in the combined company of the former Vision-Sciences and Uroplasty stockholders following the Merger. As a result, Uroplasty and its consolidated subsidiaries represent the accounting acquirer in the Merger, and Vision-Sciences and its consolidated subsidiary represent the legal acquirer in the Merger. Accordingly, while Vision-Sciences was the legal acquirer in the Merger, Uroplasty is treated as the acquiring company in the Merger for accounting purposes, and the Merger has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations.

### ***Change in Fiscal Year***

We are presenting our results of operations for the twelve-month calendar year ended December 31, 2016 and the nine-month transition period ended December 31, 2015. Unless otherwise indicated herein, comparisons of fiscal year results in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” portion of this Annual Report, and elsewhere herein, compare results for the twelve-month period ended December 31, 2016 to the nine-month transition period from April 1, 2015 through December 31, 2015, and accordingly are not comparing results for a comparable period of time.

### ***Accelmed Investment and Pell Debt Conversion***

On September 7, 2016, we entered into a securities purchase agreement (the “Purchase Agreement”) with Accelmed Growth Partners, L.P. (“Accelmed”). Under the terms of the Purchase Agreement, Accelmed agreed to purchase 16,129,033 shares of our common stock at \$1.55 per share, for an aggregate price of \$25.0 million. 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 “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 Purchase Agreement. The 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.

On November 3, 2016, our stockholders approved the transactions described above, and these transactions closed on November 3, 2016. 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. We also issued 16,129,033 shares of our common stock to Accelmed in exchange for \$25.0 million. As a result of the transactions described above, Mr. Pell and Accelmed own or control approximately 33% and 27%, respectively, of the outstanding common stock of the Company as of December 31, 2016.

In connection with the Purchase Agreement, Accelmed and Mr. Pell entered into a voting agreement (the “Voting Agreement”). Pursuant to the terms of the Voting Agreement, 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. 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 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 one of the directors nominated to the board by Accelmed 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. 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. 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.

### ***Overview of Strategy for Calendar Year 2017 and Beyond***

Our strategy for calendar year 2017 and beyond is to continue to leverage our assets to generate organic growth and to expand our product portfolio through acquisition or otherwise. We currently have a distribution platform that includes 52 direct sales representatives in the U.S., with 46 sales representatives serving the Urology, Urogynecology and Gynecology market and six sales representatives serving the non-Urology markets of Airway Management and Industrial markets. Internationally, we have 8 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 and our Urgent PC System, both in the United States and internationally. 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.

## Products and Markets

We produce and 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; and
- Other Products and Applications.

### *PrimeSight Endoscopes and PrimeSight Digital Processing Units for Medical Use*

In 2016, we initiated a program that brings the entire endoscopy portfolio under the company’s new PrimeSight brand. 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.



**Urology Market.** 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.

**Airway Management Market.** We developed 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 have 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.

#### ***Endoscopes (Borescopes) and Digital Processing Units for Industrial Use***

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.

#### ***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 TNE 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.

### ***Always Ready, Always Sterile***

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. 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” equipment, 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.

**Distributed 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.

## **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 52 direct field sales representatives, six Regional Sales Directors, and a marketing organization to market our products directly to our customers. Of our 52 direct sales representatives, 46 specialize in the urology market and six 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.

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 increase our revenues.

## **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 February 2016, all regional Medicare carriers, with approximately 55 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers insuring approximately 162 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. 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<sup>®</sup> and Toviaz<sup>®</sup> (both by Pfizer Inc.); Ditropan<sup>®</sup> (Johnson & Johnson); Enablex<sup>®</sup> (Novartis AG); Sanctura<sup>®</sup> (Allergan, Inc.) and Vesicare<sup>®</sup> (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<sup>®</sup>) 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. We believe that marketing campaigns by Allergan, Inc. will increase awareness of OAB. However, we also believe that the side effects of Botox injections for this application, which can include urinary retention and urinary tract infection, will lead many patients to choose our less invasive solution.

Medtronic's InterStim<sup>®</sup> 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. In order to obtain 501(k) approval, a device must provide proof of substantial equivalence. In the case of the NURO<sup>™</sup> device from Medtronic, the Urgent PC stimulator from Cogentix Medical was the predicate device. 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<sup>®</sup> manufactured by Carbon Medical Technologies, Inc. and distributed by Coloplast Corp; and Coaptite<sup>®</sup> 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<sup>®</sup> (manufactured by Q-Med AB, a wholly owned subsidiary of Galderma S.A., and distributed by Salix Pharmaceuticals, Ltd.) and Bulkamid<sup>®</sup> (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.

In 2016, we experienced an unexpected delay in the renewal of our CE Mark for certain of our products during the third quarter. Due to this delay, we were forced to find a new notified body on short notice in order to renew our CE certificates when AMTAC/Intertek could not fulfill its obligations to us. Subsequent to the end of the third quarter, we obtained renewal of the CE Mark for Macroplastique and Urgent PC and have resumed importing, selling and distributing our products in the European Union under Dekra, a notified body licensed in The Netherlands.

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, 2017, we hold 26 U.S. patents, and we have three U.S. patent applications pending. In addition, we have 110 foreign patents granted and have six foreign patent applications pending. The issued and granted patents will expire on various dates in the years 2017 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, 2016 and \$3.2 million for the Transition Period ended December 31, 2015.

With respect to our industrial segment, our ability to custom-design for specific applications is common practice in our business. On-wing inspections with blending borescopes have become an indispensable tool for aircraft engine manufacturers and service providers. We work closely with Pratt & Whitney, GE and other engine manufacturers, developing and producing the most efficient borescopes for their specific applications. We are developing a new processor with a video recording capability. Also, we are currently testing inexpensive C-MOS camera chips for industrial inspection applications.

### **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 2016 and the Transition Period has not had a material effect upon our capital expenditures, earnings or competitive position.

### **Dependence on Major Customers**

During calendar year 2016 and the Transition Period, 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 calendar year 2016 or the Transition Period.

## Employees

As of December 31, 2016, we had 177 employees, of which 173 were full-time and four were 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 52, 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 25 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 48, 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 20 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 49, 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 20 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.

**Brian Brown**, age 55, has served as Cogentix's Senior Vice President of R&D and Operations since November 2016. Mr. Brown recently served in the senior R&D and operations leadership roles at Ovagene Oncology, a point of care molecular diagnostics company, and Sunshine Heart, a mechanical circulatory assist heart failure company. Mr. Brown's experience spans more than 27 years in the medical device industry, including 24 years at Boston Scientific Corporation. At Boston Scientific, Mr. Brown held numerous R&D and manufacturing roles and served 10 years as the Vice President of Global R&D for the Interventional Cardiology division responsible for technology & product development and merger & acquisition activities.

**Daniel Merz**, age 39, has served as the Vice President of Regulatory, Quality and Clinical Affairs since November 2016. He has held various roles with the Company and its predecessor Uroplasty since April 2014, having led clinical research, reimbursement, quality, regulatory, operations and R&D. Prior to joining Uroplasty, Mr. Merz was the Senior Director of Clinical Research for the Transcatheter Aortic Valve Replacement program with St Jude Medical. Mr. Merz spent seven years leading clinical and regulatory affairs at American Medical Systems covering various urology applications, and has 17 years of experience in medical device businesses.

## 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.

## 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](http://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](http://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; 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:*

***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 Merger.

***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 2017. 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, 2016. As of December 31, 2016, we had an accumulated deficit of approximately \$81 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<sup>®</sup> neuromodulation device competes with our Urgent PC System, and in 2016 they formally launched an additional PTNS technology.

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 in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold.

In January 2017, Congress voted in favor of a budget resolution that will produce legislation that would repeal certain aspects of the Affordable Care Act if enacted into law. Congress is also considering subsequent legislation to replace or repeal elements or all of the Affordable Care Act. In addition, there have been recent public announcements by members of Congress and the new presidential administration regarding their plans to repeal and replace the Affordable Care Act. Further, 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. At this time, it is not clear whether the Affordable Care Act will be repealed in whole or in part, and, if it is repealed, whether it will be replaced in whole or in part by another plan. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which 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 increased 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. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claim Act action. 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.

***Currency exchange rate fluctuations could adversely affect our operating results.***

Because some of our business includes international business transactions, costs and prices of our products or components in overseas countries are affected by foreign exchange rate changes. As a result, foreign exchange rate fluctuations may adversely affect 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.

***We derive a significant portion of our sales from outside of the U.S. and are subject to the risks of international operations.***

We derived approximately 24% of our net sales in the calendar year ended December 31, 2016 from customers and operations in international markets. 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 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;
- fluctuations in the value of the U.S. dollar relative to foreign currencies;
- 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;
- 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”. As a result of the referendum, it is expected that the British government will begin 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 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.

***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, 2016. 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 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, 2016 and for each of our full quarterly periods within the Transition Period, as reported on the NASDAQ Capital Market.

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

  

<u>Transition Period ended December 31, 2015</u>	<u>Low</u>	<u>High</u>
April 1, 2015 – June 30, 2015	\$ 1.42	\$ 2.40
July 1, 2015 – September 30, 2015	\$ 1.10	\$ 1.72
October 1, 2015 – December 31, 2015	\$ 1.10	\$ 1.70

As of March 17, 2017, 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, 2016.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u> <u>(a)</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u> <u>(b)</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the column (a))</u> <u>(c)</u>
<b>Equity Compensation Plans Approved by Security Holders (1)</b>	1,680,990	\$ 3.54	1,377,130

(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, 2016 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, 2016 – March 31, 2016	-	-	-	-
April 1, 2016 – June 30, 2016	55,198	\$ 1.04	-	-
July 1, 2016 – September 30, 2016	-	-	-	-
October 1, 2016 – December 31, 2016	-	-	-	-
<b>Total</b>	<b>55,198</b>	<b>\$ 1.04</b>	<b>-</b>	<b>-</b>

**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.

**Presentation of Financial Results**

On December 10, 2015, our board approved a change in our fiscal year from a fiscal year ending on March 31<sup>st</sup> of each year to a calendar year ending on December 31, effective as of December 31, 2015. This action created a transition period of April 1, 2015 through December 31, 2015 (the “Transition Period”), which includes the first nine months immediately after the Merger. We are comparing our results of operations for the twelve-month calendar year ended December 31, 2016 and the nine-month Transition Period, unless otherwise indicated herein, and accordingly are not comparing results for a comparable period of time.

**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<sup>®</sup> 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<sup>™</sup> 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<sup>®</sup> a urethral bulking agent for the treatment of stress urinary incontinence. Outside the U.S., the company markets additional bulking agents: PTQ<sup>®</sup> for the treatment of fecal incontinence and the VOX<sup>®</sup> for vocal cord augmentation.

**Results of Operations*****Twelve-months ended December 31, 2016 compared to nine-month Transition Period ended December 31, 2015***

*Net Sales* . Consolidated net sales of \$51,852,000 in the current period represented a \$15,229,000 increase, or 41.6%, over net sales of \$36,623,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$12,207,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. The remaining increase is due primarily to a \$2,600,000 increase in PrimeSight revenue and a \$760,000 increase in Urgent PC revenue.

Consolidated net sales for PrimeSight urology technology of \$15,016,000 in the current period represented a \$5,726,000 increase, or 61.6%, over net sales of \$9,290,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$3,087,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. The remaining increase of \$2,639,000 is from our Urology PrimeSight Products and 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 \$21,237,000 in the current period represented a \$5,865,000 increase, or 38.2%, over net sales of \$15,372,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$5,107,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. Unit growth of 11% was partially offset by a 4% decline in average selling price. 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 a new entrant into the market.

Consolidated net sales of our Macroplastique product of \$7,387,000 in the current period represented a \$1,816,000 increase, or 32.6%, over net sales of \$5,571,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$1,854,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. Macroplastique serves a small market, and the focus of our sales force has been on growing our Urgent PC and endoscopy technology business.

Consolidated net sales of our non-urology products (Airway Management and Industrial Boroscopes) of \$7,102,000 in the current period represented a \$1,537,000 increase, or 27.6%, over net sales of \$5,565,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$1,873,000 for the three months ended March 31, 2016, versus nine months in the Transition Period.

Consolidated net sales to customers in the U.S. of \$39,513,000 in the current period represented an increase of \$11,944,000, or 43.3%, over net sales of \$27,569,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$8,918,000 for the three months ended March 31, 2016, versus nine months in the Transition Period.

Consolidated net sales to customers outside the U.S. of \$12,339,000 in the current period represented an increase of \$3,285,000, or 36.3%, over net sales of \$9,054,000 in the prior period. The increase is primarily due to twelve months of consolidated net sales in the current reporting period, including \$3,289,000 for the three months ended March 31, 2016, versus nine months in the Transition Period.

*Gross Profit* : Gross profit was \$35,603,000 (68.7% of net sales) in the current period versus \$24,102,000 (65.8% of net sales) in the prior period. The increase in gross profit is primarily due to twelve months of gross profit in the current reporting period, including \$8,405,000 (68.9% of net sales) for the three months ended March 31, 2016, versus nine months in the Transition Period. The increase in the gross profit percentage is attributed primarily to product mix and better utilization of manufacturing overhead, as well as the expiration of an unprofitable Stryker Corporation distribution arrangement for ureteroscopes that was not renewed at the end of calendar 2015.

*General and Administrative Expenses ("G&A")* : G&A expenses of \$6,778,000 in the current period increased \$1,247,000 from \$5,531,000 in the prior period. The increase is primarily due to twelve months of G&A expenses in the current reporting period, including \$1,662,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. For the last three quarters of the 2016, G&A decreased \$415,000. The decrease in expenses is primarily due to lower share based compensation, personnel, insurance, accounting, and consulting costs.

*Research and Development Expenses (“R&D”)* : R&D expenses of \$4,702,000 in the current period increased \$1,533,000 from \$3,169,000 in the prior period. The increase is primarily due to twelve months of R&D expenses in the current reporting period, including \$937,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. For the last three quarters of 2016, R&D expenses increased \$596,000. The increase is attributed primarily to increased spend on R&D projects and regulatory expenses offset partially by lower personnel and clinical studies costs.

*Selling and Marketing Expenses (“S&M”)* : S&M expenses of \$21,313,000 in the current period increased \$2,829,000 from \$18,484,000 in the prior period. The increase is primarily due to twelve months of S&M expenses in the current reporting period, including \$5,636,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. For the last three quarters of 2016, S&M expenses decreased \$2,806,000. The decrease is attributed primarily to decreased spend on personnel costs, the moratorium placed on the medical device excise tax, lower consulting costs and reduced marketing spend.

*Amortization of Intangibles* : Amortization of intangibles was \$2,363,000 in the current period compared to \$1,903,000 in the prior period. The increase is primarily due to twelve months of amortization expense in the current reporting period, including \$591,000 for the three months ended March 31, 2016, versus nine months in the Transition Period. The increase is due to the establishment of \$13,660,000 of identifiable intangible assets on March 31, 2015, as part of the allocation of purchase accounting in the Merger. These identifiable intangible assets are being amortized over a weighted average life of approximately 4 years.

*One-Time-Costs - Proxy Settlement Costs* : On May 23, 2016, the Company and all of the then-current members of the Board of Directors of the Company, including Director Mr. Lewis Pell who had been independently soliciting proxies to support his proposals for the Company’s 2016 Annual Meeting of Stockholders originally scheduled for May 20, 2016 and adjourned for May 24, 2016, entered into an agreement to settle the pending proxy contest between the Company and Mr. Pell and related litigation in connection with the Annual Meeting (the “Settlement”). For the twelve months ended December 31, 2016, the Company incurred \$2,258,000 of costs related to the Settlement, including \$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 prior period.

*One-Time Costs - Merger Related Costs* : Merger related costs totaled \$950,000 in the nine months ended December 31, 2015. There were no similar costs in the current period. Merger related costs include severance and retention, consulting and professional fees.

*Other Income (Expense)* : Other income (expense) includes interest income, interest expense, foreign currency exchange and other non-operating costs when incurred. Net other expense was \$20,139,000 in the current period compared to net other expense of \$1,054,000 in the prior period. Other expense increased primarily as the Company recorded non-cash debt conversion expense of \$18,841,000 million as a result of the conversion of \$29.5 million (face value) of convertible debt – related party and accrued interest into equity.

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 losses of \$26,000 in the current period.

*Income Tax Expense* : We recorded income tax expense of \$145,000 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.

## **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.

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We use these non-GAAP financial measures, and in particular non-GAAP operating 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						Non-GAAP
	GAAP	Share-based Expense	Long-term Incentive Plan	Depreciation	Disposal of Assets	Amortization of Intangibles	
<b>Twelve-months ended December 31, 2016</b>							
Gross Profit	\$ 35,603,000	\$ 33,000	\$ -	\$ 176,000	\$ -	\$ -	\$ 35,812,000
% of Net sales	68.7%						69.1%
Operating Expenses:							
General & administrative	6,778,000	(585,000)	74,000	(201,000)	(6,000)	-	6,060,000
Research and development	4,702,000	(24,000)	-	(2,000)	-	-	4,676,000
Selling and marketing	21,313,000	(106,000)	-	(394,000)	-	-	20,813,000
Amortization	2,363,000	-	-	-	-	(2,363,000)	-
One-time costs	2,258,000	-	-	-	-	-	2,258,000
	37,414,000	(715,000)	74,000	(597,000)	(6,000)	(2,363,000)	33,807,000
Operating income (loss)	\$ (1,811,000)	\$ 748,000	\$ (74,000)	\$ 773,000	\$ 6,000	\$ 2,363,000	\$ 2,005,000
One-time costs	2,258,000						2,258,000
Operating income							\$ 4,263,000

	Expense Adjustments						Non-GAAP
	GAAP	Share-based Expense	Long-term Incentive Plan	Depreciation	Disposal of Assets	Amortization of Intangibles	
<b>Nine-months ended December 31, 2015</b>							
Gross Profit	\$ 24,103,000	\$ 25,000	\$ -	\$ 180,000	\$ -	\$ -	\$ 24,308,000
% of Net sales	65.8%						66.4%
Operating Expenses:							
General & administrative	5,531,000	(679,000)	78,000	(166,000)	-	-	4,764,000
Research and development	3,169,000	(55,000)	-	(10,000)	-	-	3,104,000
Selling and marketing	18,484,000	(220,000)	-	(311,000)	4,000	-	17,957,000
Amortization	1,903,000	-	-	-	-	(1,903,000)	-
Merger related costs	950,000	-	-	-	-	-	950,000
	30,037,000	(954,000)	78,000	(487,000)	4,000	(1,903,000)	26,775,000
Operating loss	\$ (5,934,000)	\$ 979,000	\$ (78,000)	\$ 667,000	\$ (4,000)	\$ 1,903,000	\$ (2,467,000)
Merger related costs	950,000						950,000
Operating loss							\$ (1,517,000)

## Liquidity and Capital Resources

### *Cash Flows*

At December 31, 2016, our cash and cash equivalents balances totaled \$9,370,000. In addition, we have short and long term investments totaling \$18,917,000. Our net working capital as of December 31, 2016, totaled approximately \$28,611,000.

For the twelve months ended December 31, 2016, cash provided by operating activities was \$3,300,000, compared to cash used in operating activities of \$5,855,000 during the nine-month Transition Period ended December 31, 2015. For the twelve months ended December 31, 2016, we incurred a net loss of \$22,095,000. Significant non-cash expenses incurred in this 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 include lower accounts receivables of \$1,360,000 and higher accrued compensation of \$1,609,000, while cash was used as a result of inventories increasing by \$2,655,000. For the nine-month Transition Period ended December 31, 2015, we incurred a net loss of \$7,027,000 and an operating loss of \$5,934,000. Excluding non-cash charges for depreciation, amortization of intangibles and equity compensation, our operating loss for this period total \$2,500,000. Working capital changes in the nine-month Transition Period totaled \$3,800,000, primarily due to higher accounts receivables and lower accounts payables and accrued liabilities. The nine-month Transition Period ended December 31, 2015 net loss includes nonrecurring cash expenses of \$1.0 million attributed to integration costs primarily for legal, accounting and other fees associated with our merger.

During the twelve months ended December 31, 2016, we used cash in investing activities 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 nine-month Transition Period, we used \$1,411,000 of net cash 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 Purchase Agreement described in Part 1, Item 1 in the section entitled “Accelmed Investment and Pell Debt Conversion”.

### *Sources of Liquidity*

In addition to our cash and investments, we have a \$7.0 million secured revolving credit facility (“Facility”), subject to eligible accounts receivable and inventory. We may obtain additional debt and/or equity financing during 2017.

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.

### **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 Purchase Agreement described in Part I, Item 1 in the section entitled “Accelmed Investment and Pell Debt Conversion”, 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, 2016 are summarized below:

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1 – 3 Years</b>	<b>4 – 5 Years</b>	<b>More Than 5 Years</b>
Operating lease commitments	2,713,000	698,000	991,000	315,000	709,000

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.

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, 2016, and expected 2017 pension expense to the following changes in key assumptions:

	<b>Increase/(Decrease) Funded Status at December 31, 2016</b>	<b>Increase/(Decrease) 2017 Pension Expense</b>
Assumption:		
Increase in discount rate by 1 percentage point	\$ 169,000	\$ (43,000)
Decrease in discount rate by 1 percentage point	(221,000)	54,000
Increase in estimated return on assets by 1 percentage point	n/a	(6,000)
Decrease in estimated return on assets by 1 percentage point	n/a	6,000
Increase in inflation rate by 1 percentage point	(162,000)	36,000
Decrease in inflation rate by 1 percentage point	142,000	(31,000)
Increase in compensation by 1 percentage point	(45,000)	6,000
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 state inventories at the lower of cost or market using the first-in, first-out method. We value at lower of cost or market the slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. 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 of December 31, 2016, we have generated approximately \$118.5 million in U.S. net operating loss (“NOL”) carry forwards that we cannot use to offset taxable income in foreign jurisdictions. 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.

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 percent change in ownership of a company over a three-year period. Of the \$118.5M of NOLs for U.S. income tax purposes, \$88.2M are expected to expire unutilized.

We refer you to Note 8 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 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-03, “Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs.” The amendments in this update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. The Company adopted this standard in conjunction with obtaining its new loan facility. There was no impact of the retrospective adoption to prior periods.

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 November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes”, which requires that deferred tax liabilities and assets be classified as noncurrent in a classified balance sheet. Prior to the issuance of this guidance, deferred tax liabilities and assets were required to be separately classified into a current amount and a noncurrent amount in the balance sheet. The new accounting guidance represents a change in accounting principle and the standard is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years, with earlier application permitted as of the beginning of an interim or annual reporting period. The Company elected to early-adopt ASU No. 2015-17 during the fourth quarter of fiscal year 2015 and retrospectively applied the presentation.

***Recently Issued Accounting Pronouncements Not Yet Adopted.***

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 March 2016, 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. Early adoption is permitted in any interim or annual period, with adjustments reflected as of the beginning of the fiscal year of adoption. The Company believes the most significant impact of the adoption of ASU 2016-09 to the Company’s consolidated financial statements will be to recognize certain tax benefits or tax shortfalls upon a restricted-stock award or unit vesting or stock option exercise relative to the deferred tax asset position established in the provision for income taxes line of the consolidated statement of operations instead of to consolidated stockholders’ equity. ASU 2016-09 is effective beginning in the first quarter of 2017 with early adoption permitted. The Company plans to adopt ASU 2016-09 during the first quarter of 2017. The Company is still evaluating the impact of the adoption of this guidance on its 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 September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805).” The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. Under the new guidance, the acquirer should record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. On the face of the income statement or in the notes, the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods needs to be reflected as if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in ASU No. 2016-16 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We do not believe the adoption of this update will have a material impact on our consolidated financial statements.

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. The Company has completed the initial assessment and is currently in the process of determining the impact that this ASU will have on the consolidated financial statements and its method of adoption. We plan to adopt this ASU effective January 1, 2018.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2016, 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, 2016, 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, 2016, 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, 2016, 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, 2016.

## **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**

The information contained under the headings “Proposal No. 1 - Election of Directors,” “Corporate Governance – Code of Ethics and Business Conduct,” “Corporate Governance – Director Nomination Process,” “Corporate Governance – Board Committees – Audit Committee” and “Share Ownership of Certain Beneficial Owners, Management and Directors -- Section 16 Beneficial Ownership Reporting Compliance” in the Proxy Statement is incorporated herein by reference.

The information concerning our executive officers required by this Item is provided under the caption “Executive Officers” in Part I, Item 1 of this report.

## **ITEM 11. EXECUTIVE COMPENSATION**

The information contained under the heading “Executive Compensation” and “Director Compensation” in the Proxy Statement is incorporated herein by reference.

## **ITEM 12. 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 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information contained under the headings “Related Person Relationships and Transactions” and “Corporate Governance – Director Independence” in the Proxy Statement is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

This information contained under the headings “Proposal No. 2 – Ratification of Selection of Independent Registered Public Accounting Firm,” “—Audit, Audit-Related, Tax and Other Fees,” and “—Pre-Approval Policies and Procedures” in the Proxy Statement is incorporated herein by reference.

**PART IV**

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

- (a) Documents filed as part of this Annual Report on Form 10-K:
  - 1. Consolidated Financial Statements:

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Consolidated Statements of Shareholders’ Equity	F-7
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- 2. Financial Statement Schedule:

**Schedule I – Valuation and Qualifying Accounts**

	<b>Balance at beginning of fiscal year</b>	<b>Additions charged to expenses</b>	<b>Written off, less recoveries</b>	<b>Effects of foreign currency fluctuations</b>	<b>Balance at end of fiscal year</b>
<b>Allowance for doubtful accounts</b>					
Twelve months ended December 31, 2016	\$ 27,000	\$ 21,000	\$ (14,000)	\$ -	\$ 34,000
Nine-month transition period ended December 31, 2015	\$ 18,000	\$ 66,000	\$ (57,000)	\$ -	\$ 27,000

	<b>Balance at beginning of fiscal year</b>	<b>Additions charged against revenues</b>	<b>Returns written off</b>	<b>Effects of foreign currency fluctuations</b>	<b>Balance at end of fiscal year</b>
<b>Allowance for sales returns</b>					
Twelve months ended December 31, 2016	\$ 41,000	\$ 9,000	\$ (1,000)	\$ -	\$ 49,000
Nine-month transition period ended December 31, 2015	\$ 15,000	\$ 26,000	\$ -	\$ -	\$ 41,000

3. Exhibits

The exhibits to this report are listed on the Exhibit Index to this report and incorporated herein by reference. 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 contract or compensatory plan or arrangement referenced as an exhibit to this report.

**ITEM 16. FORM 10-K SUMMARY.**

None.

## 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, 2017

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.

<u>Name</u>	<u>Title / Capacity</u>	<u>Date</u>
<u>/s/ Darin Hammers</u> Darin Hammers	President and Chief Executive Officer, (Principal Executive Officer)	March 30, 2017
<u>/s/ Brett Reynolds</u> Brett Reynolds	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2017
<u>/s/ Uri Geiger</u> Uri Geiger	Chairman of the Board of Directors	March 30, 2017
<u>/s/ Nachum Shamir</u> Nachum Shamir	Director	March 30, 2017
<u>/s/ James A. D'Orta</u> James A. D'Orta	Director	March 30, 2017
<u>/s/ Cheryl Pegus</u> Cheryl Pegus	Director	March 30, 2017
<u>/s/ Lewis C. Pell</u> Lewis C. Pell	Director	March 30, 2017
<u>/s/ Kenneth S. Samet</u> Kenneth S. Samet	Director	March 30, 2017
<u>/s/ Howard I. Zauberman</u> Howard I. Zauberman	Director	March 30, 2017

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COGENTIX MEDICAL, INC. AND SUBSIDIARIES

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December 31, 2016

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Cogentix Medical, Inc.

We have audited the accompanying consolidated balance sheets of Cogentix Medical, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in shareholders’ equity, and cash flows for the year ended December 31, 2016 and the nine months ended December 31, 2015. Our audits of the basic consolidated financial statements included the financial statement schedule listed in the index appearing under Item 15(a)(2). These financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cogentix Medical, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the year ended December 31, 2016 and the nine months ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Grant Thornton LLP

Minneapolis, Minnesota  
March 30, 2017

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,369,624	\$ 1,976,594
Short-term investments	13,573,057	-
Accounts receivable, net	6,770,838	8,191,391
Inventories	7,235,043	4,584,844
Other	571,527	834,076
Total current assets	<u>37,520,089</u>	<u>15,586,905</u>
Property, plant, and equipment, net	2,115,316	2,554,822
Goodwill	18,749,888	18,749,888
Other intangibles, net	9,482,578	11,846,009
Long-term investments	5,344,004	-
Deferred tax assets and other	163,427	269,121
Total assets	<u>\$ 73,375,302</u>	<u>\$ 49,006,745</u>

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,689,035	\$ 2,209,473
Income taxes payable	113,191	20,866
Accrued liabilities:		
Compensation	4,670,640	3,281,809
Deferred revenue	597,524	307,936
Other	<u>838,272</u>	<u>641,561</u>
Total current liabilities	8,908,662	6,461,645
Convertible debt – related party, net	-	23,336,854
Interest payable	-	757,615
Accrued pension liability	308,918	663,071
Deferred rent	639,019	671,088
Other	<u>278,780</u>	<u>157,453</u>
Total liabilities	<u>10,135,379</u>	<u>32,047,726</u>
Commitments and contingencies		
Shareholders' equity:		
Common stock \$.01 par value; 100,000,000 shares authorized, 60,436,548 and 26,057,327 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively.	604,368	260,574
Additional paid-in capital	144,430,381	76,485,650
Accumulated deficit	(81,005,654)	(58,910,707)
Accumulated other comprehensive loss	<u>(789,172)</u>	<u>(876,498)</u>
Total shareholders' equity	<u>63,239,923</u>	<u>16,959,019</u>
Total liabilities and shareholders' equity	<u>\$ 73,375,302</u>	<u>\$ 49,006,745</u>

See accompanying Notes to Consolidated Financial Statements.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31	Nine Months Ended December 31
	2016	2015
Net sales	\$ 51,851,159	\$ 36,622,355
Cost of goods sold	16,248,111	12,519,443
Gross profit	35,603,048	24,102,912
Operating expenses		
General and administrative	6,778,010	5,530,909
Research and development	4,701,539	3,168,753
Selling and marketing	21,313,364	18,484,063
One-time costs	2,257,654	950,469
Amortization of intangibles	2,363,432	1,902,573
	37,413,999	30,036,767
Operating loss	(1,810,951)	(5,933,855)
Other income (expense)		
Interest income	25,455	3,337
Interest expense	(1,298,253)	(1,071,441)
Debt conversion expense	(18,841,407)	-
Foreign currency exchange gain (loss)	(25,022)	14,313
	(20,139,227)	(1,053,791)
Loss before income taxes	(21,950,178)	(6,987,646)
Income tax expense	144,769	39,832
Net loss	\$ (22,094,947)	\$ (7,027,478)
Basic and diluted net loss per common share	\$ (0.71)	\$ (0.28)
Weighted average common shares outstanding:		
Basic and diluted	30,903,035	25,377,955

See accompanying Notes to Consolidated Financial Statements.

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

	Twelve Months Ended December 31	Nine Months Ended December 31
	<u>2016</u>	<u>2015</u>
Net loss	\$ (22,094,947)	\$ (7,027,478)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments	(111,515)	(16,449)
Unrealized loss on available-for-sale investments	(21,349)	-
Pension adjustments	220,190	296,216
Total other comprehensive income, net of tax	<u>87,326</u>	<u>279,767</u>
Comprehensive loss	<u>\$ (22,007,621)</u>	<u>\$ (6,747,711)</u>

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				
<b>Balance at March 31, 2015</b>	25,676,212	\$	256,763	\$	75,530,641	\$	(51,883,229)	\$	(1,156,265)	\$	22,747,910
Share-based compensation expense	491,522		4,915		974,037		-		-		978,952
Restricted stock exchanged for taxes	(110,407)		(1,104)		(19,028)		-		-		(20,132)
Comprehensive loss	-		-		-		(7,027,478)		279,767		(6,747,711)
<b>Balance at December 31, 2015</b>	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)
<b>Balance at December 31, 2016</b>	<b>60,436,548</b>	<b>\$</b>	<b>604,368</b>	<b>\$</b>	<b>144,430,381</b>	<b>\$</b>	<b>(81,005,654)</b>	<b>\$</b>	<b>(789,172)</b>	<b>\$</b>	<b>63,239,923</b>

See accompanying Notes to Consolidated Financial Statements.

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

	Twelve Months ended December 31, <u>2016</u>	Nine Months ended December 31, <u>2015</u>
Cash flows from operating activities:		
Net loss	\$ (22,094,947)	\$ (7,027,478)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,136,109	2,569,636
Debt conversion expense	18,841,407	-
Loss on disposal of equipment	5,640	4,859
Amortization of premium on marketable securities	8,003	-
Share-based compensation expense	748,119	978,952
Amortization of discount on related party debt	940,923	807,356
Long term incentive plan	(74,404)	(78,188)
Deferred tax benefit	57,536	65,799
Deferred rent	3,777	636,615
Restricted stock exchanged for taxes	(57,343)	(20,132)
Changes in operating assets and liabilities, net of merger:		
Accounts receivable	1,359,056	(1,663,510)
Inventories	(2,655,221)	246,273
Other current assets	253,553	696,742
Accounts payable	484,237	(1,759,500)
Interest payable	292,049	233,873
Accrued compensation	1,609,281	(4,579)
Accrued liabilities, other	270,612	(1,666,431)
Accrued pension liability	(116,395)	(29,940)
Deferred revenue	288,329	154,684
Net cash provided by (used in) operating activities	<u>3,300,321</u>	<u>(5,854,969)</u>
Cash flows from investing activities:		
Purchases of available-for-sale securities	(18,945,717)	-
Purchases of property, plant and equipment	(355,145)	(1,411,042)
Net cash used in investing activities	<u>(19,300,862)</u>	<u>(1,411,042)</u>
Cash flows from financing activities:		
Proceeds from sale of common stock, net	23,428,900	-
Net cash provided by financing activities	<u>23,428,900</u>	<u>-</u>
Effect of exchange rates on cash and cash equivalents	(35,329)	(19,298)
Net increase (decrease) in cash and cash equivalents	7,393,030	(7,285,309)
Cash and cash equivalents at beginning of period	1,976,594	9,261,903
Cash and cash equivalents at end of period	<u>\$ 9,369,624</u>	<u>\$ 1,976,594</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for income tax	\$ 42,957	\$ 39,832
Cash paid during the period for interest	\$ 62,418	\$ 30,213
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, 2016 and the nine-month Transition Period ended December 31, 2015*

**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 innovative proprietary technologies serving the urology, urogynecology, gynecology, ENT (ear, nose and throat) and gastrointestinal markets. The Urgent® PC Neuromodulation System delivers percutaneous tibial nerve stimulation (PTNS) which has FDA clearance for the office-based treatment of overactive bladder (OAB) and has regulatory approvals for the treatment of OAB and fecal incontinence (FI) in various international markets. The FDA-cleared and CE marked PrimeSight Endoscopy Systems and 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. The Company also offers 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 VOX® for vocal cord augmentation and vesicourethral reflux.

The Company is the result of the Merger effective as of March 31, 2015, of two medical device companies, Uroplasty, Inc. (“UPI”) and Vision-Sciences, Inc. (“VSCI”). On the effective date of the Merger, the two companies completed an all-stock merger, pursuant to which UPI merged with and into Merger Sub, a wholly owned subsidiary of VSCI. Merger Sub was the surviving company from the Merger, and changed its name to Uroplasty, LLC. VSCI continued to be the sole member of the surviving company. After the Merger, VSCI and its consolidated subsidiaries, including the surviving company, operate under the name Cogentix Medical, Inc.

**Change in Fiscal Year.**

On December 10, 2015, the Board of Directors of the Company determined that, in accordance with its bylaws and upon recommendation of the Audit Committee, the Company’s fiscal year shall begin on January 1 and end on December 31 of each year starting on January 1, 2016. The required transition period of April 1, 2015 to December 31, 2015 is included in this Form 10K Report.

**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 4). 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 \$363,000 in the twelve months ended December 31, 2016, and \$383,000 in the nine-month transition period ended December 31, 2015, 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.

### **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 table shows 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, 2016 (in thousands):

December 31, 2016							
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-Term Investments	Long-Term Investments
Cash	\$ 3,774	\$ -	\$ -	\$ 3,774	\$ 3,774	\$ -	\$ -
<b>Level 1:</b>							
Money market funds	3,198	-	-	3,198	3,198	-	-
Subtotal	3,198	-	-	3,198	3,198	-	-
<b>Level 2:</b>							
Certificates of deposit	2,159	2	-	2,161	-	719	1,442
Commercial paper	5,985	-	(4)	5,981	2,398	3,583	-
Corporate notes/bonds	9,689	-	(14)	9,675	-	7,274	2,401
U.S. government agencies	3,503	-	(5)	3,498	-	1,997	1,501
Subtotal	21,336	2	(23)	21,315	2,398	13,573	5,344
<b>Total</b>	<b>\$ 28,308</b>	<b>\$ 2</b>	<b>\$ (23)</b>	<b>\$ 28,287</b>	<b>\$ 9,370</b>	<b>\$ 13,573</b>	<b>\$ 5,344</b>

**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.

Cash and cash equivalents include highly liquid money market funds and debt securities with original maturities of three months or less totaling \$9.4 million and \$2.0 million at December 31, 2016 and 2015, 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 \$507,000 at December 31, 2016 and 2015.

**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 \$34,000 and \$27,000 at December 31, 2016 and 2015, respectively.

**Inventories.**

We state inventories at the lower of cost or market using the first-in, first-out method. We value at lower of cost or market the slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. Inventories consist of approximately the following:

	<u>12/31/16</u>	<u>12/31/15</u>
Raw materials	\$ 4,483,000	\$ 2,385,000
Work-in-process	462,000	793,000
Finished goods	<u>2,290,000</u>	<u>1,407,000</u>
	<u>\$ 7,235,000</u>	<u>\$ 4,585,000</u>

**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:

	<u>12/31/16</u>	<u>12/31/15</u>
Land	\$ 129,000	\$ 133,000
Building	588,000	610,000
Leasehold improvements	1,240,000	1,222,000
Internal use software	821,000	782,000
Equipment	<u>3,203,000</u>	<u>3,042,000</u>
	<u>\$ 5,981,000</u>	<u>\$ 5,789,000</u>
Less accumulated depreciation and amortization	<u>(3,866,000)</u>	<u>(3,234,000)</u>
	<u>\$ 2,115,000</u>	<u>\$ 2,555,000</u>

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 3 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 \$778,000 in the twelve months ended December 31, 2016, and \$672,000 in the nine-month transition period ended December 31, 2015, respectively.

**Goodwill.**

Goodwill results from the Merger 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.

There was no goodwill impairment loss for the year ended December 31, 2016 and the period ended December 31, 2015.

**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 year ended December 31, 2016 and the period ended December 31, 2015.

**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:

	<u>12/31/16</u>	<u>12/31/15</u>
Warranty reserve at beginning of period	\$ 146,000	\$ 146,000
Warranties accrued during the period	77,000	50,000
Warranties settled during the period	<u>(96,000)</u>	<u>(50,000)</u>
Warranty reserve at end of period	<u>\$ 127,000</u>	<u>\$ 146,000</u>

**Other Current Liabilities.**

Other current liabilities consist of approximately the following:

	<u>12/31/16</u>	<u>12/31/15</u>
Sales tax and VAT payable	\$ 328,000	\$ 243,000
Accrued legal and accounting fees	101,000	70,000
Other accrued expenses	<u>409,000</u>	<u>329,000</u>
	<u>\$ 838,000</u>	<u>\$ 642,000</u>

**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 \$26,000 in the twelve months ended December 31, 2016 and \$(14,000) in the nine-month transition period ended December 31, 2015, 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:

Period ended:	<u>Number of options, warrants and unvested restricted stock</u>	<u>Range of exercise prices</u>
Twelve months December 31, 2016	2,674,000	\$ 0.88 - \$24.40
Nine-months December 31, 2015	3,637,000	\$ 1.64 - \$24.40

***Recently Adopted Accounting Pronouncements.***

In 2015, the FASB issued ASU. No. 2015-03, "Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs." The amendments in this update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. The Company adopted this standard in conjunction with obtaining its new loan facility. There was no impact of the retrospective adoption to prior periods.

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 November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes”, which requires that deferred tax liabilities and assets be classified as noncurrent in a classified balance sheet. Prior to the issuance of this guidance, deferred tax liabilities and assets were required to be separately classified into a current amount and a noncurrent amount in the balance sheet. The new accounting guidance represents a change in accounting principle and the standard is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years, with earlier application permitted as of the beginning of an interim or annual reporting period. The Company elected to early-adopt ASU No. 2015-17 during the fourth quarter of fiscal year 2015 and retrospectively applied the presentation.

***Recently Issued Accounting Pronouncements Not Yet Adopted.***

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 March 2016, 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. Early adoption is permitted in any interim or annual period, with adjustments reflected as of the beginning of the fiscal year of adoption. The Company believes the most significant impact of the adoption of ASU 2016-09 to the Company’s consolidated financial statements will be to recognize certain tax benefits or tax shortfalls upon a restricted-stock award or unit 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 to consolidated shareholders’ equity. ASU 2016-09 is effective beginning in the first quarter of 2017 with early adoption permitted. The Company plans to adopt ASU 2016-09 during the first quarter of 2017. The Company is still evaluating the impact of the adoption of this guidance 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 sheets.

In September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805).” The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. Under the new guidance, the acquirer should record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. On the face of the income statement or in the notes, the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods needs to be reflected as if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in ASU No. 2015-16 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We do not believe the adoption of this update will have a material impact on our consolidated financial statements.

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. The Company has completed the initial assessment and is currently in the process of determining the impact that this ASU will have on the consolidated financial statements and its method of adoption. We plan to adopt this ASU effective January 1, 2018.

**Note 2. Goodwill and Other Intangible Assets**

**Goodwill.**

As described in the section entitled “Merger of Uroplasty and Vision-Sciences to Create Cogentix”, on March 31, 2015, for accounting purposes, UPI was deemed to have acquired VSCI for a purchase price of \$16.5 million, and as a result, the Company recognized approximately \$18.8 million in goodwill.

**Other Intangible Assets.**

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

	December 31, 2016			December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Weighted Average Amortization period	Gross Carrying Amount	Accumulated Amortization	Weighted Average Amortization period
Developed technology	\$ 6,200,000	\$ 1,550,000	5.25	\$ 6,200,000	\$ 664,000	6.25
Patents & trademarks	5,653,000	5,616,000	8.25	5,653,000	5,586,000	9.25
Trademarks and trade names	190,000	75,000	8.25	190,000	67,000	9.25
Customer relationships	7,270,000	2,590,000	3.25	7,270,000	1,150,000	4.25
	<u>19,313,000</u>	<u>\$ 9,831,000</u>		<u>19,313,000</u>	<u>\$ 7,467,000</u>	
Accumulated amortization	9,831,000			7,467,000		
Net book value of amortizable intangible assets	<u>\$ 9,482,000</u>		4.23	<u>\$ 11,846,000</u>		5.23

Amortization costs were approximately \$2,363,000 in the year ended December 31, 2016 and \$1,903,000 in the nine-month transition period ended December 31, 2015.

Estimated amortization expense for all intangible assets for the five years subsequent to December 31, 2016 is as follows:

**Year ending December 31,**

2017	\$ 2,353,000
2018	2,347,000
2019	2,341,000
2020	1,254,000
2021	894,000
Thereafter	293,000

**Note 3. Convertible Debt – Related Party**

As of December 31, 2015, 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.

The following table is a summary of convertible debt – related party as of December 31, 2015:

	<b>Gross Principal Amount</b>	<b>Unamortized Debt Discount</b>	<b>Net Amount</b>
Note Payable A	\$ 20,000,000	\$ (3,639,000)	\$ 16,361,000
Note Payable B	3,500,000	(562,000)	2,938,000
Note Payable C	4,990,000	(952,000)	4,038,000
	<u>\$ 28,490,000</u>	<u>\$ (5,153,000)</u>	<u>\$ 23,337,000</u>

- Note Payable A accrued annual interest at the rate of 0.84%.
- Note Payable B accrued annual interest at the rate of 1.66%.
- Note Payable C accrued annual interest at the rate of 1.91%.

At December 31, 2015, we had an aggregate amount of approximately \$758,000 in accrued interest under the convertible notes payable, which is included in interest payable on our consolidated balance sheet. At the time of the conversion of the notes, accrued interest was approximately \$1,000,000.

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. 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, 2016, 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 1,377,130 shares remain available for grant at December 31, 2016.

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 1,680,990 shares of common stock granted under the 2015 Plan or predecessor companies' plans. Options generally expire over a period ranging from five to seven 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 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 \$748,000 and \$979,000 in share-based compensation expense for the year ended December 31, 2016 and the nine-month transition period ended December 31, 2015, respectively.

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 year ended December 31, 2016 and the nine-month transition period ended December 31, 2015:

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Expected life, in years	3.90	3.84
Risk-free interest rate	.98%	1.11%
Expected volatility	61.86%	63.9%
Expected dividend yield	0%	0%

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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 estimate 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.

The following table summarizes the activity related to our stock options for the year ended December 31, 2016 and the nine-month transition period ended December 31, 2015:

	Number of shares	Weighted average exercise price	Weighted average grant date fair value	Aggregate intrinsic value	Weighted average remaining life in years
Balance at March 31, 2015	2,250,865	\$ 5.32		\$ -	5.06
Options granted	617,914	1.64	\$ 0.79		
Options exercised	-				
Options surrendered	<u>(295,139)</u>	5.08			
Balance at December 31, 2015	2,573,640	4.46		-	5.24
Options granted	692,400	1.05	0.49		
Options exercised	-				
Options surrendered	<u>(1,585,050)</u>	3.90			
Balance at December 31, 2016	<u>1,680,990</u>	\$ 3.54		\$ 752,290	6.55
Options exercisable at December 31, 2016	<u>811,015</u>	\$ 3.80		\$ 607,800	3.71

The total fair value of stock options vested during the year ended December 31, 2016 and the nine-month transition period ended December 31, 2015, was approximately \$276,000 and \$519,000, respectively.

There were no options exercised for the year ended December 31, 2016 or for the nine-month transition period ended December 31, 2015.

We grant restricted shares at the discretion of our directors with vesting terms ranging from six months to one year. The following table summarizes the activity related to our restricted stock for the year ended December 31, 2016 and the nine-month transition period ended December 31, 2015:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining life in years	Aggregate intrinsic value
Balance at March 31, 2015	317,741	\$ 4.47	1.93	\$ 387,644
Shares granted	513,299	1.62		
Shares vested	(122,353)	4.42		157,835
Shares surrendered	<u>(21,777)</u>	2.73		
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	<u>(307,699)</u>	2.45		
Balance at December 31, 2016	<u>992,548</u>	\$ 1.30	1.35	\$ 1,995,021

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.

At December 31, 2016, we had approximately \$1,088,000 of unrecognized share-based compensation cost, net of estimated forfeitures, related to stock options and restricted shares that we expect to recognize over a weighted-average requisite service period of approximately 1.5 years.

**Stock Warrants-Related Party.**

At December 31, 2015, the Company had warrants outstanding that were issued to Mr. Pell to purchase an aggregate of 376,123 shares of our common stock at a weighted average exercise price of \$9.31 per share. These warrants were cancelled in November 2016.

**Long-Term Incentive Plan and Awards .**

On October 1, 2014, the compensation committee of our board of directors and our board of directors approved and adopted a Performance Award Agreement under the Uroplasty, Inc. 2006 Amended Stock and Incentive Plan, as amended (the “2016 Plan”), and on October 2, 2014, grants of Performance Awards (the “Awards”) were made to certain members of our senior management team.

Performance goals for the Awards are based on the achievement of specified stock price targets during the period beginning on the date of grant and ending on the fourth anniversary of the date of grant or, if earlier, the closing date of a change of control (as defined in the 2006 Plan) of the Company. The stock price targets under the Awards were: \$7.57 price per share of common stock, \$10.32 price per share of common stock and \$13.76 price per share of common stock. A change of control occurred in November 2016, and the Awards were terminated without any of the stock targets being attained.

**Note 5. 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, 2016, based on eligible receivables and inventory, our total available borrowing base was \$5,878,000. We did not have any borrowings under the facility as of December 31, 2016.

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 6. 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, 2016, the approximate future minimum lease payments in subsequent years under noncancelable operating leases with an initial term in excess of one year are approximately as follows:

2017	\$	698,000
2018		688,000
2019		303,000
2020		157,000
2021		158,000
Thereafter		709,000
	\$	<u>2,713,000</u>

Total operating lease expenses were approximately \$695,000 for the twelve months ended December 31, 2016 and \$580,000 for the nine-month transition period ended December 31, 2015.

**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 7: Savings and Retirement Plans**

We sponsor various plans for eligible employees in the United States, the United Kingdom (the "U.K."), 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 \$438,000 in the twelve months ended December 31, 2016 and \$261,000 in the nine-month transition period ended December 31, 2015.

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 \$38,000 for the year ended December 31, 2016, and \$33,000 in the nine-month transition period ended December 31, 2015.

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 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. 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.

As of August 1, 2016 we changed from a final salary benefit plan to a career average salary benefit plan. On July 31, 2016 the discount rate was 1.40%. The effect of the special event on the funded status was \$665,000. The effect of the change will be recognized as prior service cost, and as a result, the effect will be included in the consolidated statement of operations in future years when it is amortized during the expected future service years. The effect on accumulated other comprehensive loss as of July 31, 2016 is a gain of \$665,000.

At December 31, 2016, we project the following benefit payments in subsequent years:

2017	\$	20,000
2018		20,000
2019		21,000
2020		21,000
2021		27,000
2022 to 2026		190,000
	\$	<u>299,000</u>

We contributed approximately \$125,000 in the year ended December 31, 2016, and \$73,000 in the nine-month transition period ended December 31, 2015 and expect to contribute approximately \$101,000 in 2017.

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

	<u>Twelve months ended</u> <u>December 31, 2016</u>	<u>Nine months ended</u> <u>December 31, 2015</u>
Changes in benefit obligations:		
Projected benefit obligation, beginning of period	\$ 3,665,000	\$ 4,465,000
Service cost	104,000	109,000
Interest cost	76,000	51,000
Benefits paid	(21,000)	(16,000)
Plan amendment	(658,000)	-
Actuarial loss (gain)	474,000	(977,000)
Foreign currency translation	(130,000)	33,000
Projected benefit obligation, end of period	<u>\$ 3,510,000</u>	<u>\$ 3,665,000</u>
Changes in plan assets:		
Plan assets, beginning of period	\$ 3,002,000	\$ 3,593,000
Contributions to plan	125,000	73,000
Management cost	(12,000)	(4,000)
Actual return on assets	357,000	(670,000)
Benefits paid	(21,000)	(16,000)
Foreign currency translation	(130,000)	26,000
Plan assets, end of period	<u>\$ 3,321,000</u>	<u>\$ 3,002,000</u>

The amount recognized in other comprehensive loss consists of:

	<b>Twelve months ended December 31, 2016</b>	<b>Nine months ended December 31, 2015</b>
Unrecognized net prior service benefit	\$ (870,000)	\$ (313,000)
Unrecognized net losses	<u>779,000</u>	<u>656,000</u>
Additional other comprehensive (gain) /loss (gross of income taxes)	<u>\$ (91,000)</u>	<u>\$ 343,000</u>

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

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Projected benefit obligation	\$ 3,510,000	\$ 3,665,000
Accumulated benefit obligation	3,376,000	3,107,000
Fair value of plan assets	3,321,000	3,002,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on December 31, 2016 and 2015, of \$189,000 and \$663,000, respectively, as accrued pension liability.

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

	<b>Twelve months ended December 31, 2016</b>	<b>Nine months ended December 31, 2015</b>
Gross service cost, net of employee contribution	\$ 99,000	\$ 98,000
Interest cost	76,000	51,000
Management cost	5,000	6,000
Expected return on assets	(66,000)	(42,000)
Amortization	<u>(30,000)</u>	<u>1,000</u>
Net periodic retirement cost	<u>\$ 84,000</u>	<u>\$ 114,000</u>



Major assumptions used in the above calculations include:

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Discount rate	2.00%	2.40%
Expected return on assets	2.00%	2.40%
Expected rate of increase in future compensation:		
General	2.5%	2.5%
Individual	0-3%	0-3%

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities. The impact of the decrease in discount rate used at December 31, 2016 as compared to December 31, 2015 was an increase in the projected benefit obligation and actual return on assets. 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, 2016 and 2015, 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, 2016 we project the following benefit payments in subsequent years:

2017	\$ 23,000
2018	133,000
2019	45,000
2020	-
2021	-
2022 to 2026	652,000
	<u>\$ 853,000</u>

We contributed approximately \$ 53,000 in the twelve months ended December 31, 2016, and \$33,000 in the nine-month transition period ended December 31, 2015, and expect to contribute approximately \$43,000 in 2017.

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

	<u>Twelve months ended December 31, 2016</u>	<u>Nine months ended December 31, 2015</u>
Changes in benefit obligations:		
Projected benefit obligation, beginning of period	\$ 744,000	\$ 814,000
Service cost	4,000	4,000
Interest cost	26,000	21,000
Benefits paid	(96,000)	-
Other	(4,000)	(4,000)
Actuarial loss (gain)	197,000	(91,000)
Foreign currency translation	(135,000)	-
Projected benefit obligation, end of period	<u>\$ 736,000</u>	<u>\$ 744,000</u>
Changes in plan assets:		
Plan assets, beginning of period	\$ 775,000	\$ 730,000
Contributions to plan	53,000	33,000
Management cost	(4,000)	(4,000)
Benefits Paid	(96,000)	-
Actual return on assets	15,000	19,000
Foreign currency translation	(127,000)	(3,000)
Plan assets, end of period	<u>\$ 616,000</u>	<u>\$ 775,000</u>

The amount recognized in other comprehensive loss consists of:

	<b><u>Twelve months ended December 31, 2016</u></b>	<b><u>Nine months ended December 31, 2015</u></b>
Unrecognized net losses (gross of deferred taxes)	\$ 276,000	\$ 116,000

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

	<b><u>December 31, 2016</u></b>	<b><u>December 31, 2015</u></b>
Projected benefit obligation	\$ 736,000	\$ 744,000
Accumulated benefit obligation	736,000	744,000
Fair value of plan assets	616,000	775,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on December 31, 2016 and 2015, of \$120,000 and \$84,000, respectively, as accrued pension liability.

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

	<b><u>Twelve months ended December 31, 2016</u></b>	<b><u>Nine months ended December 31, 2015</u></b>
Gross service cost, net of employee contribution	\$ 5,000	\$ 4,000
Interest cost	26,000	21,000
Expected return on assets	(21,000)	(15,000)
Amortization	7,000	19,000
Net periodic retirement cost	<u>\$ 17,000</u>	<u>\$ 29,000</u>

Major assumptions used in the above calculations include:

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Discount rate	2.70%	4.00%
Expected return on assets	2.20%	3.00%

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:

	<u>December 31, 2016</u>		<u>December 31, 2015</u>	
	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.

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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)
<b>December 31, 2016</b>				
Other Contract (Netherlands Plan)	\$ 3,321,000	\$ (5,000)	\$ -	\$ 3,326,000
Deposit Administration Contract (U.K. Plan)	616,000	-	616,000	-
<b>December 31, 2015</b>				
Other Contract (Netherlands Plan)	\$ 3,002,000	\$ (3,000)	\$ -	\$ 3,005,000
Deposit Administration Contract (U.K. Plan)	775,000	-	775,000	-

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

	Other Contract (Netherlands Pension Plan Assets)
Beginning balance at December 31, 2015	\$ 3,005,000
Loss recognized in earnings	54,000
Actuarial gain	291,000
Purchases	130,000
Sales	(21,000)
Transfers	(3,000)
Foreign currency translation	(130,000)
Ending balance at December 31, 2016	\$ 3,326,000

**Note 8: Income Taxes**

The components of income tax expense consist of the following:

	Twelve months ended December 31, 2016	Nine months ended December 31, 2015
Income tax provision:		
Current:		
Federal and state	\$ 91,000	\$ 14,000
Foreign	49,000	35,000
Deferred:		
Federal and state	-	-
Foreign	5,000	(9,000)
Total income tax expense	\$ 145,000	\$ 40,000

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

	<b>Twelve months ended December 31, 2016</b>	<b>Nine months ended December 31, 2015</b>
Statutory federal income tax benefit	\$ (7,462,000)	\$ (2,376,000)
State tax benefit, net of federal taxes	(55,000)	(212,000)
Foreign tax	(39,000)	(18,000)
Nondeductible expenses - debt forgiveness	5,575,000	-
Nondeductible expenses – other	163,000	92,000
Nondeductible expenses – transaction costs	-	55,000
Subpart F Income	51,000	20,000
Valuation allowance increase / (decrease)	(7,334,000)	1,377,000
Stock compensation shortfall	96,000	128,000
Stock compensation true-up & expirations	958,000	83,000
NOL expiration and true-up	8,110,000	320,000
Other	80,000	571,000
<b>Total income tax expense</b>	<b>\$ 143,000</b>	<b>\$ 40,000</b>

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

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Fixed assets	\$ (51,000)	\$ (50,000)
Intangible assets	(3,479,000)	(4,378,000)
Pension liability	76,000	135,000
Stock based compensation	535,000	1,661,000
Inventory	483,000	298,000
Debt discount	-	(1,929,000)
Other reserves and accruals	778,000	437,000
Deferred rent	250,000	250,000
Undistributed foreign earnings	(504,000)	(451,000)
Foreign tax credits	68,000	68,000
Credit carryforwards	72,000	-
Net operating losses	11,230,000	20,812,000
	<b>9,458,000</b>	<b>16,853,000</b>
Less valuation allowance	(9,382,000)	(16,717,000)
	<b>\$ 76,000</b>	<b>\$ 136,000</b>

At December 31, 2016, we had U.S. net operating loss (NOL) carryforwards of approximately \$118.5 million for U.S. income tax purposes before any Section 382 limitations. The NOLs expire in years 2018 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 \$118.5M of NOLs for U.S. income tax purposes, \$88.2M are expected to expire unutilized. The NOLs for tax reporting purposes also include approximately \$1.9 million of income tax deductions in excess of previously recorded tax benefits. Although these additional tax deductions are reflected in NOL carry forwards referenced above, the related tax benefit will not be recognized until the deductions reduce taxes payable. The tax benefit of these excess deductions will be reflected as a credit to additional paid-in-capital when and if recognized. Of the \$118.5M of NOLs for U.S. income tax purposes, \$30.3M 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 that taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such deferred tax assets in the accompanying consolidated financial statements. The deferred tax asset decreased by approximately \$7,395,000 in the 12 months ending December 31, 2016, and increased by approximately \$1,313,000 in the 9 months ending December 31, 2015. The valuation allowance decreased by approximately \$9,382,000 in the 12 months ending December 31, 2016, and increased by approximately \$1,377,000 in 9 months ending December 31, 2015.

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, 2016 and 2015, 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, 2016 and 2015 for the undistributed earnings from our non-U.S. subsidiaries.

The tax years ending March 31, 2014 through December 31, 2016 remain open to examination by the Internal Revenue Service and various state taxing jurisdictions to which we are subject. In addition, we are subject to examination by UK and Netherlands taxing authorities for which the fiscal years 2010 - 2015 and 2011-2015, respectively remain open for examination.

**Note 9: 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.

For financial reporting purposes, we report one operating segment as our Chief Operating Decision Maker utilizes financial statement information provided to him on a consolidated basis.

Information regarding geographic area net sales to customers for the twelve months ended December 31, 2016 and the nine-month transition period ended December 31, 2015, is approximately as follows:

	<u>United States</u>	<u>All Other Foreign Countries (1)</u>	<u>Consolidated</u>
<b>Twelve months ended December 31, 2016</b>	\$ 39,513,000	\$ 12,339,000	\$ 51,852,000
<b>Nine-month transition period ended December 31, 2015</b>	\$ 27,236,000	\$ 9,386,000	\$ 36,622,000

(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, 2016 and December 31, 2015 is approximately as follows:

	<u>United States</u>	<u>United Kingdom/ The Netherlands</u>	<u>Consolidated</u>
<b>December 31, 2016</b>	\$ 1,676,000	\$ 439,000	\$ 2,115,000
<b>December 31, 2015</b>	\$ 2,089,000	\$ 466,000	\$ 2,555,000

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.

**COGENTIX MEDICAL, INC.**  
**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K**

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
*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)
3.1	(a) Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K for the fiscal year ended March 31, 2001 (File No. 000-20970)
	(b) Certificate of Amendment to Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K for the fiscal year ended March 31, 2001 (File No. 000-20970)
	(c) Certificate of Amendment to Certificate of Incorporation.	Incorporated by reference to Exhibit 99.2 to Current Report on Form 8-K as filed with the SEC on December 15, 2010 (File No. 000-20970)
	(d) Certificate of Amendment to Certificate of Incorporation.	Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K as filed with the SEC on August 1, 2014 (File No. 000-20970)
	(e) Certificate of Amendment to Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K as filed with the SEC on March 31, 2015 (File No. 000-20970)
	(f) Certificate of Amendment to Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K as filed with the SEC on March 31, 2015 (File No. 000-20970)
<a href="#">3.2</a>	Amended and Restated By-laws.	Filed herewith
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)



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<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
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)
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)

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<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
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)
<a href="#">10.20</a>	Fifth Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of December 12, 2014.	Filed herewith
<a href="#">10.21</a>	Sixth Amendment to Lease between Vision-Sciences, Inc. and 30 Ramland Road, LLC dated as of January 6, 2017.	Filed herewith
**10.22	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)
**10.23	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)
**10.24	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)
**10.25	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)
**10.26	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)
10.27	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)
10.28	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)
10.29	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)
**10.30	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)
**10.31	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)

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<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
**10.32	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)
**10.33	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)
**10.34	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)
**10.35	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)
**10.36	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)
**10.37	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)
**10.38	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)
**10.39	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)
**10.40	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)
**10.41	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)
** <a href="#">10.42</a>	Consulting Agreement dated March 2, 2017 between Cogentix Medical, Inc. and Howard I. Zauberman.	Filed herewith
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)

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<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
<a href="#">21.1</a>	Subsidiaries of Cogentix Medical, Inc.	Filed herewith
<a href="#">23.1</a>	Consent of Grant Thornton LLP, independent registered public accounting firm.	Filed herewith
<a href="#">31.1</a>	Certification by the PEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
<a href="#">31.2</a>	Certification by the PFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
<a href="#">32.1</a>	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
<a href="#">32.2</a>	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 ***

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\* 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.

## AMENDED AND RESTATED BY-LAWS

OF

COGENTIX MEDICAL, INC., AS AMENDED ON SEPTEMBER 12, 2016

ARTICLE 1 – Stockholders

1.1 Place of Meetings. All meetings of stockholders shall be held at such place within or without the State of Delaware as may be designated from time to time by the Board of Directors or the President or, if not so designated, at the registered office of the corporation.

1.2 Annual Meeting. The annual meeting of stockholders for the election of directors and for the transaction of such other business as may properly be brought before the meeting shall be held on a date to be fixed by the Board of Directors or the President (which date shall not be a legal holiday in the place where the meeting is to be held) at the time and place to be fixed by the Board of Directors or the President and stated in the notice of the meeting. If no annual meeting is held in accordance with the foregoing provisions, the Board of Directors shall cause the meeting to be held as soon thereafter as convenient. If no annual meeting is held in accordance with the foregoing provisions, a special meeting may be held in lieu of the annual meeting, and any action taken at that special meeting shall have the same effect as if it had been taken at the annual meeting, and in such case all references in these By-Laws to the annual meeting of the stockholders shall be deemed to refer to such special meeting.

1.3 Special Meetings. Special meetings of stockholders may be called at any time by the President or by the Board of Directors. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

1.4 Notice of Meetings. Except as otherwise provided by law, written notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. The notices of all meetings shall state the place, date and hour of the meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the corporation.

1.5 Voting List. The officer who has charge of the stock ledger of the corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting, at a place within the city where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time of the meeting, and may be inspected by any stockholder who is present.

1.6 Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these By-Laws, the holders of one-third (1/3<sup>rd</sup>) of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business.

1.7 Adjournments. Any meeting of stockholders may be adjourned to any other time and to any other place at which a meeting of stockholders may be held under these By-Laws by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum, or, if no stockholder is present, by any officer entitled to preside at or to act as Secretary of such meeting. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place of the adjourned meeting are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting.

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1.8 Voting and Proxies. Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided in the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders, or to express consent or dissent to corporate action in writing without a meeting, may vote or express such consent or dissent in person or may authorize another person or persons to vote or act for him by proxy authorized by an instrument in writing, by a transmission or another method permitted by law and in accordance with the procedures established for the meeting. A copy, facsimile telecommunication or other reliable reproduction of the writing, transmission or telecommunication created pursuant to this section may be substituted or used in lieu of the original writing, the transmission or telecommunication that could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing, transmission or telecommunication. No such proxy shall be voted or acted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.

1.9 Action at Meeting. When a quorum is present at any meeting, the holders of a majority of the stock present or represented and voting on a matter (or if there are two or more classes of stock entitled to vote as separate classes, then in the case of each such class, the holders of a majority of the stock of that class present or represented and voting on a matter) shall decide any matter to be voted upon by the stockholders at such meeting, except when a different vote is required by express provision of law, the Certificate of Incorporation or these By-Laws. Any election by stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote at the election.

1.10 Action without Meeting. Until the closing of a firm commitment underwritten public offering of the corporation's common stock (a "Public Offering"), any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of stock entitled to vote thereon were present and voted. Prompt notice of the taking of stockholder action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing. Effective upon the closing of a Public Offering, any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed by the holders of all of the outstanding shares of stock that would be entitled to vote thereon at a meeting of stockholders. Notwithstanding any other provisions of law, the Certificate of Incorporation or the By-laws of the corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes which all of the stockholders would be entitled to cast at an annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Section 1.10.

1.11 Nature of Business at Meetings of Stockholders. No business may be transacted at an annual meeting of stockholders, other than business that is either (a) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors (or any duly authorized committee thereof), (b) otherwise properly brought before the annual meeting by or at the direction of the Board of Directors (or any duly authorized committee thereof) or (c) otherwise properly brought before the annual meeting by any stockholder of the corporation (i) who is a stockholder of record on the date designated by the Board of Directors for purposes of determining the stockholders who will be entitled to vote at such annual meeting of stockholders and on the date of such stockholder's giving of the notice to this corporation as provided for in this Section 1.11 and (ii) who complies with the notice procedures set forth in this Section 1.11.

In addition to any other applicable requirements, for business to be properly brought before an annual meeting by a stockholder, such stockholder must have given timely notice thereof in proper written form to the Secretary of the corporation. For such notice to be timely, a stockholder's notice to the Secretary must be delivered to and received at the principal executive offices of the corporation not less than sixty (60) days prior to the anniversary date of the immediately preceding annual meeting of stockholders; provided, however, that in the event that the annual meeting is called for a date that is not within thirty (30) days before or after such anniversary date, notice by the stockholder, in order to be timely, must be so received not later than ten (10) calendar days before the date of the annual meeting; provided, further, that for the sole purpose of determining the timeliness of a stockholder's notice, if any, under this Section 1.11 notwithstanding Article 1, Section 1.4 hereof, the corporation's written notice of such annual meeting of stockholders shall have been given not less than twenty (20) days before the date of the annual meeting to each stockholder entitled to vote at the meeting.

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To be in proper written form, a stockholder's notice to the Secretary must set forth as to each matter such stockholder proposes to bring before the annual meeting (i) a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (ii) the name and record address of such stockholder, (iii) the class or series and number of shares of capital stock of the corporation which are owned beneficially or of record by such stockholder, (iv) a description of all arrangements or understandings between such stockholder and any other person or persons (including their names) in connection with the proposal of such business by such stockholder and any material interest of such stockholder in such business and (v) a representation that such stockholder intends to appear in person or by proxy at the annual meeting to bring such business before the meeting.

No business shall be conducted at the annual meeting of stockholders except business brought before the annual meeting in accordance with the procedures set forth in this Section 1.11; provided, however, that, once business has been properly brought before the annual meeting in accordance with such procedures, nothing in this Section 1.11 shall be deemed to preclude discussion by any stockholder of any such business. If the Chairman of an annual meeting determines that business was not properly brought before the annual meeting in accordance with the foregoing procedures, the Chairman shall declare to the meeting that the business was not properly brought before the meeting and such business shall not be transacted.

## ARTICLE 2 – Directors

2.1 General Powers. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation. In the event of a vacancy in the Board of Directors, the remaining directors, except as otherwise provided by law, may exercise the powers of the full Board until the vacancy is filled.

2.2 Number of Directors. The number of directors of the corporation shall not be less than three. The exact number of directors within the limitations specified in the preceding sentence shall be fixed from time to time pursuant to a resolution adopted by the Board of Directors.

2.3 Classes of Directors. The Board of Directors shall be and is divided into three classes: Class I, Class II and Class III. No one class shall have more than one director more than any other class. If a fraction is contained in the quotient arrived at by dividing the designated number of directors by three, then, if such fraction is one-third, the extra director shall be a member of Class I, and if such fraction is two-thirds, one of the extra directors shall be a member of Class I and one of the extra directors shall be a member of Class II, unless otherwise provided from time to time by resolution adopted by the Board of Directors.

2.4 Election of Directors. Elections of directors need not be by written ballot except as and to the extent provided in the By-laws of the corporation.

2.5 Terms of Office. Each director shall serve for a term ending on the date of the third annual meeting following the annual meeting at which such director was elected; provided, that each initial director in Class I shall serve for a term ending on the date of the annual meeting following the end of the corporation's fiscal year ending March 31, 1992; and each initial director in Class II shall serve for a term ending on the date of the annual meeting next following the end of the corporation's fiscal year ending March 31, 1993; and provided further, that the term of each director shall continue until the election and qualification of his/her successor and shall be subject to his/her earlier death, resignation or removal.

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2.6 Allocation of Directors among Classes in the Event of Increases or Decreases in the Number of Directors. In the event of any increase or decrease in the authorized number of directors, (i) each director then serving as such shall nevertheless continue as a director of the class of which he/she is a member and (ii) the newly created or eliminated directorships resulting from such increase or decrease shall be apportioned by the Board of Directors among the three classes of directors so as to ensure that no one class has more than one director more than any other class.

2.7 Quorum; Action at Meeting. A majority of the directors at any time in office shall constitute a quorum for the transaction of business. In the event one or more of the directors shall be disqualified to vote at any meeting, then the required quorum shall be reduced by one for each such director so disqualified, provided that in no case shall less than one-third of the number of directors fixed pursuant to Section 2.2 above constitute a quorum. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of those present may adjourn the meeting from time to time. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law, by the By-laws of the corporation or by this Certificate of Incorporation.

2.8 Removal. If and for so long as the Board of Directors is classified pursuant to Section 141(d) of the Delaware General Corporation Law, stockholders may effect the removal of a director or the entire Board of Directors only for cause, unless this Certificate of Incorporation otherwise provides.

2.9 Vacancies. Unless and until filled by the stockholders, any vacancy in the Board of Directors, however occurring, including a vacancy resulting from an enlargement of the Board, may be filled by a vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director. A director elected to fill a vacancy shall be elected to hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of his/her successor and to his/her earlier death, resignation or removal.

2.10 Resignation. Any director may resign by delivering his written resignation to the corporation at its principal office or to the President or Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

2.11 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place, either within or without the State of Delaware, as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.

2.12 Special Meetings. Special meetings of the Board of Directors may be held at any time and place, within or without the State of Delaware, designated in a call by the Chairman of the Board, President, two or more directors, or by one director in the event that there is only a single director in office.

2.13 Notice of Special Meetings. Notice of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (i) by giving notice to such director in person or by telephone at least 48 hours in advance of the meeting, (ii) by sending a telegram or telex, or delivering written notice by hand, to his last known business or home address at least 48 hours in advance of the meeting, or (iii) by mailing written notice to his last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

2.14 Meetings by Telephone Conference Calls. Directors or any members of any committee designated by the directors may participate in a meeting of the Board of Directors or such committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.

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2.15 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee of the Board of Directors may be taken without a meeting, if all members of the Board or committee, as the case may be, consent to the action in writing, and the written consents are filed with the minutes of proceedings of the Board or committee.

2.16 Committees. The Board of Directors may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of one or more of the directors of the corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of the General Corporation Law of the State of Delaware, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these By-Laws for the Board of Directors.

2.17 Compensation of Directors. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary corporations in any other capacity and receiving compensation for such service.

2.18 Amendments. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes which all of the stockholders would be entitled to cast at an annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article II.

### ARTICLE 3 – Officers

3.1 Enumeration. The officers of the corporation shall consist of a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, including a Chairman of the Board, a Vice-Chairman of the Board, and one or more Vice Presidents, Assistant Treasurers, and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.

3.2 Election. The President, Treasurer and Secretary shall be elected annually by the Board of Directors at its first meeting following the annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.

3.3 Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.

3.4 Tenure. Except as otherwise provided by law, by the Certificate of Incorporation or by these By-Laws, each officer shall hold office until his successor is elected and qualified, unless a different term is specified in the vote choosing or appointing him, or until his earlier death, resignation or removal.

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3.5 Resignation and Removal. Any officer may resign by delivering his written resignation to the corporation at its principal office or to the President or Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

Any officer may be removed at any time, with or without cause, by vote of a majority of the entire number of directors then in office.

Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following his resignation or removal, or any right to damages on account of such removal, whether his compensation be by the month or by the year or otherwise, unless such compensation is expressly provided in a duly authorized written agreement with the corporation.

3.6 Vacancies. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of President, Treasurer and Secretary. Each such successor shall hold office for the unexpired term of his predecessor and until his successor is elected and qualified, or until his earlier death, resignation or removal.

3.7 Chairman of the Board and Vice-Chairman of the Board. The Board of Directors may appoint a Chairman of the Board and may designate the Chairman of the Board as Chief Executive Officer. If the Board of Directors appoints a Chairman of the Board, he shall perform such duties and possess such powers as are assigned to him by the Board of Directors. If the Board of Directors appoints a Vice-Chairman of the Board, he shall, in the absence or disability of the Chairman of the Board, perform the duties and exercise the powers of the Chairman of the Board and shall perform such other duties and possess such other powers as may from time to time be vested in him by the Board of Directors.

3.8 President. The President shall, subject to the direction of the Board of Directors, have general charge and supervision of the business of the corporation. Unless otherwise provided by the Board of Directors, he shall preside at all meetings of the stockholders, if he is a director, at all meetings of the Board of Directors. Unless the Board of Directors has designated the Chairman of the Board or another officer as Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The President shall perform such other duties and shall have such other powers as the Board of Directors may from time to time prescribe.

3.9 Vice Presidents. Any Vice President shall perform such duties and possess such powers as the Board of Directors or the President may from time to time prescribe. In the event of the absence, inability or refusal to act of the President, the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the President and when so performing shall have all the powers of and be subject to all the restrictions upon the President. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

3.10 Secretary and Assistant Secretaries. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the President may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the President or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary, (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

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In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the person presiding at the meeting shall designate a temporary secretary to keep a record of the meeting.

3.11 Treasurer and Assistant Treasurers. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned to him by the Board of Directors or the President. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these By-Laws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the President or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer, (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

3.12 Salaries. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.

#### ARTICLE 4 – Capital Stock

4.1 Issuance of Stock. Unless otherwise voted by the stockholders and subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any unissued balance of the authorized capital stock of the corporation held in its treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such consideration and on such terms as the Board of Directors may determine.

4.2 Certificates of Stock. Every holder of stock of the corporation shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, certifying the number and class of shares owned by him in the corporation. Each such certificate shall be signed by, or in the name of the corporation by, the Chairman or Vice-Chairman, if any, of the Board of Directors, or the President or a Vice-President, and the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary of the corporation. Any or all of the signatures on the certificate may be a facsimile.

Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, the By-Laws, applicable securities laws or any agreement among any number of shareholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

4.3 Transfers. Except as otherwise established by rules and regulations adopted by the Board of Directors, and subject to applicable law, shares of stock may be transferred on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney Properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these By - Laws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such Stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these By - Laws.

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4.4 Lost, Stolen or Destroyed Certificates. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen, or destroyed, upon such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.

4.5 Record Date. The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders or to express consent (or dissent) to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action to which such record date relates.

If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. The record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, when no prior action by the Board of Directors is necessary, shall be the day on which the first written consent is expressed. The record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

#### ARTICLE 5 – General Provisions

5.1 Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of April in each year and end on the last day of March in each year.

5.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.

5.3 Waiver of Notice. Whenever any notice whatsoever is required to be given by law, by the Certificate of Incorporation or by these By - Laws, a waiver of such notice either in writing signed by the person entitled to such notice or such person's duly authorized attorney, or by telegraph, cable or any other available method, whether before, at or after the time stated in such waiver, or the appearance of such person or persons at such meeting in person or by proxy, shall be deemed equivalent to such notice.

5.4 Voting of Securities. Except as the directors may otherwise designate, the President or Treasurer may waive notice of, and act as, or appoint any person or persons to act as, proxy or attorney - in - fact for this corporation (with or without power of substitution) at, any meeting of stockholders or shareholders of any other corporation or organization, the securities of which may be held by this corporation.

5.5 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.

5.6 Certificate of Incorporation. All references in these By - Laws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as amended and in effect from time to time.

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5.7 Transactions with Interested Parties. No contract or transaction between the corporation and one or more of the directors or officers, or between the corporation and any other corporation, partnership, association, or other organization in which one or more of the directors or officers are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board of Directors or a committee of the Board of Directors which authorizes the contract or transaction or solely because his or their votes are counted for such purpose, if:

(1) The material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum;

(2) The material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the Stockholders; or

(3) The contract or transaction is fair as to the corporation as of the time it is authorized, approved or ratified, by the Board of Directors, a committee of the Board of Directors, or the Stockholders.

Common or interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee which authorizes the contract or transaction.

5.8 Severability. Any determination that any provision of these By - Laws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these By - Laws.

5.9 Pronouns. All pronouns used in these By - Laws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

#### ARTICLE 6 – Amendments

6.1 By the Board of Directors. These By - Laws may be altered, amended or repealed or new by-laws may be adopted by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present.

6.2 By the Stockholders. These By-Laws may be altered, amended or repealed or new by-laws may be adopted by the affirmative vote of the holders of a majority of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at any regular meeting of stockholders, or at any special meeting of stockholders, provided notice of such alteration, amendment, repeal or adoption of new by-laws shall have been stated in the notice of such special meeting.

As Amended by the Board of Directors  
September 12, 2016

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THIS FIFTH AMENDMENT TO LEASE dated as of December 12, 2014, made by and between 30 RAMLAND ROAD, LLC, having an office in care of GHP Office Realty, LLC, Four West Red Oak Lane, White Plains, New York 10604, as "Landlord," and VISION-SCIENCES, INC, having an office at 40 Ramland Road, Orangeburg, New York 10962, as "Tenant."

WITNESSETH

WHEREAS, Landlord is the Landlord of the real property and building located thereon commonly known as and located at 40 Ramland Road, Orangeburg, New York 10962 (the "Building");

WHEREAS, pursuant to that certain Agreement of Lease, dated as of March 23, 2000 (the "Original Lease"), as amended by amendments dated August 31, 2000, January 7, 2005, December 26, 2006 and April 2, 2009 (hereinafter referred to collectively as the "Lease"), Landlord leased to Tenant a portion of the First (1st) floor of the Building which shall be deemed to consist of Twenty Thousand, Five Hundred (20,500) rentable square feet and which premises are more particularly described in the Lease (the "Premises"), for a period ending on August 31, 2015;

WHEREAS, Tenant wants to extend the term of the Lease (the "Additional Term") for an additional Two (2) years commencing on September 1, 2015 (the "Additional Term Commencement Date") and expiring on August 31, 2017 (the "Expiration Date");

ARTICLE-1  
LEASE AMENDMENTS

SECTION 1.01. Effective as of September 1, 2015, the Lease is hereby modified as follows:

A. The "Term" as set forth in the Lease shall mean two (2) years as extended by this Fifth Amendment to Lease and expiring on the Expiration Date which is August 31, 2017.

B. The Lease is hereby amended to delete any obligation of Landlord to perform or pay for alterations or work to the Premises in preparation for Tenant's continued occupancy, except for the repairs listed on Exhibit A hereto, which Landlord shall perform prior to the Additional Term Commencement Date.

ARTICLE - 2 MISCELLANEOUS

SECTION 2.01. Tenant represents that in connection with this Fifth Amendment to Lease it dealt with no broker, nor has Tenant had any correspondence or other communication in connection with this Fifth Amendment to Lease with any other person who is a broker other than Cushman & Wakefield of NJ (the "Brokers"), and that so far as Tenant is aware no brokers other than the Broker negotiated this Fifth Amendment to Lease. Each party hereby indemnifies the other party and holds it harmless from any and all loss, cost, liability, claim, damage, or expense (including court costs and attorneys' fees) ("Claims") arising out of any inaccuracy of the above representation. Landlord agrees to pay the Brokers their commissions pursuant to a separate written agreement with the Brokers, and to indemnify Tenant pursuant to the preceding sentence from and against any Claims by the Brokers for any commissions.

SECTION 2.02. Tenant represents that: (i) Landlord is not in default of any of its obligations under the Lease; (ii) Tenant has no claims against Landlord as of the date of this Fifth Amendment to Lease; and (iii) Tenant is in possession of the Premises. Landlord acknowledges that Tenant is not in default of any of its obligations under the Lease and Landlord has no claims against Tenant as of the date of this Fifth Amendment to Lease.

**SECTION 2.03.** All other terms, covenants and conditions of the Lease, as amended, including, but not limited to, the obligation to pay, in addition to Fixed Rent, the Tax Payments, Expense Payments, electric and all other additional rent items, and all exhibits and schedules thereto shall remain in full force and effect, are hereby ratified, confirmed and incorporated herein by reference as though set forth fully herein at length.

IN WITNESS WHEREOF, Landlord and Tenant have executed this FIFTH AMENDMENT TO LEASE as of the date and year first above written.

**30 RAMLAND ROAD, LLC, (Landlord)**

By: /s/Andrew Greenspan

Name: Andrew Greenspan

Title: Member/Manager

**VISION-SCIENCES, INC, (Tenant)**

By: /s/Howard Zauberman

Name: Howard Zauberman

Title: CEO

## EXHIBIT A

### Landlord's Repairs

**Tenant Improvements:** Landlord, at its sole cost and expense, shall provide a turn-key installation based on the following necessary improvements and repairs:

#### Reception

- Repave entire front parking lot in order to alleviate drainage issues
- Reseal side parking lot adjacent to loading dock
- Restripe parking lot
- Provide additional lighting in the parking area.
- Replace poor fitting and damaged window screens on front of building Reception
- Clean grout and reseal ceramic floor in reception area HVAC
- Rezone and/or Rebalance existing ductwork between office and manufacturing area Kitchen/Pantry
- Provide new laminate cabinets and countertops, paint walls and replace broken tile Corridors
- Provide new vinyl base in corridors Bathrooms
- Provide two wall-hung sinks in men's bathroom (in the men's bathroom which currently only has a single sink)
- Address pressure issue in all of the men's urinals
- Provide no-touch faucets for existing toilets, urinals and sinks Electrical testing area
- Remove 40 linear feet of walls built to underside of ceiling in electrical testing area
- Lower ceiling by 8 inches in former lab area adjacent to electrical testing area
- Replace broken and/or damaged ceiling tiles in general manufacturing area (approximately 60% of the existing ceiling tiles need to be replaced)



**THIS SIXTH AMENDMENT TO LEASE** dated as of January 6, 2017, made by and between **30 RAMLAND ROAD, LLC** , having an office in care of GHP Office Realty, LLC, Four West Red Oak Lane, White Plains, New York 10604, as “ Landlord,” and **CONGENTIX MEDICAL INC. f/k/a Vision Sciences, Inc.**, having an office at 40 Ramland Road, Orangeburg, New York 10962, as “ Tenant.”

**WITNESSETH**

**WHEREAS**, Landlord is the Landlord of the real property and building located thereon commonly known as and located at 40 Ramland Road, Orangeburg, New York 10962 (the “ Building”);

**WHEREAS** , pursuant to that certain Agreement of Lease, dated as of March 23, 2000 (the “ Original Lease ”), as amended by amendments dated August 31, 2000, January 7, 2005, December 26, 2006, April 2, 2009 and December 12, 2014 (hereinafter referred to collectively as the “ Lease ”), Landlord’s predecessor in interest leased to Tenant a portion of the First (1<sup>st</sup>) floor of the Building which shall be deemed to consist of Twenty Thousand, Five Hundred (20,500) rentable square feet and which premises are more particularly described in the Lease (the “ Premises ”), for a period ending on August 31, 2017;

**WHEREAS** , Tenant wants to extend the term of the Lease (the “ Additional Term ”) for an additional Eighteen (18) months commencing on September 1, 2017 (the “ Additional Term Commencement Date ”) and expiring on February 28, 2019 (the “ Expiration Date ”), unless sooner terminated pursuant to the terms of this Lease or pursuant to law , upon the same terms and conditions as contained in the Lease, except as otherwise specifically provided for herein, and Landlord and Tenant want to extend and modify the Lease, as hereinafter provided;

**NOW, THEREFORE** , in consideration of the mutual agreements of the parties hereinafter contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is hereby agreed as follows:

**ARTICLE- 1 ADDITIONAL TERM**

SECTION 1.01. A. Landlord hereby leases to Tenant and Tenant hereby hires from Landlord the Premises for the Additional Term. The parties hereto acknowledge that Tenant presently occupies the Premises and knows the condition thereof. Except as otherwise specifically provided for in this Sixth Amendment to Lease, Landlord shall have no obligation whatsoever to perform any build-out or similar work to the Premises, and Tenant agrees to accept same in “AS IS” physical order and condition on the Additional Term Commencement Date and without any representation or warranty, express or implied, in fact or by law, by Landlord, and without recourse to Landlord, as to title thereto, the nature, square footage, condition or usability thereof or as to the use or occupancy which may be made thereof.

**ARTICLE - 2 LEASE AMENDMENTS**

SECTION 2.01. Effective as of the date of the Additional Term Commencement Date, the Lease is hereby modified as follows:

A. The “Term” as set forth in the Lease shall mean the Additional Term as defined in this Sixth Amendment to Lease.

B. The Lease is amended to provide that Fixed Annual Rent payable during the Additional Term shall be as follows:

Period	Fixed Annual Rent	Fixed Monthly Rent
September 1, 2017 to February 28, 2019 (both dates inclusive)	\$ 355,468.13	\$ 29,622.34

C. The Lease is hereby amended to delete any obligation of Landlord to perform or pay for alterations or work to the Premises in preparation for Tenant's continued occupancy.

#### **ARTICLE - 3 CONFIDENTIALITY**

SECTION 3.01.A. In anticipation of executing and delivering this Sixth Amendment to Lease, Tenant hereby agrees to keep the rent, additional rent and all other material terms of the Lease, as amended by this Sixth Amendment to Lease (hereinafter such information is referred to collectively as the "Confidential Information") secret and confidential and will not disclose it, directly or indirectly, to any other person, firm or entity without the specific written approval and consent of Landlord, except to the extent required by law.

B. The agreement to keep the Confidential Information secret and confidential pursuant to this Section shall be for a period of one (1) year succeeding the expiration or sooner termination of the Lease and shall apply to each, every and all communications, negotiations and conversations between Tenant and any other person, entity or thing.

C. Tenant acknowledges that breach of this Article will cause irreparable damage to Landlord and hereby consents to the issuance of an injunction restraining such breach as a matter of course in any action instituted for that purpose without limitation to any additional remedies Landlord may seek against Tenant to protect such Confidential Information.

#### **ARTICLE - 4 MISCELLANEOUS**

SECTION 4.01. Tenant represents that in connection with this Sixth Amendment to Lease it dealt with no broker, nor has Tenant had any correspondence or other communication in connection with this Sixth Amendment to Lease with any other person who is a broker other than GHP Office Realty, LLC (the "Broker"), and that so far as Tenant is aware no brokers other than the Broker negotiated this Sixth Amendment to Lease. Each party hereby indemnifies the other party and holds it harmless from any and all loss, cost, liability, claim, damage, or expense (including court costs and attorneys' fees) arising out of any inaccuracy of the above representation. Landlord agrees to pay the Brokers their commissions pursuant to a separate written agreement with the Brokers.

SECTION 4.02.A. Tenant represents that: (i) Landlord is not in default of any of its obligations under the Lease; (ii) Tenant has no claims against Landlord as of the date of this Sixth Amendment to Lease; and (iii) Tenant is in possession of the Premises.

B. Tenant represents and warrants that Tenant is not now acting and shall not in the future act, directly or indirectly, for or on behalf of any person, group, entity or nation named by any Executive Order or the United States Department of the Treasury as a terrorist, a Specially Designated and Blocked Persons, or other banned or blocked person, group, entity, nation or transaction pursuant to any law, order, rule or regulation that is enforced or administered by the Office of Foreign Asset Control ( A OFAC) of the United States Department of the Treasury. Tenant further represents and warrants that Tenant is not now engaged and shall not in the future be engaged, directly or indirectly, in any dealings or transactions or otherwise be associated with such person, group, entity or nation; and Tenant hereby agrees to defend, indemnify and hold Owner harmless from and against any and all claims, losses, costs, expenses, damages and liabilities (including, without limitation, attorney fees) arising from or related to any breach of the foregoing representations.

SECTION 4.03. All other terms, covenants and conditions of the Lease, as amended, including, but not limited to, the obligation to pay, in addition to Fixed Rent, the Tax Payments, Expense Payments, electric and all other additional rent items, and all exhibits and schedules thereto shall remain in full force and effect, are hereby ratified, confirmed and incorporated herein by reference as though set forth fully herein at length.

**IN WITNESS WHEREOF** , Landlord and Tenant have executed this SIXTH AMENDMENT TO LEASE as of the date and year first above written.

**30 RAMLAND ROAD, LLC, (Landlord)**

By: /s/Andrew Greenspan

Name: Andrew Greenspan

Title: Member/Manager

**CONGENTIX MEDICAL, INC. f/k/a Vision Sciences,  
Inc., (Tenant)**

By: /s/ Brett Reynolds

Name: Brett Reynolds

Title: SVP and CFO

**CONSULTING AGREEMENT**

This Consulting Agreement (“Consulting Agreement”) is entered into by and between Howard Zauberman (“you”) and Cogentix Medical, Inc., (“Cogentix”), a Delaware corporation with its principal place of business in Minnetonka, Minnesota .

WHEREAS, you have significant experience and knowledge with respect to identifying strategic opportunities for Cogentix’s Industrial and Airway Management business;

WHEREAS, Cogentix believes it would be to its advantage to retain your services on the terms and subject to the conditions set forth herein; and

WHEREAS, based on the foregoing, you and Cogentix desire to enter into this Consulting Agreement to set forth the terms and conditions under which you will serve as an independent contractor providing consulting services to Cogentix in exchange for compensation as outlined below.

NOW, THEREFORE, in consideration of the mutual promises contained in this Consulting Agreement, you and Cogentix agree as follows:

1. **TERM.** This Consulting Agreement will commence on March 2, 2017 and will continue until terminated pursuant to Section 7 herein (the “Term”). The Term is referred to as the “Consulting Period.”
2. **INDEPENDENT CONTRACTOR STATUS.** You will be an independent contractor during the Consulting Period. As an independent contractor, you will be solely responsible for satisfying your obligations to Cogentix and will control the manner in which your services are delivered. You will use your own tools and equipment in providing such services.
3. **SERVICES.** You will provide the following services and deliverables during the Consulting Period:
  - a. Provide services for business development, using criteria that Cogentix provides;
  - b. After 20 hours of service pursuant to this Consulting Agreement, prepare and submit an initial written report to Cogentix; and
  - c. After 40 hours of service pursuant to this Consulting Agreement, or after you have completed your services pursuant to this Consulting Agreement, whichever is earlier, prepare and submit a final report to Cogentix.
4. **COMPENSATION.**
  - a. During the Consulting Period, you will be paid \$250 per hour for your services.

Initials: \_\_\_\_\_

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b. You will prepare bi-weekly invoices of your consulting services to present to Cogentix.

5. **TAXES AND WITHHOLDING**. As an independent contractor, you agree and acknowledge that you will be responsible for paying all applicable federal, state, and local taxes and withholdings. You will be responsible for providing Cogentix with an accurate tax-payer ID number or for completing a Form W-9 upon request.

6. **NO BENEFITS**. As an independent contractor, you agree and acknowledge that you are not entitled to participate in any medical, dental, vision, or other benefits under any of Cogentix's employee benefits plans.

7. **TERMINATION**. You or Cogentix may terminate this Consulting Agreement at any time, for any reason, upon 5 business days' written notice.

8. **OTHER BUSINESS OPPORTUNITIES**. During the Consulting Period, you may enter into agreements with other entities to provide consulting services and to pursue and engage in other business opportunities, provided that such activities do not create a conflict of interest with Cogentix.

9. **WORK MADE FOR HIRE**. All notes, reports, promotional materials, and other work product that you create in performing services pursuant to this Consulting Agreement that are protected by copyright are "works made for hire" for which Cogentix is the "author" (as such terms are defined by the United States Copyright Act of 1976, as amended). Cogentix will exclusively own the copyright in all such works upon their creation. To the extent that any aspect of such work product is found as a matter of law to not be a "work made for hire" as contemplated above, you hereby irrevocably and unconditionally assign to Cogentix all right, title, and interest worldwide in and to such work product and all intellectual property rights thereto. You further agree that Cogentix is and will remain the exclusive owner of all Proprietary Documents (as defined below), whether created by you, Cogentix, or either or both in conjunction with any third party. "Proprietary Documents" include all documents, acquired at the expense of Cogentix, or through the labor of Cogentix's employees, including forms, informational summaries, memoranda, notes, buyer information, documents, or other writings that you make, compile, acquire, or receive during the Term.

10. **CONFIDENTIALITY**. You agree to respect all confidences of Cogentix and to not, directly or indirectly, divulge any Confidential Information (as defined below) or trade secrets to any unauthorized person within Cogentix, or to any individual outside of Cogentix, without the express permission of an officer of Cogentix. You further agree to cooperate in all efforts to see that the confidentiality of the information with which you deal, and to which you have access, will be maintained. "Confidential Information" is any information that you acquire in the course and scope of providing services for Cogentix that (a) should reasonably be understood as confidential from the nature of the information and/or circumstances under which it is disclosed or (b) that Cogentix identifies as "confidential," either verbally or in writing. "Confidential Information" also means any notes, analyses, compilations, studies, interpretations, memoranda, or other documents that you or Cogentix prepare that contain, reflect, or are based upon, in whole or in part, Confidential Information.

Initials: \_\_\_\_\_

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11. **CONTROLLING LAW**. This Consulting Agreement will be governed by and interpreted in accordance with the laws of the State of Minnesota, without regard to choice of law provisions. To the extent that any clause or provision of this Consulting Agreement is determined to be invalid or unenforceable, such clause or provision will be deleted, and the validity and enforceability of the remainder of this Consulting Agreement will be unaffected.

12. **VENUE**. The venue for any action arising out of or relating to this Consulting Agreement will be exclusively in the State of Minnesota. You and Cogentix consent to the exclusive jurisdiction of the courts of the State of Minnesota, County of Hennepin, and the United States District Court for the District of Minnesota.

13. **NON-ASSIGNABILITY**. You understand and agree that this Consulting Agreement is personal to you. You may not assign or delegate the duties, rights, or obligations set forth herein to any other person without Cogentix's prior written consent.

14. **SURVIVAL**. The provisions of Sections 5, 6, 9, 10, 11 and 12 shall survive the Term.

15. **ENTIRE AGREEMENT**. This Consulting Agreement contains all understandings and agreements between you and Cogentix regarding the subject of this Consulting Agreement. This Consulting Agreement supersedes and replaces any prior correspondence or documents evidencing negotiations between you and Cogentix, whether written or oral, and any and all understandings, agreements or representations by or among you and Cogentix, whether written or oral, that may have related in any way to the subject matter of this Consulting Agreement. Any change or addition to this Consulting Agreement must be in writing and signed by both you and Cogentix .

16. **REPRESENTATION**. You agree and acknowledge that you have received and read this Consulting Agreement, that the provisions of this Consulting Agreement are understandable to you, and that you fully appreciate and understand the meaning of the terms of this Consulting Agreement and their effect. You agree that no promise or inducement has been offered to you, except as set forth in this Consulting Agreement, and that you are signing this Consulting Agreement without reliance upon any statement or representation by Cogentix or any representative or agent of Cogentix, except as set forth in this Consulting Agreement. You agree and acknowledge that you have entered into this Consulting Agreement freely and voluntarily .

[ signature page follows ]

Initials: \_\_\_\_\_

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IN WITNESS WHEREOF, the parties have executed this Consulting Agreement by their signatures below.

Dated: March 2, 2017

/s/ Howard Zauberman

Howard Zauberman

Dated: March 2, 2017

Cogentix Medical, Inc.

By /s/ Brett Reynolds

Its SVP and CFO

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**SUBSIDIARIES OF COGENTIX MEDICAL, INC.**  
December 31, 2016

<b><u>Subsidiary</u></b>	<b><u>State or Other Jurisdiction of Incorporation</u></b>
Machida Incorporated	Delaware
Uroplasty, LLC	Delaware
Uroplasty BV	The Netherlands
Uroplasty Ltd.	United Kingdom

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Consent of Independent Registered Public Accounting Firm

We have issued our report dated March 30, 2017, with respect to the consolidated financial statements and schedule included in the Annual Report of Cogentix Medical, Inc. and subsidiaries on Form 10-K for the year ended December 31, 2016. We consent to the incorporation by reference of said report in the Registration Statement of Cogentix Medical, Inc. on Form S-8 (File No. 333-203135).

/s/ Grant Thornton LLP

Minneapolis, Minnesota  
March 30, 2017

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**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, 2016 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, 2017

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

**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, 2016 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, 2017

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

**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, 2016 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, 2017

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

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**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, 2016 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, 2017

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

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