FORM 10-K

Apollo Endosurgery, Inc. - APEN

Filed: March 24, 2017 (period: December 31, 2016)

Annual report with a comprehensive overview of the company

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

FORM 10-K

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

For the fiscal year ended December 31, 2016

OR

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

For the transition period from to

Commission file number: 001-35706

APOLLO ENDOSURGERY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**16-1630142**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1120 S. Capital of Texas Highway, Building 1, Suite #300, Austin, Texas	**78746**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number **(512) 279-5100**

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

Title of each class	Name of Exchange on which registered
Common Stock, $0.001 par value per share	The NASDAQ Global Market

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 15(d) of the Exchange Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed based on the adjusted close price of $2.18 as reported on the NASDAQ Stock Market on June 30, 2016 is $938,669. For purposes of this calculation, shares of common stock held by each officer and director and by each person or group who owns 5% or more of the outstanding common stock have been excluded from the calculation of aggregate market value as such persons or groups may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2017, there were 10,695,711 shares of the issuer's $.001 par value common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K. The Definitive Proxy Statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2016.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks, uncertainties and other important factors. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section entitled "Risk Factors" under Part I, Item 1A below. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

As used herein, "Apollo," "we," "us," "our" and "Company" refer to Apollo Endosurgery, Inc., unless the context otherwise requires.

In this Annual Report on Form 10-K, references to U.S. dollars or USD or $ are to United States Dollars.

PART I

ITEM 1. BUSINESS

Overview

We are a medical technology company primarily focused on the design, development and commercialization of innovative medical devices that can be used for the treatment of obesity.

We are one of the market share leaders in less invasive devices that treat obesity. Our products are used by general surgeons, bariatric surgeons and gastroenterologists in a variety of settings to provide interventional therapy to patients who suffer from obesity and the many co-morbidities associated with obesity.

We believe that obesity is a chronic disease and that the optimal clinical outcome for a substantial portion of patients suffering from obesity will require interventional treatments combined with ongoing, long-term physician care. As a result, our product portfolio consists of surgical and non-surgical interventional devices that fill the gap between low efficacy pharmacological treatments for obesity and highly-invasive, anatomy-altering bariatric stapling procedures. Some of our products are also used in procedures that address or repair a variety of gastrointestinal ("GI") defects.

Our strategic focus and the majority of our future revenue growth is expected to come from our Endo-bariatric product portfolio, which consists of the Orbera® and OverStitch™ systems. In the past two years, the majority of our product revenues has come from the Apollo Surgical product portfolio, which consists of the Lap-Band® System and related laparoscopic accessories. Revenues from the Surgical product portfolio had been decreasing over the past several years prior to our acquisition of those products and revenues have continued to decline since.

Corporate Background

Apollo was founded in 2005, and is currently incorporated in Delaware with headquarters in Austin, Texas. The Company was founded to develop and commercialize innovations originating from a collaboration of physicians from the Mayo Clinic, Johns Hopkins University, Medical University of South Carolina, the University of Texas Medical Branch and the Chinese University of Hong Kong, who called themselves the Apollo Group. The work of the Apollo Group resulted in a significant portfolio of patents in the field of flexible endoscopy and minimally invasive surgery aimed at minimizing the trauma of surgical access by taking advantage of natural orifices to deliver surgical tools to targeted areas.

On December 2, 2013, we entered into an asset purchase agreement to acquire the obesity intervention division of Allergan, Inc. In conjunction with this purchase agreement, we entered into several agreements whereby Allergan agreed to provide manufacturing and distribution support over a two year period as we established our own manufacturing and worldwide distribution capabilities.

From December 2, 2013, we proceeded to establish capabilities and transfer responsibility for a variety of activities related to the acquired Allergan business. Significant milestones during the transition period include:

- transfer of United States sales force in December 2013;
- transfer of United States distribution in September 2014;
- transfer of Europe, Canada and Australia sales force and distribution in November 2014;
- transfer of most worldwide regulatory activities in December 2014;
- transfer of product surveillance activities in October 2015;
- transfer of Brazilian sales and distribution activities in November 2015; and
- start of Costa Rica manufacturing operations in June 2016.

As a result of these transition activities, we established offices in England, Australia, Italy and Brazil that oversee regional sales and distribution activities outside the United States; a manufacturing facility in Costa Rica; and a device analysis lab in California. All other activities are managed and operated from our facilities in Austin, Texas.

On December 29, 2016, we completed our business combination with Lpath, Inc. ("Lpath"), a publicly traded company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated September 8, 2016 (the "Merger"). Following the Merger, Lpath was renamed "Apollo Endosurgery, Inc." and began trading on The NASDAQ Global Market under the symbol "APEN."

Our principal executive offices are located at 1120 S. Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746. Our telephone number is (512) 279-5100. We have a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees. A copy of this document is published on the Apollo website at www.apolloendo.com and may be obtained free of charge by writing to the Director of Compliance at our principal executive office or by email at *investor-relations@apolloendo.com*. The information in or accessible through the Apollo website referred to above are not incorporated into, and are not considered part of, this report.

Overview of Obesity and the Market

Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have a negative effect on an individual's health. An individual with a body mass index ("BMI") (calculated by dividing a person's weight in kilograms by their height in meters^2) of greater than 30 is generally considered to be obese.

Obesity as a disease is increasing worldwide. In the United States, it is estimated that 56 million adults are obese or clinically obese with a BMI of between 30 and 40. It is further estimated that an additional 12.7 million adults are morbidly obese in the United States, with a BMI greater than 40. Over 600 million people around the world are considered obese.

Obese individuals have an increased incidence rate of various comorbid conditions including heart disease, type 2 diabetes, hypertension, obstructive sleep apnea, high blood pressure, liver disease, infertility and cancer. According to the Center for Disease Control, there are more than 20 obesity-linked diseases and disorders-known as comorbidities. Due to these comorbidities, obesity also adds significant cost to healthcare systems around the world. In the United States, it has been reported that the cost of providing healthcare to a person with a BMI of 40 is up to two times the cost of providing the same level of healthcare to a person with a BMI less than 30.

Traditional obesity intervention has been bariatric surgery (gastric bypass, sleeve gastrectomy and laparoscopic adjustable gastric banding) which today is mostly performed laparoscopically. Bariatric surgery has been clinically demonstrated to produce medically-relevant weight loss and statistically relevant reduction to a patient's comorbid conditions. Medically-relevant weight loss for purposes of comorbid condition improvement is generally recognized as from 5% to 10% of total body weight loss ("TBWL").

Although clinically demonstrated to achieve weight loss and improve comorbid conditions, reported data indicates that U.S. bariatric volumes peaked in 2008 at approximately 220,000 procedures per year and have since declined. Today, based on United States population demographics and reported bariatric procedure volumes, less than 2% of the population eligible for bariatric surgery have a procedure. We believe that the primary detractor from bariatric surgery is patient fear; fear of surgery in general, but more specifically fear associated with the highly-invasive nature of bariatric surgery, permanent anatomical alteration, potential for non-permanent results and the post-operative severe complications that can be associated with bariatric surgery.

Apollo's Strategy

Our objective is to improve today's obesity-related health problem by facilitating less invasive, yet effective, and reversible interventional procedures for obesity through our product offerings. Our "Endo-Bariatrics" products treat obesity with procedures delivered with a flexible endoscope and without traditional surgery. We also offer surgical products, consisting of the Lap-Band and related accessory products that offers long-term weight loss and improvement of co-morbid conditions through a less-invasive, reversible procedure known as laparoscopic adjustable gastric banding ("Gastric Banding").

Our goal is to be a global leader in providing clinically proven, less invasive solutions for cost-effective treatment of chronically obese patients. The key elements of our strategy include:

- ***Support the adoption of our Endo-Bariatric products*** -We intend to continue to conduct medical education activities along with patient education and outreach initiatives. We will continue to provide field sales support and to make selective investments in reimbursement initiatives to support adoption and use of our Endo-Bariatric products.

- ***Continue to deliver innovative products and broaden the product portfolio*** -We intend to broaden our portfolio of products through internal product development efforts, and will consider acquisitions of products or companies that complement our current business.

- ***Expand into new markets*** -We intend to continue to pursue regulatory clearance for our products and improved distribution in key international markets where we believe there is or will be strong market demand for our products.

- ***Stabilize the sales of our Surgical products*** -We intend to continue to service and support our network of surgeon customers who continue to achieve positive outcomes with the Lap-Band and remain dedicated to its use.

Apollo Products

Endo-Bariatrics

The Apollo Endo-Bariatric products consist primarily of the Orbera Intragastric Balloon System and the OverStitch endoscopic suturing system.

Orbera Intragastric Balloon System

The Orbera Intragastric Balloon System is a non-surgical alternative for the treatment of overweight and obese adults. The Orbera System (the "Orbera System" or "Orbera") includes a silicone balloon that is filled with saline after endoscopic transoral placement into the patient's stomach. Once in the patient's stomach, the balloon serves to reduce stomach capacity, causing patients to consume less following the procedure, and delay gastric emptying, the primary mechanisms of action in assisting the patient in losing weight. Placement of the Orbera balloon is temporary and is removed endoscopically, under light, conscious sedation, within six months after placement. In the United States Orbera is indicated for use for adults within a BMI range of 30 to 40 who have tried other weight loss programs, such as supervised diet and exercise, but who were unable to lose weight and keep it off. Outside the United States, Orbera is also known as the BIB (BioEnterics Intragastric Balloon) System in certain markets. Outside the United States, Orbera is generally indicated for temporary weight loss for patients with a BMI greater than or equal to 27 and BIB is indicated for temporary use for weight loss in obese patients with BMI of 30-39 and also for pre-surgical temporary use in severely obese patients (BMI greater than 40 or a BMI of 35 or greater with comorbidities) prior to obesity surgery or other surgery in order to reduce surgical risk or for severely obese patients who are otherwise not candidates for obesity surgery.

Apollo's Intragastric Balloon System was CE marked in May 1997 and has been marketed continuously in Europe since the late 1990's followed by subsequent approvals and introductions in other select international markets. Orbera is the global market leader among intragastric balloons with access to over 80 countries and more than 220,000 units distributed.

Following FDA clearance in August 2015, the Orbera System was launched, and we began distribution in the United States. Following the launch of Orbera in the U.S., through 2016 we trained more than 800 physicians on the use of Orbera for non-surgical and less-invasive weight loss solutions for patients who suffer from obesity. This training outreach program reached approximately 480 bariatric surgeons and 320 gastroenterologists, which represents approximately 17% of U.S. bariatric surgeons and 3% of U.S. gastroenterologists, respectively.

In the U.S. pivotal Orbera clinical trial, a multicenter, prospective, randomized, non-blinded comparative study, patients suffering from obesity with a BMI between 30 and 40 were randomized to treatment or control in a 1:1 ratio. The treatment group underwent placement of the Orbera balloon followed by removal after six months and concurrently participated in a 12-month behavioral modification program. The control group participated in the 12-month behavioral modification program alone. A total of 125 patients were randomized to the treatment group and 130 patients were randomized to the control group. An additional 35 subjects were treated as "run-in" subjects who received a balloon on a non-randomized basis in order for physicians to gain experience with Orbera placement. The findings from the trial included:

- At month six, the treatment group achieved a mean of 38.4% Excess Weight Loss ("EWL").
- Mean TBWL at six months was 10.2% for the treatment group compared to 3.3% TBWL for the control group.
- The treatment group lost 3.1 times as much weight as the control group at six months.
- The treatment group also lost significantly more weight than the control group over the course of the study, and was able to maintain over 70% of weight loss through month twelve, six months after removal of the device.

There were no unanticipated adverse device effects or deaths reported during the U.S. pivotal trial. There were a total of fourteen device related Serious Adverse Events ("SAEs") reported during the U.S. pivotal study. The procedure related SAEs were also minimal, occurring in three of the 160 implanted subjects. The most frequently occurring SAEs (8 events) were nausea, vomiting, pain and gastroesophageal reflux leading to balloon removal prior to the six month date. Other SAEs included: dehydration (2), gastric outlet obstruction with moderate diffuse gastritis (1), gastric perforation with sepsis (1), aspiration pneumonia (1) and abdominal cramping and infection (1). The procedure related SAEs consisted of esophageal mucosal injury (2) and laryngospasm (1). The U.S. pivotal trial data established that the Orbera System is safe for its intended use.

In addition, a total of 810 device-related Adverse Events ("AEs") were reported in the 160 treated subjects. The majority of events were mild to moderate and resolved within two weeks. Of the device related AEs in the treatment group, 59.7% of the AEs were considered mild, 34.5% were considered moderate and 5.8% were categorized as severe. The control group who did not receive a balloon reported 429 AEs (72% mild, 22.1% moderate and 5.6% severe). The most common AEs include nausea:

(86.8%), vomiting (75.6%), abdominal pain (57.5%), gastroesophageal reflux (30%), eructation (24.4%), dyspepsia (21.3%), constipation (20%), upper abdominal pain (18.1%), abdominal distension (17.5%), dehydration (14.4%), diarrhea (13.1%), flatulence (11.2%) and impaired gastric emptying (8.8%).

The SAE rate related to device intolerance was greater than the global product experience with Orbera as the use of drugs to treat nausea or vomiting was prohibited under the original study protocol and the use of these medications was considered a protocol deviation. After a learning curve of how to manage the adjustment period, the protocol was amended, and the use of anticholinergic and antispasmodic drugs was allowed. In addition, there were no ulcers observed (versus a global experience rate of 0.02%) and no balloon deflations observed (versus a global experience rate of 0.31%).

The clinical effectiveness and safety profile of the Orbera System as a non-ulcerogenic weight loss device has been reported in over 230 peer reviewed publications covering over 8,000 patients. Although not specifically indicated for the treatment of obesity-related comorbidities, studies have reported resolution or improvement in a patient's pre-existing comorbidities at the time of Orbera removal. The Orbera Intragastric Balloon is currently the only balloon or other endoscopic product that has been recognized in the American Society for Gastrointestinal Endoscopy ("ASGE") Preservation and Incorporation of Valuable Endoscopic Innovations assessment to have met its threshold standards for the treatment of obesity. The meta-analysis performed by the ASGE was based on the aggregation of certain clinical studies conducted outside the U.S. and indicates an estimated TBWL at six months of approximately 13.2%.In most countries, the Orbera procedure is generally a cash-pay procedure.

In May of 2016, we launched the Orbera Coach platform, an on-demand telehealth program that provides virtual post-implant support tailored to meet the needs of patients who undergo the Orbera procedure, which was co-developed with Zillion Health, a private company.

OverStitch Endoscopic Suturing System

The OverStitch Endoscopic Suturing System ("OverStitch") enables advanced endoscopic procedures by allowing physicians to place full-thickness sutures and secure the approximation of tissue through an Olympus dual-channel flexible endoscope. OverStitch is currently the only U.S. cleared flexible endoscopic suturing device capable of full-thickness suturing of tissue. OverStitch is a mechanical suturing device that operates in cooperation with a flexible endoscope and allows a user to access portions of a patient's gastrointestinal tract and place sutures through the full thickness of a patient's tissue using endoscopic visualization.

The OverStitch system is comprised of four devices: the OverStitch Endoscopic Suturing System, a proprietary suture, a Suture Cinch used for "knot tying", the OverTube Endoscopic Access System to provide safe access and maintain insufflation during endoscopic procedures, and the Tissue Helix to grab and manipulate tissue. The OverStitch Endoscopic Suture System, including Tissue Helix, received United States FDA 510(k) clearance in August 2008 and CE Mark approval in November 2012. Our four devices are sold separately. In certain procedures, all four devices are utilized during the procedure and in other instances, a user may choose not to use all four devices during a procedure.

The functionality of the OverStitch device allows it to be used for a broad number of bariatric (both revisional and primary) and non-bariatric applications. Since its market introduction, over 16,000 OverStitch units have been sold for procedures worldwide.

Gastric bypass procedures carry a long-term failure rate estimated to be from 20 to 35%. In super-obese patients, the failure rate can be as high as 40 to 60%. Sleeve gastrectomy procedures may also require revision following patient weight regain. These procedures typically fail due to tissue remodeling that results over time from the surgical alteration of the patient's GI tract. These changes include gastro-gastric fistulas (when the surgically created barrier between the stomach pouch and the bypassed stomach breaks down); pouch dilation (where the stomach pouch enlarges); or, anastomotic dilation (where the connection between the stomach pouch and the bypassing intestine stretches out). These conditions result in the patient being able to eat more than what is required to retain their weight loss and in the case of the gastro-gastric fistula, the patient can develop gastroesophageal reflux. Neither of these stapling procedures are reversible and once the procedure fails, the patient's options are limited. OverStitch may be used to revise or repair failed bypass procedures without requiring another highly-invasive and complicated laparoscopic or open surgical form of revision or repair. In recent years, revisional bariatric surgery has been reported by the ASMBS as one of the fastest growing bariatric procedures. We estimate that approximately one-third of procedures performed with OverStitch are in connection with revisions or repairs of failed bariatric surgeries.

One of the most promising endoscopic weight-loss procedures is endoscopic sleeve gastroplasty ("ESG"), which transorally uses endoscopic suturing with OverStitch to reduce the volume of the stomach, similar to a surgical sleeve gastrectomy procedure without the invasiveness and need for amputation of the gastric remnant. During an ESG, a physician creates a small diameter sleeve similar to a sleeve gastrectomy while offering advantages such as maintaining the structural integrity of the gastric wall, reversibility and reduced costs.

ESG is a development stage procedure that requires a relatively high level of endoscopic skill. The first multicenter study was reported in May 2016 at Digestive Disease Week. This was a three center (two in the U.S. and one in Spain) study of medical records of patients who underwent ESG from January 2013 to November 2015. All procedures were performed in a similar fashion using the OverStitch device to place full-thickness sutures to fold in the greater curvature of the stomach, creating a narrow lumenal sleeve with the goal of reducing gastric functional capacity by up to an estimated 80%.

A total of 242 patients were included in the study. Patient BMI at the start of the study was 37.8, plus or minus 5.5.

- 137 patients reached 6-months follow-up and the study reported an average TBWL of 16.8%, with a range of plus or minus 6.4%.
- 53 patients reached 12-months follow-up and the study reported an average TBWL of 18.2%, with a range of plus or minus 10%.
- 30 patients reached 18-month follow-up and the study reported an average TBWL of 19.8%, with a range of plus or minus 11.6%. 20 patients at 18-month follow-up had sustained TBWL of greater than or equal to 15%.
- There was no difference in weight loss between the three centers. The only predictor for weight loss at six months was a lower age, even after adjusting for BMI, gender and center.

Five (2%) serious adverse events occurred: two perigastric inflammatory fluid collections that resolved with percutaneous drainage and antibiotics, one self-limited hemorrhage from splenic laceration, one pulmonary embolism 72 hours after the procedure, and one pneumoperitoneum and pneumothorax requiring chest tube placement. All 5 patients recovered fully.

In addition, OverStitch has application for treating GI defects in both the upper and lower GI tract; including closure of acute perforations and chronic fistulas; inadvertent perforation of the intestines, tissue closure after the removal of abnormal lesions in the esophagus, stomach or colon (also known as endoscopic submucosal dissections and endoscopic mucosal resections) and in the treatment of swallowing disorders (peroral endoscopic myotomy, POEM). It is also used to suture in place esophageal stents in order to prevent their migration. We estimate that approximately 60% of procedures performed with OverStitch are in connection with the treatment of such GI defects.

Surgical

Our Surgical products consist primarily of the Lap-Band System and accessories used in laparoscopic bariatric surgeries. The Lap-Band System is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. The Lap-Band System is an adjustable silicone band that is laparoscopically placed around the upper part of the stomach through a small incision, creating a small pouch at the top of the stomach, which slows the passage of food and creates a sensation of fullness. The procedure can normally be performed as an outpatient procedure, where the patient is able to go home the day of the procedure without the need for an overnight hospital stay.

The Lap-Band System has been in use in Europe since 1993 and was CE marked in 1997. FDA approval in the United States was obtained in 2001 and the Lap-Band System has been approved in many countries around the world. More than 800,000 Lap-Band systems have been distributed worldwide.

The Lap-Band System was approved for use in the United States for patients with BMI greater than or equal to 40 or a BMI greater than or equal to 35 with one or more severe comorbid conditions. In 2011, the United States FDA granted approval for an expanded indication for the Lap-Band System to include patients with a BMI in the range of 30 to 35 and with one or more comorbid conditions. In October 2015, we concluded a multicenter pivotal study detailing five-year outcomes for Lap-Band with patients at the lower BMI range of 30 to 40 which showed:

- sustained long term weight loss over the 5 year period with the average percent TBWL at five-years of 15.9% plus or minus 12.4%, corresponding to 62.7% EWL; and
- a device explant rate of 14.8% which was substantially below the study's safety objective of less than 32.5% at 5 years. Excluding patients who elected to exercise their option to have the band removed at no cost to them on completion of the study, the explant rate was 5.4% at 5 years.

No unanticipated adverse device effects were reported. All device-related serious adverse events were resolved with all but one resolving without sequelae. The majority of device-related adverse events were mild (53.2%) or moderate (37.2%) in severity. The most common device related adverse events were vomiting (16.4%), gastroesophageal reflux disease (12.1%) and dysphagia (11.5%).

More than 400 peer-reviewed publications and extensive real-world experience demonstrate that laparoscopic adjustable gastric banding surgery using Lap-Band is a safe and effective treatment option for obesity. Adjustable gastric banding using the Lap-Band System has been reported to be significantly safer than gastric bypass while statistically producing the same weight loss 5 years after surgery when accompanied by an appropriate post-operative follow-up and adjustment protocol. Studies have reported sustained resolution or improvement in type 2 diabetes, gastroesophageal reflux, obstructive sleep apnea, asthma, arthritis, hypertension and other pre-existing obesity related comorbidities following gastric banding. The gastric banding surgical procedure is generally reimbursed by most payors and insurance programs that otherwise cover bariatric surgery.

Competition

We face competition from other interventional therapies for the treatment of obesity that do not use our products as well as from other manufacturers with similar products to ours with the same intended mode of action.

Competing therapies are primarily surgical in nature, such as sleeve gastrectomy and gastric bypass. Sleeve gastrectomy is a surgical weight-loss procedure in which the stomach is reduced to about 15% of its original size, by the longitudinal resection and removal of a large portion of the stomach along the greater curvature. The result is a sleeve or tube like structure. The procedure permanently reduces the size of the stomach. The procedure is generally performed laparoscopically and is irreversible. Gastric bypass surgery refers to a surgical procedure in which the stomach is divided into a small upper pouch and a much larger lower remnant pouch and then the small intestine is rerouted to connect to the small upper pouch. The procedure leads to a marked reduction in the functional volume of the stomach, accompanied by an altered physiological and physical response to food. Both procedures are normally performed laparoscopically and rely upon surgical staplers as their principal surgical tool. As a result, these procedures are supported by the suppliers of surgical staplers, the largest of whom are Johnson & Johnson (Ethicon) and Medtronic (Covidien). Both companies have substantially more resources than we do.

Outside the United States, there are a variety of local and regional competitive intragastric balloon and gastric band manufacturers including Spatz Laboratories, Obalon Therapeutics, Inc., ReShape Medical Inc., Cousins BioTech, Medical Innovation Development (Midband) and Johnson & Johnson. In the United States, there are two other manufacturers with intragastric balloons approved by the FDA at this time, ReShape Medical Inc. and Obalon Therapeutics, Inc. and one other manufacturer with an approved gastric band, Ethicon, a Johnson & Johnson company. In 2016, Ethicon announced to customers a plan to phase out its gastric band product at the end of 2016.

Sales and Distribution

We currently market and sell our products principally to providers of medical services and procedures including hospitals, outpatient surgical centers, clinics and physicians through an employee sales force in the United States, Brazil, Canada, Australia and key markets in Europe. As of December 31, 2016, we employed 55 sales and marketing personnel in the United States and another 46 employees in all of the markets outside of the United States. In addition, we sell products to third party distributors who sell our products in over 60 countries.

In the United States, the gastric banding procedure which uses our Surgical products has obtained reimbursement approval with Medicare, Medicaid and other third-party payors for patients meeting applicable coverage requirements. Additional markets outside the United States also offer reimbursement approval and coverage requirements for gastric banding. Obesity procedures that utilize the Endo-Bariatric products are generally cash pay procedures. Revisions of prior bariatric surgery using endoscopic suturing have received reimbursement approval on a case-by-case basis. Medical procedures that utilize endoscopic suturing products in the treatment of GI defects generally receive reimbursement approval but coverage can vary by country, state and procedure performed.

Manufacturing and Product Supply

We manage all aspects of product supply through our operations team based in Austin, Texas. We operate a manufacturing facility in the Coyol Free Trade Zone in Alajuela, Costa Rica that performs final assembly for the Lap-Band and Orbera products. Beginning in 2016, we started producing components related to the OverStitch product line in our Costa Rica facility. In addition, we rely on third-party suppliers to provide components used in existing products and we expect to continue to do so for products under development, including final assembly of the OverStitch endoscopic suturing system.

We believe that our existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months. Our manufacturing facility is certified by the International Organization for Standardization, or ISO, and operates under the FDA's good manufacturing practice requirements for medical devices set forth in the Quality System Regulation, ("QSR").

Research and Development

As of December 31, 2016, we had 13 employees focused on research and development. Research and development expenses for the years ended 2016 and 2015 were $7.8 million and $9.6 million, respectively.

Intellectual Property

We have developed and acquired significant know-how and proprietary technology, upon which our business depends. To protect our know-how and proprietary technology, we rely on trade secret laws, patents, copyrights, trademarks and confidentiality agreements and contracts. However, these methods afford only limited protection. Others may independently develop substantially equivalent proprietary information or technology, gain access to our trade secrets or disclose or use such secrets or technology without our approval.

We protect trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. We cannot assure you that our trade secrets will not become known to or be independently developed by our competitors.

Apart from the portfolio of patents and applications to the Lpath technology, we own over 157 U.S. patents and 298 foreign patents. Our U.S. patents have expiration dates ranging from 2017 to 2035 and our foreign patents have expiration dates ranging from 2020 to 2034 subject to the payment of the requisite renewal fees. We also own more than 42 pending U.S. patent applications and 68 pending foreign patent applications. We believe patents will be issued pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we are generally required to pay royalties. While our patents are an important element of our products and future product development, our business as a whole is not significantly dependent on any one patent.

Our patents may not provide us with effective competitive advantages. Our pending or future patent applications may not be issued. Others may hold or obtain patents that cover aspects or uses of our innovations. The patents of others may render our patents obsolete, limit our ability to patent or practice our innovations, or otherwise have an adverse effect on the ability to conduct business. Because foreign patents may afford less protection than U.S. patents, they may not adequately protect our technology.

In 2009 we entered into an Intellectual Property Assignment Agreement, with Olympus Corporation and the "FTE Group" comprised of The Johns Hopkins University, Mayo Foundation for Medical Education and Research, The University of Texas Medical Branch, MUSC Foundation for Research Development and the Chinese University of Hong Kong, whereby the "FTE Group" has assigned to us a Joint Research Agreement with Olympus Corporation, including their rights in certain inventions, patents and IP rights developed by FTE Group under the Joint Research Agreement, which relate to the field of flexible endoscopy and minimally invasive surgery. Olympus Corporation has retained rights as a joint owner of certain inventions and related patents developed jointly by FTE Group and Olympus Corporation under the Joint Research Agreement and retained a license granted by FTE Group to Olympus Corporation to the inventions and related patents developed by FTE Group under the Joint Research Agreement. The patents covered by the agreement pertain to endoscopic procedures and endoscopic suturing devices that relate to the OverStitch products and may also be incorporated into potential new products that we may develop in the future. Any royalties now due under the Joint Research Agreement will be paid by Olympus to us and we will pay FTE Group 50% of the royalties received from Olympus Corporation. As consideration for the assignment, we are obligated to pay to each of Olympus and the FTE Group one half of a royalty in the low single digits on net sales of our products covered by the patents, which royalty shall be reduced if related patents have expired or no longer exist. In addition, we have the right to sublicense our rights under the Joint Research Agreement to the patents and technologies. The term of the Intellectual Property Assignment Agreement is through and until termination. The agreement may be terminated upon written notice a) by Olympus if we materially breach any material terms that pertain to Olympus and the breach is not cured within 30 days after notice, b) by the FTE Group if we materially breach any of the material terms that pertain to the FTE Group and the breach is not cured within 30 days after notice or c) by us if Olympus materially breaches any material terms that pertain to Olympus and the breach is not cured within 30 days after notice.

Following the Merger, we also own 47 U.S. and foreign issued patents and 29 pending U.S. and foreign patent applications relating to technologies and inventions developed by Lpath prior to the Merger (the “Lpath IP”). The Lpath IP is not aligned with our current business activities and is not a strategic asset.

Government Regulation

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, (or "FD&C Act") also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

Device Classification

Under the FD&C Act, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

The Orbera intragastric balloon and the Lap-Band System are Class III devices. The OverStitch Device is a Class II Device. We also sell accessory products, some of which are Class I.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and postmarket surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to either:

- a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- another commercially available, similar device that was cleared through the 510(k) process.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

After a 510(k) notice is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification, including modification to or deviation from design, manufacturing processes, materials, packaging and sterilization that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k), for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or clearance of a 510(k) or result in the imposition of new requirements or testing;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- data collection, monitoring and analysis is not performed in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;

- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;

- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;

- changes in government regulations or administrative actions;

- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or

- the FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and efficacy.

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;

- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;

- the manufacturing process or facilities may not meet applicable requirements; and

- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, components, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may require postmarket surveillance for certain devices approved under a PMA or cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility, devices where the failure of which would be reasonably likely to have serious adverse health consequences, or devices expected to have significant use in pediatric populations. The FDA may also approve a PMA

application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

Pervasive and Continuing FDA Regulation

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval or clearance of a 510(k) of product modifications;
- medical device reporting, or MDR, 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 the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and have obtained authorization to manufacture from the FDA. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA Office of Compliance within the Center for Devices and Radiological Health to determine our compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of our suppliers.

Fraud and Abuse Laws

Our business is regulated by laws pertaining to healthcare fraud and abuse including anti-kickback laws and false claims laws. Violations of these laws are punishable by significant criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid. Because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws, or the adoption of new laws or regulations, could adversely affect arrangements with customers and physicians. In addition, any violation of these laws or regulations could have a material adverse effect on the financial condition and results of our operations.

Anti-Kickback Statute

Subject to a number of statutory exceptions, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the furnishing, recommending, purchasing, leasing, ordering, or arranging for, a good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including payments to physicians or other providers, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything of value at less than fair market value. The Office of the Inspector General of the U.S. Department of Health and

Human Services, or the OIG, and the U.S. Department of Justice are responsible for enforcing the federal Anti-Kickback Statute and the OIG is primarily responsible for identifying fraud and abuse activities affecting government healthcare programs.

Penalties for violating the federal Anti-Kickback Statute include substantial criminal fines and/or imprisonment, substantial civil fines and possible exclusion from participation in federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs and do not include comparable exceptions to those provided by the federal Anti-Kickback Statute.

The OIG has issued safe harbor regulations that identify activities and business relationships that are deemed safe from prosecution under the federal Anti-Kickback Statute. There are safe harbors for various types of arrangements, including certain investment interests, leases, personal service arrangements, discounts and management contracts. The failure of a particular activity to comply with all requirements of an applicable safe harbor regulation does not mean that the activity violates the federal Anti-Kickback Statute or that prosecution will be pursued. However, activities and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

In recent years, the federal government and several states have enacted legislation requiring biotechnology, pharmaceutical and medical device companies to establish marketing compliance programs and file periodic reports on sales, marketing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities that we do business with are found to have not complied with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

Federal False Claims Act

The federal False Claims Act prohibits knowingly filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. A claim that is filed pursuant to an unlawful kickback may be a false claim under this law and, in a number of cases, manufacturers of medical products have entered into settlements of False Claims Act allegations that their financial relationships with customers "caused" these customers to submit false claims. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Private individuals can file suits under the False Claims Act on behalf of the government. These lawsuits are known as "qui tam" actions, and the individuals bringing such suits, sometimes known as "relators" or, more commonly, "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Since complaints related to “qui tam” actions are initially filed under seal, the action may be pending for some time before a defendant is even aware of such action. Thus, we may currently be subject to an investigation for alleged FCA violations pursuant to one or more qui tam actions, which may be under full or partial seal, thereby preventing disclosure of such action or actions. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action. The time and expense associated with responding to such investigations, and any related qui tam or other actions, may be extensive, and we cannot predict the results of our review of the responsive documents and underlying facts or the results of such actions. The costs of responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties (including under the FCA), settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

HIPAA also protects the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses and their business associates. HIPAA restricts the use and disclosure of patient health information, including patient records. Although we believe that HIPAA does not apply directly to the Company, most of our customers have significant obligations under HIPAA, and we intend to cooperate with customers and others to ensure compliance with HIPAA with respect to patient information. Failure to comply with HIPAA obligations can result in civil fines and/or criminal penalties. Some states have also enacted rigorous laws or regulations protecting the security and privacy of patient information. If we fail to comply with these laws and regulations, we could face additional sanctions.

Healthcare Reform and Compliance

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or together, the ACA. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform in the form of a medical device excise tax on United States sales of most medical devices beginning in 2013. We began paying the medical device excise tax in January 2013.

In December 2015, the Protecting Americans from Tax Hikes Act of 2015 ("PATH Act") was implemented, which suspended the medical device excise tax implemented as part of the ACA for a two-year period through December 31, 2017. Additionally, the PATH Act permanently extended the research and development tax credit. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal portions of the ACA. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the ACA. Among other changes, the American Health Care Act would eliminate the 2.3% excise tax on medical devices. The American Health Care Act would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. While it is uncertain when or if the provisions in the American Health Care Act will become law, or the extent to which any legislation changes may impact our business, it is clear that concrete steps are being taken to repeal and replace certain aspects of the ACA.

The Physician Payments Sunshine Act, or PPSA, which is part of the ACA, requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report these data to CMS, for subsequent public disclosure. Similar reporting requirements have also been enacted in several states, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals. Particularly, some states such as Massachusetts and Vermont impose an outright ban on certain gifts to physicians. Failure to report appropriate data may result in civil or criminal fines and/or penalties. We have reported the information as required by the PPSA from the August 1, 2013 effective date through December 31, 2016.

Additionally, the compliance environment is changing, with more states, such as California, Connecticut, Nevada and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, requiring reporting to state governments of gifts, compensation and other remuneration to physicians. The shifting regulatory environment, along with the requirement to comply in multiple jurisdictions with different compliance and reporting requirements, increases the possibility that a company may run afoul of one or more laws.

International Regulation

Our business is also subject to regulation in each of the foreign countries in which our products are sold. Many of the regulations applicable to our products in these countries are similar to those of the FDA. The European Union requires that medical devices comply with the Medical Device Directive or the Active Implantable Medical Device Directive, which includes quality system and CE certification requirements. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality (i.e., the essential requirements) and then undergo an appropriate conformity assessment procedure. A Notified Body assesses the quality management systems of the manufacturer and verifies the conformity of devices to the essential and other requirements within the Medical Device Directive. In the European Union, we are also required to maintain certain ISO certifications in order to sell products. We are also subject to regulations and periodic

review from various regulatory bodies in other countries where our products are sold. Lack of regulatory compliance in any of these jurisdictions could limit our ability to distribute products in these countries. We are also subject to foreign laws and regulations governing the marketing and promotion of our products including as transparency reporting obligations.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. Many of the customer relationships of the Company outside of the U.S. are, either directly or indirectly, with governmental entities and employees (such as physicians) and are therefore subject to various anti-bribery laws. Although our corporate policies mandate compliance with these anti-bribery laws, we sell to customers in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not always protect the Company from reckless or criminal acts committed by employees, distributors, consultants or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our business, results of operations and financial condition.

Other Regulations

We are also subject to various international, federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development and manufacturing activities. Specifically, the manufacture of our products is subject to compliance with various international and federal laws and regulations and by various foreign, state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with these and other laws or regulations in the future.

Employees

As of December 31, 2016, we had a total of 193 full-time employees. None of our U.S. employees are represented by a labor union or subject to a collective bargaining agreement. Our non-U.S. employee employment contracts comply with the applicable country mandated collective agreement in the locations where we operate. We have never experienced any work stoppage and consider our relations with our employees to be good.

Management

The following table sets forth information about our executive officers and other key clinical, operations and sales officers as of March 23, 2017.

Name	Age	Position(s)
Todd Newton	54	Chief Executive Officer and Director
Dennis L. McWilliams	46	President and Chief Commercial Officer
Stefanie Cavanaugh	52	Chief Financial Officer, Treasurer and Secretary
Christopher Gostout	66	Chief Medical Officer
Bret Schwartzhoff	45	Vice President, U.S. Sales and Marketing
Charles Tribié	64	Executive Vice President of Operations

Todd Newton. Mr. Newton has served as Chief Executive Officer and as a member of the board of directors of Apollo since 2014. From 2009 to 2014, Mr. Newton served as Executive Vice President, Chief Financial Officer and Chief Operating Officer at ArthroCare Corporation, a medical device company. Prior to his leadership at ArthroCare, Mr. Newton served in a number of executive officer roles, including President and Chief Executive Officer, at Synenco Energy, Inc., a Canadian oilsands company. From 1994 to 2004, Mr. Newton was a Partner at Deloitte & Touche LLP. Mr. Newton holds a B.B.A. in accounting from The University of Texas at San Antonio.

Dennis L. McWilliams. Mr. McWilliams has served as President and Chief Commercial Officer of Apollo since 2014. Mr. McWilliams co-founded Apollo in 2006 and served as President and Chief Executive Officer until 2014. From 2004 to 2006, Mr. McWilliams was an Entrepreneur in Residence at PTV Sciences LP, a venture capital fund focusing on life science and medical devices. Prior to this, Mr. McWilliams served as Chief Operating Officer at Chrysalis BioTechnology, Inc., a development stage biopharmaceutical company focused on developing novel drug therapies for tissue regeneration, which he

co-founded in 1996 and sold in 2003. Mr. McWilliams holds a B.S. with Honors in aerospace engineering from the University of Texas at Austin and a M.S. in engineering management from Stanford University.

Stefanie Cavanaugh. Ms. Cavanaugh has served as Chief Financial Officer of Apollo since 2015. From 2014 to 2015, Ms. Cavanaugh provided advisory services to several healthcare companies. From 2010 to 2014, Ms. Cavanaugh served as Senior Vice President of Finance at Harden Healthcare, LLC, a provider of healthcare services for the long-term care industry, until its sale to Gentiva Health Services, Inc. She began her career with Ernst & Young before serving in executive management positions at The Cancer Therapy and Research Center, an affiliate of The University of Texas Health Science Center; Encore Medical Corporation, a medical device company; and Solis Women's Health, a diagnostic imaging company. Ms. Cavanaugh holds a B.B.A. in accounting and finance from the University of Texas at Austin and is a Certified Public Accountant.

Dr. Christopher J. Gostout, M.D. Dr. Gostout has served as the Chief Medical Officer of Apollo since December 2016. Between August 2013 and December 31, 2016 Mr. Gostout served as a consultant to Apollo. In 2006, Mr. Gostout co-founded Apollo. Since July 1983, Mr. Gostout has been a gastroenterologist at the Mayo Clinic in the Division of Gastroenterology and Hepatology. Since 2005, he has held a joint appointment in the Department of Surgery. Since, July 2000, he has been a Professor of Medicine in the Mayo Clinic College of Medicine and the Director of the Developmental Endoscopy and Research Unit since 1998. From 2006 to 2010, he served as a Member of Medical & Scientific Advisory Board at Vysera Biomedical Limited and on the board of EnteroMedics Inc. between 2004 and 2006. He founded The Mayo Clinic GI Bleeding Team and the Developmental Endoscopy Unit in 1986 and 1998 and the ASGE Interactive Training and Technology center in 2004. Between 1994 and 1997 Dr. Gostout was a Member of the Board of Trustees in the American College of Gastroenterology and between 2003 and 2004 was the President of the American Society of Gastrointestinal Endoscopy (ASGE). Mr. Gostout holds a B.S. in Biology from Villanova University and a M.D. from the State University of New York Downstate Medical Center.

Bret Schwartzhoff. Mr. Schwartzhoff has served as Vice President, U.S. Sales and Marketing of Apollo since December 2015 and from December 2014 to December 2015 served as Apollo's Vice President U.S. Sales. From 2011 to 2014, Mr. Schwartzhoff served as Vice President of Marketing, Sports Medicine, and from 2013 to 2014 also served as Vice President of Sales and Marketing, Spine at ArthroCare Corporation and Smith & Nephew plc, which acquired ArthroCare, both medical device companies. Mr. Schwartzhoff holds a B.S. in business from Mankato State University and an M.B.A. from Wake Forest University.

Charles Tribié. Mr. Tribié has served as Executive Vice President of Operations at Apollo since 2014. From 2008 to 2014, Mr. Tribié served as Senior Vice President Operations at IDev Technologies, Inc., a medical device company. Mr. Tribié began his career at U.S. Surgical Corporation, spending 19 years there while continuing to increase his responsibilities within operations. At the time of its acquisition by Tyco International Ltd. in 1998, he was Senior Vice President Operations at U.S. Surgical Corporation. Mr. Tribié holds a B.A. in economics from Fordham University and an M.B.A. from Long Island University.

ITEM 1A. RISK FACTORS

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

Risks Related to Our Business

We have incurred significant operating losses since inception and may not be able to achieve profitability.

We have incurred net losses since our inception in 2005. For the years ended December 31, 2016 and 2015, we had net losses of $41.2 million and $27.4 million, respectively. As of December 31, 2016, we had an accumulated deficit of $149.7 million. To date, we have financed our operations primarily through private placements of our equity securities, certain debt-related financing arrangements and from sales of our products. We have devoted substantially all of our resources to the acquisition of products, the research and development of products, sales and marketing activities and clinical and regulatory initiatives to obtain approvals for our products. Our ability to generate sufficient revenue from our existing products, and to transition to profitability and generate consistent positive cash flows is uncertain. We may need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all. We expect that our operating expenses may increase as we continue to build our commercial infrastructure, develop, enhance and commercialize our products and incur additional costs associated with being a public company. As a result, we may incur operating losses for the foreseeable future and may never achieve profitability.

Our long-term growth depends on our ability to successfully develop the endo-bariatric market and successfully commercialize our Endo-bariatric products.

It is important to our business that we continue to build a market for endo-bariatric procedures within the bariatric market. The bariatric market is traditionally a surgical market. Our endo-bariatric products offer non-surgical and less-invasive weight loss solutions and technology that enable new options for physicians treating their patients who suffer from obesity. However, this is a new market and developing this market is expensive and time-consuming and may not be successful due to a variety of factors including lack of physician adoption, patient demand, or both. Even if we are successful in developing additional products in the endo-bariatric market, the success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- effectively train physicians on how to use our products and achieve good patient outcomes;
- effectively communicate with patients and educate them on the benefits of endo-bariatric procedures;
- influence procedure adoption in a timely manner;
- develop clinical data that demonstrate the safety and efficacy of the procedures that use our products;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- be FDA-compliant with marketing of new devices or modified products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- successfully train the sales and marketing team to effectively support our market development efforts.

If we are unsuccessful in developing and commercializing the endo-bariatric market, our ability to increase our revenue will be impaired.

Adverse U.S. and international economic conditions may reduce consumer demand for our products, causing our sales and profitability to suffer.

Adverse economic conditions in the U.S. and international markets may negatively affect our revenues and operating results. Our endo-bariatric products, such as the Orbera managed weight loss system, has limited reimbursement and in most cases is not reimbursable by governmental or other health care plans and instead are partially or wholly paid for directly by patients. The gastric banding procedure that uses our LapBand system is generally covered by most insurance programs that cover bariatric procedures, however, a gastric banding procedure is an elective procedure and may also require significant co-pay and other out of pocket expenses by the patient. Sales of our products may be negatively affected by adverse economic conditions impacting consumer spending, including among others, increased taxation, higher unemployment, lower consumer confidence in the economy, higher consumer debt levels, lower availability of consumer credit, higher interest rates and hardships relating to declines in the housing and stock markets which have historically caused consumers to reassess their spending choices and reduce their likelihood to pursue elective surgical procedures. Any reduced consumer demand due to adverse economic or market conditions could have a material adverse effect on our business, cause sales and profitability to suffer, reduce operating cash flow and result in a decline in the price of our common stock. Adverse economic and market conditions could also have a negative impact on our business by negatively affecting the parties with whom we do business, including among others, our business partners, creditors, third-party contractors and suppliers, causing them to fail to meet their obligations to us.

Our future growth depends on physician adoption and recommendation of procedures utilizing our products.

Our ability to sell our products depends on the willingness of our physician customers to adopt our products and to recommend corresponding procedures to their patients. Physicians may not adopt our product unless they determine that they have the necessary skills to use our products and based on their own experience, clinical data and published peer-reviewed research that our products provide a safe and effective treatment option. Even if we are able to raise favorable awareness among physicians, physicians may be hesitant to change their medical treatment practices and may be hesitant to recommend procedures that utilize our products for a variety of reasons, including:

- existing preferences for competitor products or with alternative medical procedures and a general reluctance to change to or use new products or procedures;
- lack of experience with our products;

- time and skill commitment that may be necessary to gain familiarity with a new product or new treatment;
- a perception that our products are unproven or experimental;
- reluctance for a related hospital or healthcare facility to approve the introduction of a new product or procedure;
- a preference for an alternative procedure that may afford a physician or a related hospital or healthcare facility greater remuneration;
- development of new weight loss treatment options, including pharmacological treatments, that are less costly, less invasive, or more effective.

Our future growth depends on patient awareness of and demand for procedures that use our products.

The procedures that utilize our products are generally elective in nature and demand for our products is driven significantly by patient awareness and preference for the procedures that use our products. We educate patients about our products and related procedures through various forms of media. However, the general media, social media and other forms of media outside of our control as well as competing organizations may distribute information that is unfavorable to our products and related procedures. If patient awareness and preference for procedures is not sufficient or is not positive, our future growth will be impaired. In addition, our future growth will be impacted by the level of patient satisfaction achieved from procedures that use our products. If patients who undergo treatment using our product are not satisfied with their results, our reputation and that of our products may suffer. Even if we are able to raise favorable awareness among patients, patients may be hesitant to proceed with a medical treatment for various reasons including:

- perception that our products are unproven or experimental;
- reluctance to undergo a medical procedure;
- reluctance of a prospective patient to commit to long term lifestyle changes;
- previous long term failure with other weight loss programs;
- out of pocket cost for an elective procedure; and
- alternative weight loss treatments that are perceived to be more effective or less expensive.

We may not be able to successfully introduce new products to the market in a timely manner.

Our future financial performance will depend in part on our ability to develop and manufacture new products or to acquire new products in a cost-effective manner, to introduce these products to the market on a timely basis and to achieve market acceptance of these products. Factors which may result in delays of new product introductions include capital constraints, research and development delays, lack of personnel with sufficient experience or competence, delays in acquiring regulatory approvals or clearances or delays in closing acquisition transactions. Future product introductions may fail to achieve expected levels of market acceptance including physician adoption, patient awareness or both. Factors impacting the level of market acceptance include the timeliness of our product introductions, the effectiveness of medical education efforts, the effectiveness of patient awareness and educational activities, successful product pricing strategies, available financial and technological resources for product promotion and development, the ability to show clinical benefit from future products and the availability of coverage and reimbursement for procedures that use future products.

If we are unable to manage and maintain our direct sales and marketing organizations we may not be able to generate anticipated revenue.

Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales representatives fail to adequately promote, market and sell our products, our sales may suffer. In order to generate our anticipated sales, we will need to maintain a qualified and well trained direct sales organization. As a result, our future success will depend largely on our ability to hire, train, retain and motivate skilled sales managers and direct sales representatives. Because of the competition for their services, we cannot assure you we will be able to hire and retain direct sales representatives on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales. Additionally, new hires require training and take time before they achieve full productivity. If we fail to train new hires adequately, new hires may not become as productive as may be necessary to maintain or increase our sales and we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition.

Our long-term growth depends on the ability to stabilize revenue from the sale of our surgical products.

Our surgical products consist of the Lap-Band System and related laparoscopic accessories. In the past two years, the majority of our revenue has come from our surgical products. Revenue from the surgical product portfolio has been decreasing over several years due to a shift in procedure mix to bariatric stapling procedures such as sleeve gastrectomy or gastric bypass procedures. It is important to our long-term growth to stabilize revenue from our surgical product business so that the decline of our surgical products business does not offset growth from other parts of our business.

There can be no assurance that we will be able to stabilize the declining revenue for our surgical products. Our surgical product revenue in 2016 was $32.5 million, compared with $47.6 million in 2015.

We are dependent on certain suppliers, and supply disruptions could materially adversely affect our business and future growth.

If the supply of materials from our suppliers were to be interrupted, replacement or alternative sources might not be readily obtainable. In particular, the products which together comprise our OverStitch Endoscopic Suturing System are sourced from a variety of suppliers and these suppliers further depend on many component providers. As OverStitch sales increase, we have experienced times of temporary supply disruption for a variety of reasons and this has caused delays in our fulfillment of customer orders. However, if such a condition were to persist, our business could suffer as our reputation with customers could be damaged and eventually could lead to reduced future demand for our products. An inability to continue to source materials or components from any of our suppliers could be due to reasons outside of our direct control, such as regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages at the supplier and unexpected demands or quality issues. Moreover, if we are unable to secure, or continue to secure, an approved long-term qualified supplier of certain components used in the Orbera System before we run out of our current supply, our business will be harmed.

If we are required to replace a vendor, a new or supplemental filing with applicable regulatory authorities may be required before the product could be sold with a material or component supplied by a new supplier. The regulatory approval process may take a substantial period of time and we cannot assure investors that we would be able to obtain the necessary regulatory approval for a new material to be used in products on a timely basis, if at all. This could create supply disruptions that would materially adversely affect our business. For example, in instances where we are changing our supplier of a key component of a product, we will need to ensure that we have sufficient supply of the component while the change is reviewed by regulatory authorities.

We are dependent on warehouses and service providers in the U.S., Brazil, Australia and the Netherlands for product logistics, order fulfillment and distribution support that are owned and operated by third parties. Our ability to supply products to our customers in a timely manner and at acceptable commercial terms could be disrupted or continue to be disrupted by factors such as fire, earthquake or any other natural disaster, work stoppages or information technology system failures that occur at these third party warehouse and service providers.

It is difficult to forecast future performance, which may cause operational delays or inefficiency.

We create internal operational forecasts to determine requirements for components and materials used in the manufacture of our products and to make production plans. Our limited operating history and commercial experience make it difficult for us to predict future production requirements. If we forecast inaccurately, this may cause us to have shortfalls or backorders that may negatively impact our reputation with customers and cause them to seek alternative products, or could lead us to have excessive inventory, scrap or similar operational and financial inefficiency that could harm our business.

We compete or may compete in the future against other companies, some of which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and activities of other industry participants. Many of the companies developing or marketing bariatric surgical products are publicly-traded companies such as Obalon Therapeutics, Inc. or divisions of publicly-traded companies including Johnson & Johnson and the Covidien division of Medtronic PLC. In addition, there are several privately-held companies with whom we compete, including Spatz Laboratories, Cousins BioTech and Medical Innovation Development (Midband). These companies may enjoy several competitive advantages, including:

- greater financial and human capital resources;
- significantly greater name recognition;

- established relationships with physicians, referring physicians, customers and third-party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- established sales, marketing and worldwide distribution networks.

If another company successfully develops an approach for the treatment of obesity that is less invasive or more effective than our current product offerings, including pharmacological treatment options, sales of our products would be significantly and adversely affected.

We may be unable to manage our growth effectively.

Our integration of the obesity intervention business of Allergan has provided, and our future growth may create, challenges to our organization. From the acquisition date of December 2, 2013, to December 31, 2016, the number of our employees increased from 50 to 193. In the future, should we grow, we expect to incrementally hire and train new personnel and implement appropriate financial and managerial controls, systems and procedures in order to effectively manage our growth. As a public company, we will need to further expand our financial and potentially other resources to support our public company reporting and related obligations. If we fail to manage these challenges effectively, our business could be harmed.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved or cleared for commercial sale by the FDA and manufactured in facilities regulated by the FDA, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to or are alleged to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against it. Product liability claims may be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourself against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our products or, if approved or cleared, our product candidates;
- decreased demand for our products or, if approved or cleared, product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse effect on our business.

In addition, although we maintain product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be

available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

The misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The products we currently market have been approved or cleared by the FDA for specific indications. We train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved or cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved or cleared by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

If our facilities or the facility of a supplier become inoperable, we will be unable to continue to research, develop, manufacture and commercialize our products and, as a result, our business will be harmed.

We do not have redundant facilities. We perform substantially all of our manufacturing in a single location in Costa Rica. Our manufacturing facility and equipment would be costly to replace and would require substantial lead time to repair or replace. The manufacturing facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, flooding, fire, earthquakes, volcanic activity and power outages, which may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. The inability to perform those activities, combined with our limited inventory of reserve raw materials and finished product, may result in the inability to continue manufacturing our products during such periods and the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on information technology systems for the efficient functioning of our business, including but not limited to accounting, data storage, compliance, sales operations and inventory management. A number of information technology systems in use to support our business operations are owned and/or operated by third-party service providers over whom we have no or very limited control, and upon whom we have to rely to maintain business continuity procedures and adequate security controls to ensure high availability of their information technology systems and to protect our proprietary information.

While we will attempt to mitigate interruptions, we may experience difficulties in implementing and maintaining a resilient enough information technology infrastructure which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into our information systems and may obtain our proprietary information.

Fluctuations in insurance costs and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

Our ability to maintain our competitive position depends on our ability to attract and retain highly qualified personnel.

We believe that our continued success depends to a significant extent upon our efforts and ability to retain highly qualified personnel. All of our officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business.

Many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave the Company if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate. We do not carry any "key person" insurance policies.

Risks Related to Regulatory Review and Approval of Our Products

Our products are subject to extensive regulation by the FDA, including the requirement to obtain premarket approval and the requirement to report adverse events and violations of the FDC Act that could present significant risk of injury to patients. Even though we have received FDA approval of our PMA applications and 510(k) clearances to commercially market our products, we will continue to be subject to extensive FDA regulatory oversight.

Our products are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Although FDA has granted PMA approval for our class III products, holding those approvals in good standing requires ongoing compliance with FDA reporting requirements and conditions of approval including the completion of lengthy and expensive post market approval studies. Despite the time, effort and cost required to obtain approval, there can be no assurance that we will be able to meet all FDA requirements to maintain our PMA approvals or that circumstances outside of our control may cause the FDA to withdraw our PMA approvals.

Although the FDA has granted 510(k) clearances for our Class II products, any modification to or deviation (including changes to design, manufacturing, materials, packaging and sterilization) that may affect the safety or effectiveness of a product or that constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending upon the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with the manufacturer's determination. If the FDA disagrees with our determination regarding the appropriateness of an action taken following the modification of an existing 510(k) cleared product, the FDA can require us to cease manufacturing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. In addition, FDA can impose regulatory fines or penalties for failure to undertake what FDA considers to be the appropriate action. With respect to modified 510(k) cleared products, there can be no assurance that 510(k) clearance or PMA applications for modified products will be approved or that FDA will agree with our determination that certain modifications do not require a new 510(k) clearance or a PMA application.

Our marketed products are subject to Medical Device Reporting, or MDR, obligations, which require that it report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. Adverse Events related to our products reported from any region in the world must be assessed for MDR reportability if the subject device is approved in the U.S. at the time the event occurred. As of August 5, 2015 (date of the Orbera system PMA approval), any Adverse Event related to the Orbera system reported from any region in the world must be assessed for MDR reportability

to FDA. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by the device or to address a violation of the United States Food, Drug and Cosmetic Act, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

We are also required to keep internal records of any actions we take to correct a device or to address a violation that presents a risk to health. FDA may review these records and disagree with our risk determination or actions, and request that we retrospectively submit a notice of correction and removal.

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

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

If we fail to comply with U.S. federal and state healthcare regulatory laws, we could be subject to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs and the curtailment of our operations, any of which could adversely impact our reputation and business operations.

There are numerous U.S. federal and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, physicians, hospitals, ambulatory surgery centers, group purchasing organizations and our international distributors are subject to scrutiny under these laws. Violations of these laws can subject us to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that

are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented, a claim to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;

- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;

- the federal Foreign Corrupt Practices Act of 1997, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and

- foreign or U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

While we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting agreements with physicians, including some who influence the ordering of and use our products in procedures they perform. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. The medical device industry's relationship with physicians is under increasing scrutiny by the Department of Health and Human Services Office of Inspector General ("OIG"), the Department of Justice ("DOJ"), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies could significantly harm our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, physicians, hospitals, ambulatory surgery centers, group purchasing organizations and our independent distributors and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to onerous additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting off-label uses of their products. Pursuant to FDA regulations, we can only market our products for

cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA in their professional medical judgment, we are prohibited from promoting products for off-label uses. We market our products and provide educational and promotional materials and training programs to physicians regarding the use of our products. If it is determined that our business activities, including our marketing, educational and promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In certain cases, actions to pursue claims under the False Claims Act may be brought by private individuals on behalf of the government. These lawsuits are known as "qui tam" actions and the individuals bringing such suits, sometimes known as "relators" or, more commonly, "whistleblowers" may share in any amounts paid by the entity to the government in fines or settlement. In March 2017, we were informed by the Department of Justice that the Company is a subject in a federal False Claims Act investigation. The government's investigation concerns whether there has been or is a violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. related to our marketing of the Lap-Band System, including the web-based physician locator provided on our website Lap-Band.com. We believe the investigation covers the period before and after our acquisition of the obesity intervention division of Allergan, Inc. in December 2013. We are cooperating fully with the investigation, but we cannot predict the outcome of the investigation or the effect of the findings of the investigation on our business, but it is possible that the foregoing matter could result in a material adverse effect on our business, reputation, results of operation and financial condition.

In addition, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The ACA's provision commonly referred to as the Physician Payment Sunshine Act imposes annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Most of these laws apply to not only the actions taken by us, but also actions taken by our distributors. We have limited knowledge and control over the business practices of our distributors, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of the Company, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive reimbursement practices of third-party payors could decrease the demand for our products, the prices that customers are willing to pay and the number of procedures performed using our products, which could have an adverse effect on our business.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. These cost-control methods include prospective payment systems, bundled payment models, capitated arrangements, group purchasing, benefit redesign, pre-authorization processes and requirements for second opinions prior to major surgery. These cost-control methods also potentially limit the amount that healthcare providers may be willing to pay for medical devices. Therefore, coverage or reimbursement for medical devices may decrease in the future.

Federal and state governments in the United States have enacted legislation to overhaul the nation's healthcare system that has resulted in increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. President Trump ran for office on a platform that supported the repeal of the ACA and one of his first actions after his inauguration was to sign an Executive Order commanding federal agencies to try to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that impose fiscal or regulatory burdens on states, individuals, families, the health-care industry and others. The Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the states more flexibility and control to create a more free and open healthcare market." At this time, it is not clear whether the ACA will be repealed in its entirety, whether it will be replaced in whole or in part by another plan, and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. 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 payors are willing to pay. These changes could result in reduced demand for our product candidates once approved or additional pricing pressures, and may adversely affect our operating results.

Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. In cases where the cost of certain of our products are recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed or paid directly by the patient, these updates could directly impact the demand for our products. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business.

If we materially modify our FDA-approved or cleared products, we may need to seek and obtain new approvals or clearances, which, if not granted, would prevent us from selling our modified products.

A component of our strategy is to continue to modify and upgrade our products. Medical devices can be marketed only for the indications for which they are approved or cleared. FDA grants approvals or clearances based on the product information (e.g., design specifications, component suppliers / materials, manufacturing and quality control processes) provided for review in support of the 510(k) or PMA submission. We may not be able to obtain additional regulatory approvals or clearances for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future approvals or clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. If we determine that a modification to a product does not require any additional approval or clearance, the FDA can review such decision and may disagree with our determination. The FDA may require a new 510(k) clearance or PMA approval, may require us to cease manufacturing or recall the modified product and may impose significant fines or penalties that would harm our business and reputation.

Our international operations present certain legal and operating risks, which could adversely impact our business, results of operations and financial condition.

We currently operate in the U.S., Canada, Brazil, Costa Rica, Australia and key European markets and our products are approved for sale in over 80 different countries; our activities are subject to U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance.

Other laws and regulations that can significantly impact the Company include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws and economic sanctions laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant costs and disruption of business associated with an internal and/or government investigation, criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations present the same risks as presented by our United States operations plus unique risks inherent in operating in foreign jurisdictions. These unique risks include:

- foreign regulatory approval which could result in delays leading to possible insufficient inventory levels;
- foreign currency exchange rate fluctuations;
- reliance on sales people and distributors;
- pricing pressure that we may experience internationally;

- competitive disadvantage to competitors who have more established business and customer relationships in a given market;
- reduced or varied intellectual property rights available in some countries;
- economic instability of certain countries;
- the imposition of additional U.S. and foreign governmental controls, regulations and laws;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on the Company; and
- laws and business practices favoring local companies.

If we experience any of these events, our business, results of operations and financial condition may be harmed.

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain approval or clearance, and the manufacturing processes, reporting requirements, post-market clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers are required to comply with the QSR. The QSR covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements in the United States or experience delays in obtaining necessary regulatory approvals or clearances, this could delay production of our products and lead to fines, difficulties in obtaining regulatory approvals or clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by the Company or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in a failure to produce our products on a timely basis and in the required quantities, if at all.

Our products and operations are required to comply with standards set by foreign regulatory bodies, and those standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to comply with any of these standards adequately or if changes to our manufacturing or supply practices require additional regulatory approval, a foreign regulatory body may take adverse actions or cause delays within their jurisdiction similar to those within the power of the FDA. Any such action or circumstance may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in their respective jurisdictions in the event of material deficiencies or defects in the design or manufacture of our products. We may, under our own initiative, recall a product if any material deficiency in our products is found. The FDA requires that recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by the Company or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require that we report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. For example, two fluid filled intragastric balloons, including our Orbera System, have been the subject of an FDA announcement that a) adverse event reports of spontaneous inflation and, in separate instances, b) adverse event reports of an occurrence of acute pancreatitis have been received. If these adverse events occur more frequently or other serious adverse effects are detected in fluid filled intragastric balloons, our product may be subject to adverse FDA action, which could harm our business. In addition, the FDA could take enforcement action for failing to report any recalls when they were conducted.

If the third parties on which we rely to conduct our clinical trials and to assist us with post market studies do not perform as contractually required or expected, we may not be able to maintain regulatory approval for our products.

We often must rely on third parties, such as medical institutions, clinical investigators, contract research organizations and contract laboratories to conduct our clinical trials and provide data or prepare deliverables for our PMA post market studies required to support our PMA approvals. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to applicable clinical protocols or regulatory requirements or for other reasons, our clinical activities or clinical trials may be extended, delayed, suspended or terminated, and we may be at risk of losing our regulatory approvals, which could harm our business.

Our operations involve the use of hazardous and toxic materials, and we must comply with environmental laws and regulations, which can be expensive, and may affect our business and operating results.

We are subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal and human exposure to hazardous materials. Liability under environmental laws can be joint and several and without regard to comparative fault, and environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could harm our business. Although we believe that our activities conform in all material respects with environmental laws, there can be no assurance that violations of environmental and health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. The failure to comply with past, present or future laws could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have a material adverse effect on our business.

Failure to comply with the United States Foreign Corrupt Practices Act and similar laws associated with any activities outside the United States could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act ("FCPA") and other anti-bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, 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 may face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, some of which represent significant markets for us, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees, distributors, consultants and agents to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. There can be no assurance that our employees, distributors, consultants and agents, or those companies to which we outsource certain of our business operations will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could have a material and adverse effect on our reputation, business, operating results and financial condition.

Risks Related to Our Intellectual Property

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

Our success depends significantly on our ability to protect our proprietary rights to the technologies and inventions used in, or embodied by, our products. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality and other contractual restrictions in our consulting and employment agreements. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Patents

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that all of our patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage and they could be opposed, contested or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings.

We own numerous issued patents and pending patent applications that relate to our products, as well as individual components of our products. If any of our patents are challenged, invalidated or legally circumvented by third parties, and if we do not own other enforceable patents protecting our products, competitors could market products and use processes that are substantially similar to, or superior to, ours, and our business will suffer. In addition, the patents we own may not be sufficient in scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes comparable to ours without infringing on our intellectual property rights.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act ("the Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office ("USPTO"), developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications.

We may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to

commercialize our technology or products and compete directly with us, without payment to the Company, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Moreover, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

Furthermore, we do not have patent rights in certain foreign countries in which a market may exist in the future, and the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products.

Trademarks

We rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. Our trademark applications may not be approved, however. For example, we have pending LapBand trademark registration actions in Australia, Canada, Costa Rica, India, Norway, Switzerland and Thailand where the distinctiveness of the LapBand trademark has been challenged and where trademark registration may not be granted or maintained. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Trade Secrets and Know-How

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

Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

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

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Additionally, the bariatric market is extremely competitive. Our competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our products. In the event that we become involved in such a dispute, we may incur significant costs and expenses and may need to devote resources to resolving any claims, which would reduce the cash we have available for operations and may be distracting to management. We do not know whether our competitors or potential competitors have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our products.

Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries. We may also initiate litigation against third parties to protect our own intellectual property. Most of our intellectual property has not been tested in litigation. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages and attorneys' fees, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our products unless we can obtain licenses to use technology or ideas covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon our products altogether. As a result, our ability to grow our business and compete in the market may be harmed.

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

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Capital Requirements and Finances

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.

Our ability to continue as a going concern may require it to obtain additional financing to fund our operations. We may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations and clinical studies;
- continue our research and development activities;
- support and expand ongoing manufacturing activities;
- defend, in litigation or otherwise, any claims that it infringes third-party patents or other intellectual property rights;
- enforce our patent and other intellectual property rights;
- address legal or enforcement actions by the FDA or other governmental agencies and remediate underlying problems;
- commercialize our new products in development, if any such products receive regulatory clearance or approval for commercial sale; and
- acquire companies or products and in-license products or intellectual property.

We believe that our existing cash and cash equivalents, revenue, proceeds from prior funding and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations at least through December 2017. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the scope, rate of progress and cost of our clinical studies;

- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that our product infringes third-party patents or other intellectual property rights;
- the cost of defending, in litigation or otherwise, products liability claims;
- the cost and timing of additional regulatory clearances or approvals;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs.

We cannot be certain that additional funding will be available on acceptable terms, if at all. 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. Any of these factors could harm our operating results.

Our outstanding debt financing arrangements contain restrictive covenants that may limit our operating flexibility.

Our outstanding debt facility with Athyrium Opportunities II Acquisition LP is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent of the lenders. We cannot assure you that we will be able to generate sufficient cash flows or revenue to meet the financial covenants or pay the principal and interest on our debt. Furthermore, we cannot assure you that future working capital, borrowings or equity financing will be available to repay or refinance any such debt.

Risks Related To Ownership Of Our Common Stock

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage medical device, pharmaceutical and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- a slowdown in the medical device industry or the general economy;
- inability to obtain adequate supply of the components for any of our products, or inability to do so at acceptable prices;
- performance of third parties on whom the we may rely, including for the manufacture of the components for our product, including their ability to comply with regulatory requirements;
- the results of our current and any future clinical trials of our devices;

- unanticipated or serious safety concerns related to the use of any of our products;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by us, our commercial partners or our competitors of new products or product enhancements, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- competition from existing technologies and products or new technologies and products that may emerge;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who may cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the low trading volume and the high proportion of shares held by affiliates;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and The NASDAQ Stock Market LLC. Our executive officers and other personnel will need to devote substantial time to these rules and regulations. These rules and regulations are expected to increase our legal and financial compliance costs and to make some other activities more time-consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of the Company, which may adversely affect investor confidence and could cause our business or stock price to suffer.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove Company management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future. In addition, our ability to pay dividends is limited by covenants in our credit agreement. Additionally, we are a holding company, and our ability to pay dividends will be dependent upon our subsidiaries' ability to make distributions, which may be restricted by covenants in our credit agreement or any future contractual obligations.

Future sales and issuances of our common stock or other securities may result in significant dilution or could cause the price of our common stock to decline.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, if certain of our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We also expect that additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The ownership of our common stock will be initially highly concentrated, and may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

As of December 31, 2016, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

The limited public float and trading volume for our common stock may have an adverse impact and cause significant fluctuation of market price.

Our common stock is held by a relatively small number of stockholders. Our officers, directors, and members of management acquire stock or have the potential to own stock through previously granted equity awards. Consequently, our common stock has a relatively small float and low average daily trading volume, which could affect a stockholder's ability to sell our stock or the price at which it can be sold. In addition, future sales of substantial amounts of our common stock in the public market by those larger stockholders, or the perception that these sales could occur, may adversely impact the market price of the stock and our stock could be difficult for a stockholder to liquidate.

There can be no assurance that an active trading market for our common stock will be sustained in the future. The lack of an active trading market may make it more difficult for you to sell our shares and could lead to our share price being depressed or more volatile.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located in an 18,388 square foot facility in Austin, Texas. The term of the lease for our Austin facility extends through August 31, 2018. Our principal office in Austin houses research and development, sales, marketing, finance and administrative activities. We operate an approximately 18,200 square foot manufacturing facility in the Coyol Free Trade Zone in Alajuela, Costa Rica that performs final assembly for the Lap-Band and Orbera products. Beginning in 2016, we started producing components related to the OverStitch product line in our Costa Rica facility. The term of the lease for our Costa Rica facility extends through September 30, 2021. Additionally, we have a R&D facility in Austin, Texas and a device analysis lab in Carpinteria, California. We believe that our facilities are currently adequate for our needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in legal proceedings. The results of such legal proceedings and claims cannot be predicted with certainty, and regardless of the outcome, legal proceedings could have an adverse impact on our business because of defense and settlement costs, diversion of resources and other factors.

Federal False Claims Act Investigation

In March 2017, we were informed by the Department of Justice that the Company is a subject in a federal False Claims Act investigation. The government's investigation concerns whether there has been or is a violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. related to the marketing of the Lap-Band System, including the web-based physician locator provided on our website Lap-Band.com. We believe the investigation covers the period before and after our acquisition of the obesity intervention division of Allergan, Inc. in December 2013. We are cooperating fully with the investigation, but we cannot predict the outcome of the investigation or the effect of the findings of the investigation on our business, but it is possible that the foregoing matter could result in a material adverse effect on our business, reputation, results of operation and financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

On December 29, 2016, Apollo Endosurgery Inc. and Lpath, Inc. completed the Merger. Immediately following the Merger, we completed a 1-for-5.5 reverse stock split. Following the Merger, we changed the name of the combined company to Apollo Endosurgery, Inc. and changed the symbol to "APEN." Lpath, Inc. common stock originally began trading on The NASDAQ Global Market on January 11, 2007. Prior to January 11, 2007, there was no public market for Lpath, Inc. common stock. The following table sets forth the high and low sales prices per share of the combined company's common stock as reported on The NASDAQ Global Market for the period indicated, adjusted for the reverse stock split.

	Price Range	
	High	Low
Year Ended December 31, 2016		
First Quarter	$ 18.48	$ 10.79
Second Quarter	32.34	9.91
Third Quarter	22.27	9.24
Fourth Quarter	20.62	11.00
Year Ended December 31, 2015		
First Quarter	$ 288.82	$ 170.93
Second Quarter	192.49	17.71
Third Quarter	27.72	13.89
Fourth Quarter	24.64	12.32

Holders of Record

As of February 28, 2017, there were approximately 139 stockholders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never paid or declared any cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future, and we intend to retain all available funds and any future earnings to fund the development and expansion of our business. In addition, our ability to pay dividends is limited by covenants in our credit agreement. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

On October 7, 2016 Lpath issued 27,875 shares of Lpath common stock as consideration for and in connection with a fee reimbursement pursuant to a letter agreement. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 4(a)(2) of the Securities Act.

ITEM 6. SELECTED FINANCIAL DATA

This item has been omitted as we qualify as a smaller reporting company.

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

You should read the following discussion and analysis in conjunction with our consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K and those discussed in other documents we file with the SEC. In light of these risks, uncertainties, and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward-looking statements represent beliefs and assumptions only as of the date of this Annual Report on Form 10-K. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this Annual Report on Form 10-K to reflect future events or circumstances.

Recent Developments

On December 29, 2016, we completed our business combination with Lpath in accordance with the terms of the Merger Agreement, dated September 8, 2016. Following the merger, Lpath was renamed "Apollo Endosurgery, Inc." and began trading on The NASDAQ Global Market under the symbol "APEN."

Overview

We are a medical technology company primarily focused on the design, development and commercialization of innovative medical devices that can be used for the interventional treatment of obesity. We develop and distribute minimally invasive surgical products for bariatric and gastrointestinal procedures that are used by general surgeons, bariatric surgeons and gastroenterologists in a variety of settings to provide interventional therapy to patients who suffer from obesity and the many co-morbidities associated with obesity.

Our strategic focus and the majority of our future revenue growth is expected to come from our Endo-bariatric product portfolio, which consists of the Orbera and OverStitch systems. Historically, the majority of our revenues have come from surgical product sales although in 2016 endo-bariatric product sales reached just under 50% of total revenues.

On December 2, 2013, we entered into an asset purchase agreement to acquire the obesity intervention division of Allergan, Inc. In conjunction with this purchase agreement, we entered into several agreements whereby Allergan agreed to provide manufacturing and distribution support over a two year period as we established our own manufacturing and worldwide distribution capabilities.

From December 2, 2013, we proceeded to establish capabilities and transfer responsibility for a variety of activities related to the acquired Allergan business. Significant milestones during the transition period included:

- transfer of United States sales force in December 2013;
- transfer of United States distribution in September 2014;
- transfer of Europe, Canada and Australia sales force and distribution in November 2014;
- transfer of most worldwide regulatory activities in December 2014;
- transfer of product surveillance activities in October 2015;
- transfer of Brazilian sales and distribution activities in November 2015; and
- start of Costa Rica manufacturing operations in June 2016.

As a result of these transition activities, we have established sales distribution offices in England, Australia and Brazil that oversee regional sales and distribution activities outside the United States, a products manufacturing facility in Costa Rica and a device analysis lab in California. All other activities are managed and operated from facilities in Austin, Texas.

Financial Operations Overview

Revenues

Our principal source of revenues has come from and is expected to continue to come from sales of our endo-bariatric products and our surgical products. In our direct markets, product sales are made to end customers by our employed sales representatives or independent sales agents. In other markets, we sell our products to distributors who resell our products to end

customers. Revenues between periods will be impacted by several factors, including physician procedures and therapy preferences, patient procedures and therapy preferences, other market trends, the stability of the average sales price we realize on products and changes in foreign exchange rates used to translate foreign currency denominated sales into U.S. dollars.

Our Endo-bariatric sales grew 86.4% in 2016 compared to 2015 and 270% in 2015 compared to 2014 due to the introduction of the Orbera intra-gastric balloon system in the U.S. market following approval by the FDA in August 2015, transition of direct sales activity from Allergan in Europe, Australia and Canada in the fourth quarter of 2014 and in Brazil in the fourth quarter of 2015 and increased sales of the OverStitch endoscopic suturing system. We cannot predict the future growth rate of our Endo-bariatric sales as we continue to launch Orbera and Overstitch in our direct and distributor markets.

Cost of Sales

Historically, we have relied on third-party suppliers to manufacture our products. However, since June 2016 the products which comprise the majority of our revenue are manufactured in our Costa Rica facility. Our historical cost of sales primarily consist of costs of products purchased from our third-party suppliers, excess and obsolete inventory charges, royalties, shipping, inspection and related cost incurred in making our products available for sale or use. Our historical cost of sales also includes certain start-up costs associated with establishing our Costa Rica facility. As our Costa Rica facility begins manufacturing, costs include raw materials, labor, manufacturing overhead and other direct costs. Raw materials used to produce our products are generally not subject to substantial commodity price volatility and most of our product manufacturing costs are incurred in U.S. dollars. Manufacturing overhead is a significant portion of our cost of sales and is generally a fixed cost. Cost of sales could vary as a percentage of revenue between periods as a result of manufacturing rates and the degree to which manufacturing overhead is allocated to production during the period. As we move towards manufacturing our own products, overhead costs may be higher than the costs we acquired inventory from third parties in the past due to different economies of scale. Additionally, gross margin will be impacted by the shift in our revenue mix from low-growth potential but high gross margin surgical products to lower gross margin but high-growth potential endo-bariatric products. As our revenue continues to shift between our product portfolios, our gross margin will likely experience some intervening pressure. Comparability of cost of sales between periods could also be affected by any inventory valuation allowances related to obsolete or excess inventory.

Sales and Marketing Expense

Sales and marketing expense primarily consists of salaries, commissions, benefits and other related costs, including stock-based compensation, for personnel employed in our sales, marketing and medical education departments. In addition, our sales and marketing expense includes costs associated with advertising, industry events and other promotional activities. In 2015, sales and marketing expense also included excise tax of 2.3% on the sale of medical devices in the U.S. This tax was suspended in December of 2015.

General and Administrative Expense

General and administrative expense primarily consists of salaries, benefits and other related costs, including stock-based compensation, for personnel employed in corporate management, finance, legal, compliance, administrative, information technology and human resource departments. General and administrative expense also includes facilities cost, insurance, bad debt expense and legal expenses related to the development and protection of our intellectual property portfolio. We expect our general and administrative expense to increase in 2017, including increased payroll, consulting, legal, accounting and investor relations expenses associated with being a public company.

Research and Development Expense

Research and development expense include product development, clinical laboratory and vendor experts related to the execution of clinical trials, quality and regulatory compliance, consulting services, outside prototyping services, outside research activities, materials, depreciation and other costs associated with development of our products. Research and development expense also includes related personnel and consultants' compensation and stock-based compensation expense. Research and development expense will fluctuate between periods dependent on the activity in the period associated with our various product development and clinical obligations.

Intangible Amortization

Definite-lived intangible assets primarily consist of customer relationships, product technology, trade names, patents and trademarks purchased in connection with the Allergan asset acquisition. Intangible assets are amortized over the asset's estimated useful life.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which management has prepared in accordance with existing U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. Management evaluates estimates and judgments on an ongoing basis. Estimates relate to aspects of our revenue recognition, useful lives with respect to intangible and long-lived assets, inventory valuation, deferred tax asset valuation and allowances for doubtful accounts. We base our estimates on historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

The critical accounting policies addressed below reflect our most significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our principal source of revenues is from the sale of our products to hospitals, physician practices and distributors. We utilize a network of employee sales representatives in the U.S. and a combination of employee sales representatives, independent agents and distributors in markets outside the United States ("OUS"). Revenue is recognized when pervasive evidence of an arrangement exists, fees are fixed or determinable, collection of the fees is reasonably assured, and delivery or customer acceptance of the product has occurred and no other significant obligations remain. Generally, these conditions are met upon product shipment. Customers generally have the right to return or exchange products purchased from us for up to ninety days from the date of product shipment. Distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at the time of shipment. Our distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. At the end of each period, we determine the extent to which our revenues need to be reduced to account for expected returns and exchanges and a reserve is recorded against revenue recognized. Our policy is to classify shipping and handling cost billed to customers as revenue and the related expenses as cost of sales.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are at the invoiced amount less an allowance for doubtful accounts. On a regular basis, we evaluate accounts receivable and estimate an allowance for doubtful accounts, as needed, based on various factors such as customers' current credit conditions, length of time past due and the general economy as a whole. We write off receivables against the allowance when they are deemed uncollectible.

Inventory

Inventory is stated at the lower of cost or market, net of any allowance. Charges for excess and obsolete inventory are based on specific identification of excess and obsolete inventory items and an analysis of inventory items approaching expiration date. We evaluate the carrying value of inventory in relation to the estimated forecast of product demand. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. When quantities on hand exceed estimated sales forecasts, we record estimated excess and obsolescence charges to cost of sales. Our inventories are stated using the weighted average cost approach, which approximates actual costs.

Intangible and Long-lived Assets

Definite-lived intangible assets consist of customer relationships, product technology, trade names, patents and trademarks which are amortized over their estimated useful lives.

Long-lived assets, including definite-lived intangible assets, are monitored and reviewed for impairment whenever events or circumstances indicate that the carrying value of any such asset may not be recoverable. The determination of recoverability is based on an estimate of undiscounted cash flows expected to result from the use of an asset and its eventual disposal. The estimate of undiscounted cash flows is based upon, among other things, certain assumptions about expected future operating performance. Our estimates of undiscounted cash flows may differ from actual cash flows. If the sum of the undiscounted cash flows is less than the carrying value of the asset, an impairment charge is recognized, measured as the amount by which the carrying value exceeds the fair value of the asset.

Income Taxes

We account for deferred income taxes using the asset and liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more-likely than-not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

In the ordinary course of business, there are many transactions for which the ultimate tax outcome is uncertain. We regularly assess uncertain tax positions in each of the tax jurisdictions in which it has operations and accounts for the related consolidated financial statement implications. The amount of unrecognized tax benefits is adjusted when information becomes available or when an event occurs indicating a change is appropriate. We include interest and penalties related to our uncertain tax positions as part of income tax expense.

Results of Operations

Comparison of the Years Ended 2016 and 2015

	Year Ended December 31, 2016		Year Ended December 31, 2015	
	Dollars	% of Revenue	Dollars	% of Revenue
Revenues	$ 64,868	100.0 %	$ 67,790	100.0 %
Cost of sales	25,255	38.9	20,510	30.3 %
Gross margin	39,613	61.1	47,280	69.7 %
Operating expenses:				
Sales and marketing	31,751	48.9	36,167	53.4 %
General and administrative	13,625	21.0	11,412	16.8 %
Research and development	7,805	12.0	9,558	14.1 %
Amortization of intangible assets	7,193	11.1	6,826	10.1 %
Total operating expenses	60,374	93.1	63,963	94.4 %
Loss from operations	(20,761)	(32.0)	(16,683)	(24.6)%
Interest expense, net	18,168	28.0	10,036	14.8 %
Other expense	1,851	2.9	663	1.0 %
Net loss before income taxes	(40,780)	(62.9)	(27,382)	(40.4)%
Income tax expense	387	0.6	49	0.1 %
Net loss	$ (41,167)	(63.5)	$ (27,431)	(40.5)%

Revenues

Product sales by product group and geographic market for the periods shown were as follows:

	Year Ended December 31, 2016				Year Ended December 31, 2015			
	U.S.	OUS	Total Revenue	% Total Revenue	U.S.	OUS	Total Revenue	% Total Revenue
Endo-bariatric	$ 15,525	$ 16,382	$ 31,907	49.2%	$ 9,119	$ 8,003	$ 17,122	25.3%
Surgical	21,778	10,706	32,484	50.1%	34,975	12,628	47,603	70.2%
Other	453	24	477	0.7%	425	2,640	3,065	4.5%
Total revenues	$ 37,756	$ 27,112	$ 64,868	100.0%	$ 44,519	$ 23,271	$ 67,790	100.0%
% Total revenue	58.2%	41.8%			65.7%	34.3%		

Endo-bariatric product sales increased $14.8 million, or 86.4%, in 2016 compared to 2015. In the U.S., sales increased $6.4 million, or 70.2%, in 2016 compared to 2015 primarily due to both the introduction of the Orbera intra-gastric balloon system in the U.S. market following approval by the FDA in August 2015 and increased sales of the OverStitch endoscopic suturing system. In OUS markets, sales increased $8.4 million or 104.7%, in 2016 compared to 2015 primarily due to the start

of Brazil direct sales activity to us following the transition of this market activity from Allergan in November 2015 and increased OverStitch sales by our direct and distributor markets.

Surgical product sales decreased $15.1 million, or 31.8%, in 2016 compared to 2015. In the U.S., surgical product sales declined $13.2 million or 37.7%, in 2016 compared to 2015 due to the decline in gastric banding procedures being performed in the U.S. and the loss of a significant customer in the U.S. following that customer's acquisition by a third party. The significant customer represented 13% of U.S. surgical sales in the year ended December 31, 2015. In OUS markets, surgical product sales declined by $1.9 million, or 15.2%, for 2016 compared to 2015 due to the decline in gastric banding procedures being performed.

Other revenues during 2015 primarily represented fees received from Allergan under our distribution services arrangement while we established our own distribution capabilities. Other revenues decreased by $2.6 million, or 84.4%, in 2016 compared to 2015 due to the cessation of these distribution services in November of 2015. Other revenues in 2016 consisted mostly of freight charges invoiced to customers.

Gross Margin

Gross margin as a percentage of revenues was 61.1% for 2016 compared to 69.7% for 2015. During the year ended December 31, 2016, we recorded an inventory impairment charge of $3.8 million related to expiring finished goods inventory and excess raw materials transferred from Allergan in June 2016 that we were required to purchase in accordance with the transition services agreement. Excluding the impact of the inventory impairment, gross margin as a percentage of revenues was 66.8%. The remaining decline in gross margin results from the planned change in product mix to our endo-bariatric products that carry lower margins compared to our surgical products.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense decreased $4.4 million to 48.9% of total revenue in 2016 from 53.4% in 2015. Approximately $3.5 million of the reduction in sales and marketing expense was due to a reduction of our sales and marketing personnel, lower travel and reduced professional services spending following the completion of integration activities. The remainder of the decrease in sales and marketing expense is due to the suspension at the end of 2015 of the medical device tax originally imposed by the Affordable Care Act.

General and Administrative Expense. General and administrative expense included $3.6 million of transaction costs associated with the Lpath merger. This one-time cost increase is offset by $1.3 million of reduced professional services and travel costs associated with cost saving initiatives in 2016 following completion of the integration activities.

Research and Development Expense. Research and development expense decreased $1.8 million, or 18.3%, in 2016 compared to 2015 primarily due to the elimination of research and development charges paid to Allergan under the transition services agreements which expired in December 2015, lower contracted services, and a reduction in quality and regulatory personnel following the completion of the integration activities in December 2015.

Amortization of Intangible Assets. Amortization of intangible assets increased $0.4 million, or 5.4%, in 2016 compared to 2015 due to increased investment in patent and trademark activities and capitalized software costs.

Interest Expense. Interest expense increase of $8.1 million, or 81.0%, in 2016 compared to 2015 is primarily due to $8.7 million of non-cash interest associated with the resolution of contingent beneficial conversion features related to the convertible notes upon their conversion into common stock in December 2016. Additionally, interest expense in both periods includes additional costs in the form of early payment fees, debt issuance cost amortization, amortization of beneficial conversion features, and changes in the fair value of warrants issued in connection with our debt instruments. The amount expensed for these items in 2015 was $0.6 million higher compared to 2016 primarily due to changes in the fair value of our warrants.

Other Expense. Other expense primarily consists of realized and unrealized foreign exchange gains or losses. The increase in other expense of $1.2 million, or 179.2%, in 2016 compared to 2015 was primarily caused by the movement in exchange rates on short-term intercompany loans denominated in U.S. dollars payable by our foreign subsidiaries. Unrealized losses on exchange rates were $1.3 million and $0.5 million in 2016 and 2015, respectively.

Income Tax Expense. Income tax expense was $0.4 million in 2016 compared to $0 million in 2015. We established a valuation allowance equal to the total net deferred tax assets due to our lack of earnings history. Tax expense in 2016 and 2015 relates to foreign income taxes on earnings generated in our foreign subsidiaries. We began our OUS sales and distribution activities in December 2014.

Comparison of the Years Ended December 31, 2015 and 2014

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Dollars	% of Revenue	Dollars	% of Revenue
Revenues	$ 67,790	100.0 %	$ 69,998	100.0 %
Cost of sales	20,510	30.3 %	21,843	31.2 %
Gross margin	47,280	69.7 %	48,155	69.7 %
Operating expenses:				
Sales and marketing	36,167	53.4 %	35,032	53.4 %
General and administrative	11,412	16.8 %	10,313	14.7 %
Research and development	9,558	14.1 %	8,826	12.6 %
Amortization of intangible assets	6,826	10.1 %	6,258	8.9 %
Reversal of accrued contingent consideration	—	— %	(4,320)	(6.2)%
Total operating expenses	63,963	94.4 %	56,109	80.2 %
Loss from operations	(16,683)	(24.6)%	(7,954)	(11.4)%
Interest expense, net	10,036	14.8 %	5,131	7.3 %
Other expense	663	1.0 %	310	0.4 %
Net loss before income taxes	(27,382)	(40.4)%	(13,395)	(19.1)%
Income tax expense	49	0.1 %	—	— %
Net loss	$ (27,431)	(40.5)%	$ (13,395)	(19.1)%

Product Sales

Product sales by product group and geographic market for the periods shown were as follows:

	Year Ended December 31, 2015				Year Ended December 31, 2014			
	U.S.	OUS	Total Revenue	% Total Revenue	U.S.	OUS	Total Revenue	% Total Revenue
Endo-bariatric	$ 9,119	$ 8,003	$ 17,122	25.3%	$ 3,641	$ 983	$ 4,624	6.6%
Surgical	34,975	12,628	47,603	70.2%	51,742	2,616	54,358	77.7%
Other	425	2,640	3,065	4.5%	490	10,526	11,016	15.7%
Total revenues	$ 44,519	$ 23,271	$ 67,790	100.0%	$ 55,873	$ 14,125	$ 69,998	100.0%
% Total revenue	65.7%	34.3%			79.8%	20.2%		

Endo-bariatric product sales increased by $12.5 million, or 270%, in 2015 compared to 2014. U.S. sales increased $5.5 million, or 150%, due to higher sales of our Orbera intra-gastric balloon system following our FDA approval in August 2015 and increased OverStitch sales. The $7.0 million increase in OUS sales was due to the transition of direct sales activity from Allergan in Europe, Australia and Canada in the fourth quarter of 2014 and in Brazil in the fourth quarter of 2015. OUS sales also increased due to higher OverStitch sales in our direct markets.

Surgical product sales decreased $6.8 million, or 12.4%, in 2015 compared to 2014 as a result of a decline in gastric banding procedures being performed in the United States which is due to loss of market share to sleeve gastrectomy and gastric bypass procedures. This decline was partially offset by the transition of direct sales activity from Allergan in Europe, Australia and Canada in the fourth quarter of 2014.

Other revenues includes license fees received from Allergan associated with the distribution of our products in most OUS markets during the majority of 2014 and for certain Latin American markets for the majority of 2015 as required under the transition services agreement between us and Allergan. Other revenue in 2015 primarily consists of machine shop billings for external customer projects and freight charges invoiced to customers.

Gross Margin

Gross margin as a percentage of revenues was 69.7% for 2015 compared to 68.8% for 2014. Costs of sales was $20.5 million for 2015 compared to $21.8 million for 2014. Cost of sales in 2014 included $7.6 million related to the amount of

the Allergan purchase price allocated to inventory which was sold during the year. Cost of sales in 2015 included $6.3 million due to the start-up cost for the Costa Rica manufacturing facility and additional shipping and warehousing costs due to the transfer of OUS direct sales and distribution activities in December 2014.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense increased $1.1 million, or 3.2%, in 2015 compared to 2014 due to an increase in sales and marketing personnel costs OUS resulting from the transition of direct sales activity in Europe, Canada and Australia to us from Allergan in the fourth quarter of 2014, partially offset by lower U.S. sales compensation and lower spending on U.S. Lap-Band direct to consumer marketing campaigns.

General and Administrative Expense. General and administrative expense increased $1.1 million, or 10.7%, in 2015 compared to 2014 due to the establishment of supporting OUS infrastructure upon completion of the transition of direct sales activity in Europe, Canada and Australia to us from Allergan in the fourth quarter of 2014.

Research and Development Expense. Research and development expense increased $0.7 million, or 8.3%, in 2015 compared to 2014 primarily due to activities supporting the integration of products acquired from Allergan into our quality system, transferring regulatory clearances from Allergan to us, and supporting manufacturing transfer activities.

Amortization of Intangible Assets. Intangible amortization increased by $0.6 million, or 9.1%, in 2015 compared to 2014 due to increased investment in capital software and patent and trademark activities.

Reversal of Accrued Contingent Consideration. Previously accrued contingent purchase price consideration related to the Allergan acquisition was reversed in 2014 based on our determination that the required Lap-Band future revenue performance thresholds would not be achieved.

Interest Expense

Interest expense increased to $10.0 million in 2015 from $5.1 million for 2014. Interest expense for 2015 included $3.2 million in prepayment charges related to refinancing our long-term debt in February and the write-off of unamortized debt issue cost and discount. The remaining increase in interest expense is primarily due to $1.3 million of beneficial conversion feature amortization related to the July 2015 issuance of $22.2 million of convertible notes and non-cash interest of $0.5 million associated with these notes.

Other Expense

Other expense primarily consists of realized and unrealized foreign exchange gains and losses. Realized losses on foreign exchange were $0.1 million for each of 2015 and 2014.

Income Tax Expense

Income tax expense was $0.1 million for 2015 compared to no expense for 2014. We have established a valuation allowance equal to total net deferred tax assets due to our lack of earnings history. Tax expense in 2015 relates to income generated in our OUS tax jurisdictions. We began our OUS sales and distribution activities in December 2014.

Liquidity and Capital Resources

On December 29, 2016, we completed our business combination with Lpath, Inc. ("Lpath"), a publicly held company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated September 8, 2016 (the "Merger"). Under the terms of the Merger Agreement, each share of our common stock was converted into Lpath common stock at an exchange rate of approximately 0.3163 per share ("Exchange Ratio") and the $0.0001 par value of our common stock was adjusted to the Lpath $0.001 par value. Immediately following the Merger, the Company effected a reverse stock split at a ratio of one new share for every five and one-half shares of our common stock outstanding (the "1:5.5 Reverse Stock Split"). No fractional shares were issued and instead, stockholders received cash in the amount they would have been entitled to receive.

We have experienced significant losses and cumulative negative cash flows from operations since our inception and have an accumulated deficit of $149.7 million as of December 31, 2016. From our inception, we have financed our operations primarily through private equity offerings and issuance of debt instruments. Through December 31, 2016, we have received $29.0 million from the sale of common stock, $127.1 million from the sale of redeemable preferred stock, $22.2 million from the sale of convertible notes and $50.0 million from the issuance of senior debt. In connection with the Merger, all of the common stock, redeemable preferred stock and convertible notes of the Company were converted to Lpath common stock.

Senior Secured Credit Facility

In February 2015, we entered into a senior secured credit facility (the "Credit Agreement") with Athyrium Opportunities II Acquisition LP ("Athyrium") to borrow $50.0 million which is due in February 2020. The facility bears interest at 10.5% annually including 3.5% payment-in-kind during the first year. An additional 2% of the outstanding amount will be due upon prepayment or repayment of the loan in full. We used the proceeds of this facility to refinance existing indebtedness incurred as part of the December 2013 Allergan acquisition. This facility includes covenants and terms that place certain restrictions on our ability to incur additional indebtedness, incur additional liens, make investments, effect mergers, declare or pay dividends, sell assets, engage in transactions with affiliates or make capital expenditures. The facility also includes financial covenants including minimum consolidated quarterly revenue, and a consolidated debt to revenue ratio. We have not been in compliance with financial covenants in the past and received waivers or amendments from the lender in respect of these covenants. If we are not able to maintain compliance with our ongoing financial covenants or are otherwise unable to negotiate a waiver or amendment to the covenant requirements, the repayment of the facility could be accelerated at Athyrium's discretion.

On October 10, 2016, we amended our senior secured credit facility with Athyrium pursuant to the Fourth Amendment to the Credit Agreement (the "Fourth Amendment"). The Fourth Amendment set new minimum quarterly revenue requirements of $15.7 million for the three months ended September 30, 2016 and $16.0 million for the three months ended December 31, 2016, and set the debt-to-revenue ratio to 0.80 for the third and fourth quarters of 2016. We repaid $11.0 million of the outstanding principal, plus fees and prepayment expenses upon completion of the Merger on December 29, 2016 as required by the Fourth Amendment.

In addition, pursuant to the Fourth Amendment, we issued Athyrium a new warrant to purchase 163,915 shares of our common stock with an exercise price of $21.29 per share. The new warrant replaced a similar warrant previously issued to Athyrium for the same number of shares of common stock and the same exercise price per share. The new warrant does not contain prior anti-dilution provisions and we canceled the prior warrant.

On March 7, 2017, we amended our senior secured credit facility pursuant to the Fifth Amendment to the Credit Agreement, the net effect of which is to improve our net liquidity by $1.0 million, reduce future interest expense and improve our financial covenants. Specifically, the Amendment (i) reduced the minimum cash balance requirement to $0.0 from $8.0 million, (ii) reduced the minimum quarterly revenue requirement to $13.0 million from $18.0 million, (iii) increased the maximum debt-to-revenue ratio to 0.65 from 0.60 and (iv) required us to make a principal repayment of $7.0 million. The minimum quarterly revenue requirement will increase by $1.0 million quarterly over the remaining term of the facility, and the maximum debt-to-revenue ratio will decline gradually each quarter, from 0.65 to 0.25, over the remaining term of the facility.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2016 and 2015:

	2016	2015
Net cash used in operating activities	$ (12,901)	$ (16,005)
Net cash used in investing activities	(2,165)	(6,926)
Net cash provided by financing activities	12,617	33,484
Effect of exchange rate changes on cash	(96)	(216)
Net change in cash, cash equivalents and restricted cash	$ (2,545)	$ 10,337

Operating Activities

Cash used in operating activities of $12.9 million for the year ended December 31, 2016 was primarily the result of a net loss of $41.2 million net of non-cash charges of $27.5 million primarily related to depreciation, amortization, non-cash interest expense, inventory impairment and unrealized foreign exchange losses. Additionally, cash provided by operating assets and liabilities of $0.8 million related to the build-up of inventory supply in order to mitigate supply risks offset by an increase in payables associated with the inventory build-up.

Cash used in operating activities of $16.0 million for the year ended December 31, 2015 was primarily the result of a net loss of $27.4 million net of non-cash charges of $14.8 million primarily related to depreciation, amortization and non-cash interest expense. In addition, operating assets and liabilities used $3.4 million of cash primarily related to the build-up of inventory supply in order to mitigate supply risks in the event of unforeseen delays in the establishment or regulatory approval of our manufacturing capability.

Investing Activities

Cash used for investing activities of $2.2 million for the year ended December 31, 2016 primarily related to ongoing investments in our intellectual property portfolio and purchases of property and equipment associated with establishing our mobile learning center in the U.S. and additional equipment for our manufacturing facility in Costa Rica.

Cash used for investing activities of $6.9 million for the year ended December 31, 2015 primarily related to purchases of property and equipment associated with establishing our manufacturing facility in Costa Rica, investments in our intellectual property portfolio and, to a lesser extent, purchases of property and equipment associated with establishing our sales offices in England, Brazil and Australia.

Financing Activities

Cash provided by financing activities of $12.6 million for the year ended December 31, 2016 primarily relates to the $29.0 million in proceeds from the issuance of common stock in connection with the Merger, offset by the repayment of $11.2 million in principal and accrued interest on the senior secured credit facility. In addition, we paid $5.0 million in contingent consideration to Allergan resulting from the FDA approval of Orbera.

Cash provided by financing activities of $33.5 million for the year ended December 31, 2015 primarily relate to the issuance of $22.2 million of convertible notes in July 2015 and the February 2015 refinancing of our senior secured credit facility resulting in the receipt of $50 million of proceeds offset by $37.7 million of payment of the former facility and $1.1 million of debt issuance costs.

Future Funding Requirements

As of December 31, 2016, we had cash, cash equivalents and restricted cash balances totaling $20.0 million. We believe our existing cash and cash equivalents will be sufficient to meet our liquidity and capital requirements through at least the end of 2017. Any future capital requirements will depend on many factors including market acceptance of our products, the cost of our research and development activities, the cost and timing of additional regulatory clearances or approvals and the costs of establishing additional sales, marketing and distribution capabilities. We may be required to seek additional equity or debt financing. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, operating results and financial condition could be adversely affected.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC and accordingly, no such arrangements are likely to have a current or future effect on our financial position.

Recent Accounting Pronouncements

See Note 2(s) to the Consolidated Financial Statements in Item 8 of this Report for a discussion of recently enacted accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This item has been omitted as we qualify as a smaller reporting company.

ITEM 8. FINANCIAL STATEMENTS

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Apollo Endosurgery, Inc.:

We have audited the accompanying consolidated balance sheets of Apollo Endosurgery, Inc. and subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, changes in redeemable preferred stock and stockholders' equity / (deficit), and cash flows for each of the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 Apollo Endosurgery, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Austin, Texas
March 23, 2017

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2016 and 2015
(In thousands, except for share data)

	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 19,111	$ 21,715
Accounts receivable, net	10,509	10,498
Inventory, net	12,163	12,793
Prepaid expenses and other current assets	1,838	2,081
Total current assets	43,621	47,087
Restricted cash	930	871
Property and equipment, net	6,889	7,972
Goodwill	6,828	184
Intangible assets, net	43,315	48,987
Other assets	541	87
Total assets	$ 102,124	$ 105,188
Liabilities, Redeemable Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,145	$ 4,684
Accrued expenses	6,630	6,546
Payable to related parties	8,505	5,074
Contingent consideration	—	5,000
Total current liabilities	20,280	21,304
Warrant liability	—	2,912
Convertible notes	—	20,498
Long-term debt	39,427	49,305
Total liabilities	59,707	94,019
Commitments and contingencies		
Redeemable preferred stock:		
Redeemable convertible Series A preferred stock; $0.0001 par value; 0 and 10,006,345 shares authorized, 0 and 9,588,891 shares issued and outstanding, liquidation preference of 0 and $19,482 at December 31, 2016 and 2015, respectively	—	19,301
Redeemable convertible Series B preferred stock; $0.0001 par value; 0 and 45,431,126 shares authorized, 0 and 45,406,582 shares issued and outstanding, liquidation preference of 0 and $73,620 at December 31, 2016 and 2015, respectively	—	72,390
Redeemable convertible Series C preferred stock; $0.0001 par value; 0 and 52,137,271 shares authorized, 0 and 37,617,334 shares issued and outstanding, liquidation preference of 0 and $53,527 at December 31, 2016 and 2015, respectively	—	53,246
Total redeemable preferred stock	—	144,937
Stockholders' equity/ (deficit):		
Common stock; $0.001 par value; 100,000,000 shares authorized; 10,688,992 and 755,606 shares issued and outstanding at December 31, 2016 and 2015, respectively	11	1
Additional paid-in capital	190,664	(25,215)
Accumulated other comprehensive income	1,471	8
Accumulated deficit	(149,729)	(108,562)
Total stockholders' equity (deficit)	42,417	(133,768)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	$ 102,124	$ 105,188

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2016 and 2015
(In thousands, except for share data)

	2016	2015
Revenues	$ 64,868	$ 67,790
Cost of sales	25,255	20,510
Gross margin	39,613	47,280
Operating expenses:		
Sales and marketing	31,751	36,167
General and administrative	13,625	11,412
Research and development	7,805	9,558
Amortization of intangible assets	7,193	6,826
Total operating expenses	60,374	63,963
Loss from operations	(20,761)	(16,683)
Other expenses:		
Interest expense, net	18,168	10,036
Other expense	1,851	663
Net loss before income taxes	(40,780)	(27,382)
Income tax expense	387	49
Net loss	(41,167)	(27,431)
Current dividends on convertible preferred stock	—	(8,951)
Net loss attributable to common stockholders	(41,167)	(36,382)
Other comprehensive income:		
Foreign currency translation	1,463	26
Comprehensive loss	$ (39,704)	$ (27,405)
Net loss per share, basic and diluted	$ (105.69)	$ (151.90)
Shares used in computing net loss per share, basic and diluted	389,501	239,509

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Redeemable Preferred Stock and Stockholders' Equity/(Deficit)
Years Ended December 31, 2016 and 2015
(In thousands, except for share data)

	Redeemable Convertible Series A Preferred stock		Redeemable Convertible Series B Preferred stock		Redeemable Convertible Series C Preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2014	9,588,891	$18,363	45,431,125	$67,985	49,897,462	$65,976	626,605	$ 1	$ (36,522)	$ (18)	$ (81,131)	$34,654
Exercise of common stock options	—	—	—	—	—	—	58,232	—	123	—	—	123
Beneficial conversion feature associated with issuance of convertible notes	—	—	—	—	—	—	—	—	3,325	—	—	3,325
Accretion of dividends on Series A preferred stock	—	938	—	—	—	—	—	—	(938)	—	—	—
Accretion of dividends on Series B preferred stock	—	—	—	4,442	—	—	—	—	(4,442)	—	—	—
Accretion of dividends on Series C preferred stock	—	—	—	—	—	4,577	—	—	(4,577)	—	—	—
Conversion of preferred stock	—	—	(24,543)	(37)	(12,280,128)	(17,307)	70,769	—	17,344	—	—	—
Stock based compensation	—	—	—	—	—	—	—	—	472	—	—	472
Foreign currency translation	—	—	—	—	—	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	—	—	—	—	—	(27,431)	(27,431)
Balances at December 31, 2015	9,588,891	19,301	45,406,582	72,390	37,617,334	53,246	755,606	1	(25,215)	8	(108,562)	11,169
Exercise of common stock options	—	—	—	—	—	—	22,964	—	53	—	—	53
Accretion of dividends on Series A preferred stock	—	940	—	—	—	—	—	—	(940)	—	—	—
Accretion of dividends on Series B preferred stock	—	—	—	4,433	—	—	—	—	(4,433)	—	—	—
Accretion of dividends on Series C preferred stock	—	—	—	—	—	3,667	—	—	(3,667)	—	—	—
Issuance of common stock	—	—	—	—	—	—	1,019,441	1	28,999	—	—	29,000
Conversion of convertible preferred stock into common stock	(9,588,891)	(11,530)	(45,406,582)	(54,241)	(37,617,334)	(45,699)	5,326,500	6	111,464	—	—	—
Conversion of convertible notes into common stock	—	—	—	—	—	—	1,269,900	1	24,004	—	—	24,005
Common stock issued for preferred stock dividends	—	(8,711)	—	(22,582)	—	(11,214)	2,000,143	2	42,505	—	—	—
Beneficial conversion feature associated with conversion of convertible notes	—	—	—	—	—	—	—	—	8,678	—	—	8,678
Business combination with Lpath, Inc.	—	—	—	—	—	—	—	—	7,087	—	—	7,087
Reclassification of warrant liability to equity	—	—	—	—	—	—	—	—	1,286	—	—	1,286
Conversion of common and preferred stock warrants into common stock	—	—	—	—	—	—	294,438	—	462	—	—	462
Stock based compensation	—	—	—	—	—	—	—	—	381	—	—	381
Foreign currency translation	—	—	—	—	—	—	—	—	—	1,463	—	1,463
Net loss	—	—	—	—	—	—	—	—	—	—	(41,167)	(41,167)
Balances at December 31, 2016	—	$ —	—	$ —	—	$ —	10,688,992	$ 11	$ 190,664	$ 1,471	$ (149,729)	$42,417

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
Years Ended December 31, 2016 and 2015
(In thousands)

	2016	2015
Cash flows from operating activities:		
Net loss	$ (41,167)	$ (27,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,092	8,060
Amortization of deferred financing costs	425	886
Non-cash interest expense	13,317	4,560
Change in fair value of warrant liability	(1,163)	(49)
Provision for doubtful accounts receivable	331	387
Change in inventory reserve	3,750	(54)
Stock based compensation	381	472
Foreign exchange on short-term intercompany loans	1,332	522
Changes in operating assets and liabilities:		
Accounts receivable	(426)	1,268
Due from related party	—	107
Inventory	(3,054)	(6,352)
Prepaid expenses and other assets	327	(342)
Accounts payable and accrued expenses	523	512
Payable to related party	3,431	1,449
Net cash used in operating activities	(12,901)	(16,005)
Cash flows from investing activities:		
Purchases of property and equipment	(1,028)	(4,763)
Purchase of intangibles and other assets	(1,337)	(2,019)
Acquisitions, net of cash acquired	200	(144)
Net cash used in investing activities	(2,165)	(6,926)
Cash flows from financing activities:		
Proceeds from exercise of stock options	53	123
Proceeds from long-term debt	—	50,000
Proceeds from the issuance of convertible notes	—	22,166
Proceeds from issuance of common stock	29,000	—
Payments of deferred financing costs	(216)	(1,088)
Payment of debt	(11,220)	(37,717)
Payment of contingent consideration	(5,000)	—
Net cash provided by financing activities	12,617	33,484
Effect of exchange rate changes on cash	(96)	(216)
Net increase (decrease) in cash, cash equivalents and restricted cash	(2,545)	10,337
Cash, cash equivalents and restricted cash at beginning of year	22,586	12,249
Cash, cash equivalents and restricted cash at end of year	$ 20,041	$ 22,586
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,791	$ 4,965
Cash paid for income taxes	318	49
Supplemental disclosure of non-cash investing and financing activity:		
Conversion of convertible notes into common stock	$ 24,005	$ —
Conversion of preferred stock and accumulated dividends into common stock	153,977	—
Reclassification of warrant liability to equity	1,286	—
Conversion of common and preferred stock warrants to common stock	462	—
Warrants issued with long-term debt	—	1,951
Accretion of dividends on preferred stock	9,040	9,957
Forfeiture of dividends upon conversion of preferred stock into common stock	—	(2,304)
Beneficial conversion feature on convertible notes	8,678	3,325

See accompanying notes to the consolidated financial statements.

(1) Organization and Business Description

Apollo Endosurgery, Inc. is a Delaware corporation with both domestic and foreign wholly-owned subsidiaries. Throughout these Notes "Apollo" and the "Company" refer to Apollo Endosurgery, Inc. and its consolidated subsidiaries.

Apollo is a medical technology company primarily focused on the design, development, and commercialization of innovative medical devices that can be used for the treatment of obesity. The Company's core products include the Orbera® intra-gastric balloon system, the OverStitch™ endoscopic suturing system and Lap-Band® adjustable gastric banding system. All devices are regulated by the United States Food and Drug Administration (the "FDA") or an equivalent regulatory body outside the United States. The Company's products are sold throughout the world with principal markets in the United States of America, Europe, Australia, Brazil and Canada. The Company also has a manufacturing facility located in Costa Rica.

On December 29, 2016, Apollo completed its business combination with Lpath, Inc. ("Lpath"), a publicly held company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated September 8, 2016 (the "Merger"). Under the terms of the Merger Agreement, each share of Apollo common stock was converted into Lpath common stock at an exchange rate of approximately 0.3163 per Apollo share ("Exchange Ratio") and the $0.0001 par value of Apollo common stock was adjusted to the Lpath $0.001 par value. Immediately following the Merger, the Company effected a reverse stock split at a ratio of one new share for every five and one-half shares of its common stock outstanding (the "1:5.5 Reverse Stock Split"). No fractional shares were issued and instead, stockholders received cash in the amount they would have been entitled to receive. The accompanying financial statements and notes to the consolidated financial statements give retroactive effect to the common stock conversion ratio and reverse stock split for all periods presented, including common stock warrants.

Following the Merger, Lpath was renamed "Apollo Endosurgery, Inc." and began trading on The NASDAQ Global Market under the symbol "APEN." Prior to the Merger, Lpath was traded on The NASDAQ Capital Market under the symbol "LPTN."

(2) Significant Accounting Policies

(a) Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all of its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

(b) Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results are likely to differ from those estimates, and such differences may be material to the consolidated financial statements. Significant items subject to such estimates and assumptions include intangibles and long-lived assets, stock compensation, deferred tax asset valuation, accounts receivable, inventory and warrant liability.

(c) Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity at date of purchase of three months or less to be cash equivalents.

(d) Restricted Cash

The Company entered into irrevocable letters of credit with three banks to secure obligations under lease agreements and performance based obligations. These letters of credit total $930 and $871 and are recorded in restricted cash on the balance sheet as of December 31, 2016 and 2015, respectively.

(In thousands, except for share data)

(e) Accounts Receivable

The Company generally extends credit to certain customers without requiring collateral. The Company provides an allowance for doubtful accounts based on management's evaluation of the collectability of accounts receivable. Accounts receivable are written off when it is determined amounts are uncollectible. The recorded allowance for doubtful accounts was $479 and $630 as of December 31, 2016 and 2015, respectively. Accounts receivable of $482 and $141 were written off during the years ended December 31, 2016 and 2015, respectively.

(f) Inventory

Inventory is stated at the lower of cost or market, net of any allowances. Charges for obsolete inventory are based on specific identification of obsolete inventory items and an analysis of inventory items approaching expiration date. We record estimated obsolescence charges to cost of sales. The Company's inventories are stated using the weighted average cost approach, which approximates actual costs.

(g) Fair Value Measurements

The carrying amounts of the Company's financial instruments, which primarily include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of the Company's long-term debt is estimated by management to approximate $40,500 at December 31, 2016. At December 31, 2015, the carrying value of the Company's debt approximated fair value based on the borrowing rates available to the Company at that time. Management's estimates are based on comparisons of the characteristics of the Company's obligations, comparable ranges of interest rates on recently issued debt, and maturity. Such valuation inputs are considered a Level 3 measurement in the fair value valuation hierarchy.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company issued preferred stock and common stock warrants in connection with the senior-secured credit facility (see note (10)(a)) and convertible notes to a consortium of lenders (see note (10)(b)). As discussed in notes 10 and 11, these warrants were converted to common stock, or in the case of the common stock warrants in connection with the senior-secured credit facility, were reissued and reclassified as equity. Prior to the Merger, these warrants had "down-round" price protection and were recorded as a warrant liability and re-measured on the Company's reporting date at fair value. The fair value of the warrants, classified within the Level 3 designation, was determined using the Black-Scholes option pricing model and was affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate.

	Year Ended December 31,			
	2016		2015	
	Carrying Value	Level 3 Fair Value	Carrying Value	Level 3 Fair Value
Warrants classified as a liability	$ —	$ —	$ 2,912	$ 2,912

(h) Property and Equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, except for leasehold improvements, which are depreciated straight-line over the shorter of the estimated useful life or the life of the lease. Major renewals and betterments are capitalized. Validation costs (including materials and labor) that are required to bring the machinery to working condition are capitalized. Expenditures for repairs and maintenance and minor replacements are charged to expense as incurred.

(i) Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of purchase price over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

(j) Goodwill and Other Intangible Assets

Goodwill is not amortized but is tested annually for impairment or more frequently if impairment indicators exist. The Company adopted accounting guidance related to annual and interim goodwill impairment tests which allows the Company to first assess qualitative factors before performing a quantitative assessment of the fair value of a reporting unit. If it is determined on the basis of qualitative factors that the fair value of the reporting unit is more likely than not less than the carrying amount, a quantitative impairment test is required. The Company's evaluation of goodwill completed on December 31, 2016 and 2015 resulted in no impairment losses.

Definite-lived intangible assets consist of customer relationships, product technology, trade names, patents and trademarks and capitalized software which are amortized over their estimated useful lives. Costs to extend the lives of and renew patents and trademarks are capitalized when incurred.

(k) Valuation of Long-Lived Assets

Long-lived assets, including definite-lived intangible assets, are monitored and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of any such asset may not be recoverable. The determination of recoverability is based on an estimate of undiscounted cash flows expected to result from the use of an asset and its eventual disposition. The estimate of undiscounted cash flows is based upon, among other things, certain assumptions about expected future operating performance. The Company's estimates of undiscounted cash flows may differ from actual cash flows. If the sum of the undiscounted cash flows is less than the carrying value of the asset, an impairment charge is recognized, measured as the amount by which the carrying value exceeds the fair value of the asset. No impairment losses were recorded during the years December 31, 2016 and 2015.

(l) Revenue Recognition

The Company's principal source of revenue is from the sale of its products. Revenue is recognized when evidence of an arrangement exists, fees are fixed or determinable, collection of the fees is reasonably assured, and delivery or customer acceptance of the product has occurred and no other significant obligations remain. Generally, these conditions are met under the Company's agreements with most customers upon product shipment. The Company accounts for taxes collected from customers and remitted to governmental authorities on a net basis. Accordingly, such amounts are excluded from revenues.

Prior to the transition of the international commercial operations (refer to note 3(c)), the Company recognized license fee revenue paid by Allergan on a net basis.

Customers generally have the right to return products purchased from the Company for up to three months from the date of product shipment or exchange products within six months. At the end of each period end, the Company determines the extent to which its revenues need to be reduced to account for expected returns and exchanges and a reserve is recorded against revenue recognized.

Amounts billed to customers related to shipping and handling are included in revenues. Shipping and handling costs related to revenue producing activities are included in cost of goods sold.

(m) Research and Development

Research and development costs are expensed as incurred.

(n) Stock-based Compensation Plans

The Company recognizes compensation costs for all stock-based awards based upon each award's estimated fair value as determined on the date of grant. The Company utilizes the Black-Scholes option-pricing model to determine the fair value of stock option awards. The Black-Scholes option-pricing model requires management to make various assumptions, including valuing the Company's common stock which was done by an independent valuation firm using a blend of an income approach, market approach and cost approach before the Company became public on December 29, 2016. Compensation cost is recognized on a straight-line basis over the respective vesting period of the award, net of an estimated forfeiture rate. Adjustments for actual forfeitures are made in the period which they occur.

(o) Advertising

The Company expenses advertising costs as incurred. The Company incurred approximately $3,484 and $2,319 in advertising costs during the years ended December 31, 2016 and 2015, respectively.

(p) Income Taxes

The Company accounts for deferred income taxes using the asset and liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more-likely than-not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

In the ordinary course of business, there are many transactions for which the ultimate tax outcome is uncertain. The Company regularly assesses uncertain tax positions in each of the tax jurisdictions in which it has operations and accounts for the related consolidated financial statement implications. The amount of unrecognized tax benefits is adjusted when information becomes available or when an event occurs indicating a change is appropriate. The Company includes interest and penalties related to its uncertain tax positions as part of income tax expense.

(q) Medical Device Excise Tax

Effective as of January 1, 2013, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, imposed a medical device excise tax (MDET) of 2.3% on any entity that manufactures or imports certain medical devices offered for sale in the United States. The Company accounts for the MDET as a component of sales and marketing expense within operating expense and recognized approximately zero and $754 during the years ended December 31, 2016 and 2015, respectively. In December 2015, the medical device tax was suspended for two years and thus no tax was imposed during 2016 or will be imposed during 2017.

(r) Foreign Currency

The Company is exposed to foreign currency exchange risk as foreign subsidiaries generally operate and utilize functional currencies in local currencies other than the U.S. Dollar, which is the Company's reporting currency. The Company translates their foreign assets and liabilities at exchange rates in effect at the balance sheet dates, and the revenues and expenses using average rates during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive income in the accompanying consolidated balance sheets. We do not hedge foreign currency translation risk in the net assets and income we report from these sources. Exchange rate fluctuations on short-term intercompany loans are included in other expense in the consolidated statement of operations and comprehensive loss.

(s) Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 replaces most existing revenue recognition guidance in GAAP. In July 2015, the FASB approved a one-year deferral of this standard, with a revised effective date for annual and interim reporting in fiscal years beginning after December 15, 2017. In March 2016 and April 2016, the FASB issued ASU 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus*

Net) and ASU 2016-10, *Identifying Performance Obligations and Licensing*, respectively. ASU 2014-09 permits the use of either the retrospective or modified retrospective (cumulative effect) transition method. The Company has not yet completed its final review of the impact of this guidance, although the Company does not anticipate a material impact on its revenue recognition practices. The Company continues to review this guidance, potential disclosures and the Company's method of adoption to complete its evaluation of the impact on its consolidated financial statements. In addition, the Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact the Company's current conclusions.

Apollo has adopted the provisions of ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). This ASU requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. The adoption of ASU 2014-15 resulted in no material impact on the Company's consolidated financial statements.

Apollo has adopted the provisions of ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. This update requires that debt issuance costs be presented in the balance sheet as a reduction of the carrying value of the debt instead of being classified as a deferred charge. As retrospective application is required by this standard, December 31, 2016 and 2015 have been adjusted with no material impact, respectively.

In July 2015, the FASB, issued ASU 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"), which simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. ASU 2015-11 will be effective for the Company on January 1, 2017. The Company does not expect the adoption of ASU 2015-11 will have a material impact on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17") which requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. ASU 2015-17 will be effective for the Company on January 1, 2017. The adoption of ASU 2015-17 will not have a material impact on the presentation of the Company's consolidated balance sheet.

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02") which requires a lessee to recognize assets and liabilities for leases with a maximum possible term of more than 12 months. A lessee would recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the leased asset (the underlying asset) for the lease term which will require companies to recognize most leases on the balance sheet, thereby increasing reported assets and liabilities. Extensive quantitative and qualitative disclosures, including significant judgments made by management, will be required. ASU 2016-02 requires adoption using a modified retrospective transition with application of the guidance at the beginning of the earliest comparative period presented. ASU 2016-02 will be effective for the Company on January 1, 2019. Early adoption is permitted. The Company is evaluating the effect that ASU 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), which contains guidance on accounting for certain aspects of share-based payments to employees. ASU 2016-09 requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. Furthermore, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. ASU 2016-09 also allows companies to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting, clarifying that all cash payments made on an employee's behalf for withheld shares should be presented as a financing activity in the consolidated statements of cash flows and provides an accounting policy election to account for forfeitures as they occur. ASU 2016-09 will be effective for the Company on January 1, 2017. The Company does not expect the adoption of ASU 2016-09 to have a material impact on its consolidated financial statements.

The Company adopted the provisions of ASU 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15") which addresses questions about the presentation and classification of certain cash receipts and payments in the statement of cash flows, including debt prepayment costs. The adoption of ASU 2016-15 resulted in no material impact to the Company's consolidated financial statements for the periods presented.

(In thousands, except for share data)

The Company adopted the provisions of ASU 2016-18, *Statement of Cash Flows: Restricted Cash* ("ASU 2016-18") which clarifies the classification and presentation of changes in restricted cash on the statement of cash flows. With the adoption of ASU 2016-18 restricted cash is now included in the statement of cash flows.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations: Clarifying the Definition of a Business* ("ASU 2017-01") which changes the definition of a business. If substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, then the acquisition is not a business. ASU 2017-01 requires a business to include at least one substantive process. ASU 2017-01 will be effective for the Company on January 1, 2018. Early adoption is permitted. The effect of ASU 2017-01 on the Company's consolidated financial statements will be dependent on any future acquisitions.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment* ("ASU 2017-04") to simplify the accounting for goodwill impairment. The guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. ASU 2017-04 will be effective for the Company for annual and interim reporting in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company does not expect the adoption of ASU 2017-04 to have a material impact on its consolidated financial statements.

(3) Acquisitions

(a) Lpath

On December 29, 2016, the Company completed the Merger with Lpath as discussed in note 1. The Merger was accounted for as a reverse merger under the acquisition method of accounting whereby Apollo was considered to have acquired Lpath for financial reporting purposes because, immediately upon completion of the Merger, Apollo stockholders held a majority of the voting interest of the combined company. Immediately after the Merger, holders of Apollo and Lpath common stock, warrants and options owned approximately 95.9% and 4.1% of the fully-diluted common stock of the Company, respectively. In addition, transaction costs associated with the Lpath merger of $3,640 are included in general and administrative expense.

The total purchase price for Lpath was $7,087 based on the fair value of the Lpath stock price and market capitalization and was allocated as follows:

	December 29, 2016
Cash	$ 200
Other assets	519
Assumed liabilities	(276)
Fair value of net assets	443
Goodwill	6,644
Total purchase consideration	$ 7,087

The preliminary allocation of the Lpath Merger purchase price resulted in $6,644 of goodwill. The final allocation of the purchase price is dependent on the value, if any, resulting from the final disposition of the Lpath IP and may differ from the amounts included in these financial statements. The Company expects to complete the final allocation as soon as practical but no later than one year from the acquisition date. Management does not expect adjustments, if any, resulting from changes to the purchase price allocation, to have a material effect on the Company's financial position or results of operations.

The following summary pro forma condensed consolidated financial information reflects the Merger with Lpath as if it had occurred on January 1, 2015 for purposes of the statements of operations. This summary pro forma information is not necessarily representative of what the Company's results of operations would have been had the Merger in fact occurred on January 1, 2015, and is not intended to project the Company's results of operations for any future period.

Pro forma condensed consolidated financial information for 2016 and 2015 (unaudited):

(In thousands, except for share data)

	Year Ended December 31,	
	2016	2015
Pro form combined revenues	$ 65,163	$ 69,390
Pro forma combined net loss	$ (33,269)	$ (34,521)
Pro forma combined earnings per share	$ (3.11)	$ (4.23)

Pro forma combined net loss includes adjustments to remove transactions costs of $5,140 for the year ended December 31, 2016 because they will not have a continuing impact on operations, and a reduction in historical interest expense of $13,258 and $2,920 for the year ended December 31, 2016 and 2015, respectively, due to the conversion of the convertible notes and warrants.

(b) Starhealth

On June 3, 2015, the Company entered into a purchase agreement to acquire the shares of Starhealth Distribuidora ("Starhealth") in Brazil for $144. Starhealth included certain business licenses needed for conducting business in Brazil. As a result of the transaction, the Company recorded $144 of intangible assets in the form of business licenses which were amortized over one year.

(c) Allergan

On December 2, 2013, the Company entered into an asset purchase agreement to acquire the bariatric assets of Allergan, Inc. ("Allergan") which was accounted for as a taxable asset acquisition for tax purposes. Pursuant to the purchase agreement, the Company paid $62,460 and agreed to pay future contingent consideration, and the seller purchased $15,000 of Series C preferred stock for cash. Additionally, certain contingent payments were due if (1) U.S. Lap-Band revenues exceeded certain thresholds in the initial three years following the acquisition date, or (2) Orbera Post-Market Approval from the FDA was received in the United States prior to December 2, 2015. A contingent consideration payment of $5,000 was paid on May 26, 2016 for obtaining Orbera post market approval.

The Lap-Band and Orbera products were manufactured by Allergan until transition to the Company on December 2, 2015. A manufacturing fee of 115% of the cost to manufacture the Lap-Band and Orbera product was charged to the Company. The Company recorded inventory purchases of $7,667 and $13,555 related to the manufacturing agreement during 2016 and 2015, respectively.

Allergan distributed the Lap-Band and Orbera products outside of the United States and continued to employ all employees that support those sales until transition to the Company, which occurred in Canada, Australia and all direct selling markets in Europe prior to December 2, 2014, with Latin America transition following on December 2, 2015. Distribution relationships and contracts that related to sales of the Lap-Band and Orbera products outside of the United States transitioned to the Company prior to December 2, 2015. For the rights to distribute the Company's Lap-Band and Orbera products, the Company was paid a license fee and recognized $2,624 of licensing fee revenue related to this distribution agreement during 2015.

Worldwide technical research and development product support for the Lap-Band and Orbera products was provided until transition to the Company on December 2, 2015. The Company recognized in research and development $1,240 of related expense under this transition agreement during 2015.

(4) Concentrations

Consolidated financial instruments that potentially subject the Company to a concentration of credit risk principally consist of cash and cash equivalents and accounts receivable. At December 31, 2016, the Company's cash and cash equivalents and restricted cash are held in deposit accounts at three different banks totaling $20,041. The Company has not experienced any losses in such accounts, and management does not believe the Company is exposed to any significant credit risk. Management further believes that the concentration of credit risk in the Company's accounts receivable is substantially mitigated by the Company's evaluation process, relatively short collection terms, and the high level of creditworthiness of its customers. The Company continually evaluates the status of each of its customers, but generally requires no collateral.

The Company had no customers that comprised a concentration greater than 10% of the Company's total accounts receivable as of December 31, 2016 or 2015, or revenues for the years ended December 31, 2016 and 2015.

(In thousands, except for share data)

(5) Inventory

Inventory consists of the following as of December 31:

	2016	2015
Raw materials	$ 5,031	$ —
Work in progress	346	—
Finished goods	10,520	13,021
Less inventory reserve	(3,734)	(228)
Total inventory, net	$ 12,163	$ 12,793

The Company commenced its manufacturing operations in Costa Rica in June 2016. The Company recorded an inventory impairment charge of $3,750 for the year ended December 31, 2016 consisting of $1,226 of estimated obsolescence charges for raw materials transferred in June 2016 in accordance with the Allergan manufacturing agreement and $2,524 related to expiring finished goods products.

(6) Property and Equipment

Property and equipment consists of the following as of December 31:

	Depreciable Lives	2016	2015
Equipment	5 years	$ 4,949	$ 2,070
Furniture, fixtures and tooling	4 - 8 years	3,533	3,429
Computer hardware	3 - 5 years	1,057	1,063
Leasehold improvements	3 - 5 years	1,149	919
Construction in process		605	4,365
		11,293	11,846
Less accumulated depreciation		(4,404)	(3,874)
Property and equipment, net		$ 6,889	$ 7,972

The Company recorded depreciation expense of $1,862 and $1,225 for the years ended December 31, 2016 and 2015, respectively. There were no impairment charges for the years ended December 31, 2016 or 2015. The Company capitalized interest of $109 and $269 for the years ended December 31, 2016 and 2015, respectively related to our manufacturing facility in Costa Rica. The Company disposed of $1,270 of property and equipment which was fully depreciated as of December 31, 2016 and no longer being utilized by the Company.

(7) Goodwill and Other Intangible Assets

The following table reflects the changes in goodwill for the years ended December 31, 2016 and 2015:

December 31, 2014	$ 184
December 31, 2015	$ 184
Goodwill associated with Lpath, Inc. merger	6,644
December 31, 2016	$ 6,828

(In thousands, except for share data)

Other intangible assets consist of the following as of December 31:

	Useful Life	2016	2015
Customer relationships	9 years	$ 30,300	$ 30,300
Lap-Band technology	10 years	15,500	15,500
Orbera technology	12 years	4,600	4,600
Trade names	10 years	7,900	7,900
Patents and trademarks	5 years	4,178	2,907
Other	1 - 4 years	1,796	1,460
		64,274	62,667
Less accumulated amortization		(20,959)	(13,680)
		$ 43,315	$ 48,987

Amortization expense related to the above intangible assets was $7,230 and $6,835 during 2016 and 2015, respectively. Additionally, we capitalized $1,271 and $1,256 related to the extension and renewal of our patents and trademarks during 2016 and 2015, respectively.

Amortization for the next five years is as follows:

2017	$ 7,360
2018	7,233
2019	6,932
2020	6,508
2021	6,209
Thereafter	9,073
Total	$ 43,315

(8) Accrued Expenses

Accrued expenses consist of the following as of December 31:

	2016	2015
Accrued compensation and travel	$ 3,040	$ 3,447
Accrued professional service fees	1,521	608
Accrued returns and rebates	366	453
Accrued insurance, property and sales taxes	256	618
Accrued interest	186	155
Deferred rent	152	173
Deferred revenue	88	—
Other	1,021	1,092
Total accrued expenses	$ 6,630	$ 6,546

(9) Convertible Notes

From July through November 2015, the Company entered into various convertible note purchase agreements which resulted in gross proceeds of $22,166. The notes accrued interest at a rate of 6% per annum which was added to the outstanding amount until conversion. Interest accrued for the notes was $1,326 and $513 for the years ended December 31, 2016 and 2015, respectively. The notes had an optional voluntary conversion feature in which the holder could convert the notes into the Company's Series C preferred stock at a rate of 115% times the sum of the outstanding principal and unpaid accrued interest at

(In thousands, except for share data)

the issuance price of $1.2223 per share on or after July 29, 2016. Alternatively, the notes converted into common stock or preferred stock equal to a range of 115% to 150% of the sum of outstanding principal and interest upon certain contingent qualifying events such as a public offering or liquidation event. The intrinsic value of this beneficial conversion feature was $3,325 upon issuance of the notes and was recorded as additional paid-in capital on the statement of stockholders' deficit and as a debt discount which accreted to interest expense through the first optional conversion date of July 29, 2016. Interest expense included discount amortization of $2,073 and $1,252 for the years ended December 31, 2016 and 2015, respectively. The debt discount was fully amortized at July 29, 2016.

Immediately prior to the Merger, all of the convertible notes and accrued interest thereon were converted into 1,269,900 shares of common stock on December 29, 2016 at 150% of the sum of the outstanding principal and interest and a conversion price of $1.6361. The additional intrinsic value of the contingent beneficial conversion feature of $8,678 was included in interest expense in 2016 and was recorded as additional paid in capital upon conversion of the notes.

	2015
Convertible notes	$ 22,166
Interest accrued	513
	22,679
Discount	(2,073)
Deferred financing costs	(108)
Convertible notes	$ 20,498

(10) Long-Term Debt

Long-term debt consists of the following as of December 31:

	2016	2015
Senior secured credit facility	$ 39,000	$ 50,000
Payment-in-kind interest	2,046	1,679
Long-term debt	41,046	51,679
Discount on long-term debt	(952)	(1,606)
Deferred financing costs	(667)	(768)
Long-term debt	$ 39,427	$ 49,305

(a) Senior Secured Credit Facility

On February 27, 2015, the Company entered into a senior secured credit facility (the "Credit Facility") with a lender to borrow $50,000 which is payable in a lump sum on February 27, 2020. The Credit Facility is secured by all of the Company's assets and has priority over all other debt. The Credit Facility bears interest at 10.5% per annum. In the first year, 7% cash interest was paid quarterly and 3.5% of payment-in-kind which was added to the outstanding debt. After March 15, 2016, 10.5% of interest became payable in cash on a quarterly basis. An additional 2% of the outstanding amount will be due at end of the loan term. The Company is accruing this additional payment-in-kind interest as interest expense using the effective interest rate method. The Company used $39,500 of these proceeds in 2015 to pay off the outstanding long-term debt to the consortium of lenders discussed below. On December 29, 2016, the Company paid $11,000 of the outstanding balance of the Credit Facility and prepayment and payment-in-kind interest of $770, included in interest expense. Unamortized deferred financing costs of $127 and unamortized discount of $269 were written off in December 2016 in connection with this payment.

The Credit Facility includes covenants and terms that place certain restrictions on the Company's ability to incur additional debt, incur additional liens, make investments, effect mergers, declare or pay dividends, sell assets, engage in transactions with affiliates, or make capital expenditures. The Credit Facility also includes financial covenants including minimum consolidated quarterly revenue, consolidated debt to revenue ratio and minimum cash balances and provides certain limited cure provisions in the event these requirements are not met. During 2015 the Company was required to hold a minimum of $5,000 of cash. The Company amended the Credit Facility in March 2016 and amended its debt covenants, which resulted in the Company being subject to lower minimum quarterly revenue requirements, a lower maximum debt-to-revenue ratio and a

requirement to hold a minimum of $10,000 of cash. During the second quarter of 2016 the Company was not in compliance with the debt-to-revenue covenant and received a waiver from the lender.

On October 10, 2016, the Company entered into a Fourth Amendment to the Credit Agreement in connection with the Merger Agreement. The amendment amended and restated certain clauses within the debt agreement to conform to public company standards as well as adjusted the financial covenants as follows:

- Minimum revenue requirement increased quarterly from $15,700 to $25,000 from September 30, 2016 through February 27, 2020;
- Minimum debt to revenue ratio decreased quarterly from 0.80 to 0.40 from September 30, 2016 through February 27, 2020; and
- Minimum cash requirement reduced to $8,000.

As of December 31, 2016, the Company was in compliance with the financial covenants after utilization of the available cure provision rights.

In connection with the Credit Facility, the Company granted a warrant to purchase a total of 163,915 shares of common stock with an exercise price of $21.29 per share. The warrant is exercisable at the option of the holder at any time and expires on February 7, 2022. The fair value of the warrant issued was $1,951 using the Black-Scholes model and was recorded as a warrant liability on the balance sheet and as a debt discount which is being amortized to interest expense over the term of the related note payable using the interest method. The warrant liability was reduced by $641 and $24 for the years ended December 31, 2016 and 2015, respectively in order to reflect fair value with an offsetting credit to interest expense. In connection with the Fourth Amendment, the Company issued the lender a new warrant to purchase 163,915 shares of common stock with an exercise price of $21.29 per share. This warrant replaced the warrant issued in connection with the Credit Facility for the same number of shares and exercise price per share and removed the anti-dilution provisions included in the prior warrant. This warrant is classified as equity.

(b) Note with a Consortium of Lenders

In November 2013, the Company entered into a credit agreement with a consortium of lenders to borrow $50,000. Amounts outstanding under this credit agreement beared interest at 8.25% and were collateralized by all assets of the Company. Loan commitment fees related to this transaction of $750, plus legal fees of $241 were capitalized as other noncurrent assets and were being amortized to interest expense over the note term of 60 months using the interest method. The outstanding balance under the credit agreement was prepaid in February 2015, including prepayment penalties of $1,795, which were included in interest expense. Unamortized deferred financing costs of $641 were written off in February 2015 when the debt was repaid.

In connection with the credit agreement, the Company granted a warrant to purchase a total of 70,580 shares of Series C preferred stock with an exercise price of $21.29 per share. The warrant was exercisable at the option of the holder at any time and expired on November 30, 2020. The fair value of the warrant issued was $1,142 using the Black-Scholes model and was recorded as warrant liability on the balance sheet and as a debt discount which was amortized to interest expense over the term of the related note payable using the interest method until the debt was refinanced and unamortized discount was written off to interest expense. The Company reduced the warrant liability by $522 and $25 for the years ended December 31, 2016 and 2015 respectively to reflect fair value with an offsetting credit to interest expense. The warrant was net exercised and exchanged for 44,027 shares of common stock immediately prior to the Merger and is no longer outstanding at December 31, 2016.

(11) Stockholders' Equity

(a) Authorized Stock

The Company’s amended and restated certificate of incorporation, effective upon the completion of the Merger, authorizes the Company to issue 115,000,000 shares of common and preferred stock, consisting of 100,000,000 shares of common stock with $0.001 par value and 15,000,000 shares of preferred stock with $0.001 par value. The Company has reserved common shares for issuance upon the exercise of the authorized and issued common stock options and warrants.

Prior to the Merger, the Company had authorized 107,574,742 shares of preferred stock, of which 10,006,345 shares were designated as Series A convertible preferred stock ("Series A"), 45,431,126 shares are designated as Series B convertible preferred stock ("Series B") and 52,137,271 shares are designated as Series C convertible preferred stock ("Series C"). Holders

of the preferred stock were entitled to receive dividends out of any assets legally available for payment of cumulative dividends at the annual rate of 8%. As of December 31, 2015, the Company had outstanding 9,588,891 shares of Series A, 45,406,582 shares of Series B and 37,617,334 shares of Series C.

(b) Merger

In the Merger, the previously outstanding shares of convertible preferred stock were converted on a one-to-one basis into shares of common stock and then subject to the Exchange Ratio and 1:5.5 Reverse Stock Split, resulting in all of the outstanding shares of Series A, Series B and Series C preferred stock and the accumulated dividends of $42,507 thereon being converted into 7,326,643 shares of common stock. Following the merger, there were no shares of preferred stock outstanding.

Immediately prior to the Merger, the Company issued and sold an aggregate of 1,019,441 shares of common stock for approximately $29,000.

(c) Warrants

Immediately prior to the Merger, preferred stock warrants were net exercised and exchanged for 15,866 shares of common stock.

Immediately prior to the Merger, common stock warrants were net exercised and exchanged for 234,545 shares of common stock.

In connection with the Merger, Lpath issued warrants to purchase 40,456 shares of common stock to its financial adviser, which are currently outstanding at December 31, 2016. The warrants have an exercise price of $13.70 and expire on December 29, 2021.

Additionally, Lpath had previously issued 59,537 warrants that as of December 31, 2016 were outstanding with an exercise price of $324.08, expiring through September 2019.

(12) Stock Option Plans

(a) Plans

2006 Plan

The Company's 2006 Equity Incentive Plan (the "2006 Plan") allows that employees, consultants, and nonemployee directors of the Company may be granted incentive stock options or nonqualified stock options to purchase shares of the Company's common stock. Options to date have been granted to employees at 100% of the fair value at the date of the grant. The fair value, vesting period, and expiration dates of the options granted are determined by the Board of Directors at the time of grant. The maximum term of options granted under the 2006 Plan is 10 years from the date of grant. Options generally vest over a period of time, typically not more than 5 years. The Company also has the right of first refusal for any proposed disposition of shares under the 2006 Plan. Under certain circumstances, the Company may repurchase previously granted options or shares issued upon the exercise of a previously granted option. The 2006 Plan expired in May 2016.

2016 Plan

The Company's 2016 Equity Incentive Plan (the "2016 Plan") allows that employees, consultants, and nonemployee directors of the Company may be granted incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards restricted stock units and other stock awards to purchase shares of the Company's common stock. Options to date have been granted to employees at 100% of the fair value at the date of the grant. The fair value, vesting period, and expiration dates of the options granted are determined by the Board of Directors at the time of grant. The maximum term of options granted under the 2016 Plan is 10 years from the date of grant. Options generally vest over a period of time, typically not more than 5 years. The Company also has the right of first refusal for any proposed disposition of shares under the 2016 Plan.

Shares subject to awards granted under the 2006 Plan or 2016 Plan which expire, are repurchased, or are canceled or forfeited will again become available for issuance under the 2016 Plan. The shares available will not be reduced by awards settled in cash or by shares withheld to satisfy tax withholding obligations. Only the net number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise will be deducted from the shares available

under the 2016 Plan. As of December 31, 2016, the Company has 21,319,756 shares of common stock reserved for issuance under the 2016 Plan.

Lpath Plan

The Lpath Amended and Restated 2005 Equity Incentive Plan (the "Lpath Plan") allows for grants of incentive stock options with exercise prices of at least 100% of the fair market value of Lpath's common stock, nonqualified options with exercise prices of at least 85% of the fair market value of the company's common stock. All stock options granted to date have a 10 year life and vest over 0 to 5 years. At December 31, 2016, Lpath optionees had 3,182 outstanding options, expiring through March 2017.

(b) Stock Option Activity

A summary of the stock option activity under the 2006 Plan, 2016 Plan and Lpath Plan (collectively the "Equity Plans") as of December 31, 2016 is presented below. Note that the Company did not account for the Lpath plan until the close of the Merger on December 29, 2016 and the tables below reflect Lpath information only after this date.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(Years)	($000's)
Options outstanding, December 31, 2015	972,565	$2.96	7.6 years	$—
Options granted	235,414	1.99		
Options exercised	(22,964)	2.35		
Options forfeited	(168,368)	1.88		
Options outstanding, December 31, 2016	1,016,647	$2.94	7.0 years	$9,343
Options vested and expected to vest, December 31, 2016	1,011,863	$2.94	7.0 years	$9,343
Options exercisable, December 31, 2016	548,262	$2.79	6.3 years	$5,137

The fair value for options under the Equity Plans was estimated at the date of grant using the Black-Scholes option pricing model in valuing its stock awards. Prior to the Merger, the value of the Company's common stock was determined by an independent valuation firm using a blend of an income approach, market approach and cost approach. The Black-Scholes model requires estimating dividend yield, volatility, risk-free rate of return, estimated forfeitures during the service period and the expected term of the award. The expected dividend yield assumption is based on the Company’s expectation of zero future dividend payouts. The volatility assumption is based on the historical volatilities of the Company’s common stock and of comparable public companies. The risk free rate of return assumption utilizes yields on U.S. treasury zero-coupon bonds with maturity that is commensurate with the expected term for awards issued to employees and the contractual term for awards issued to non-employees. The expected term is derived using the simplified method and represents the weighted average period that the stock awards are expected to remain outstanding.

The fair value of stock option grants has been estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for the years ended December 31:

	2016	2015
Risk free interest rate	1.4%	1.7%
Expected dividend yield	—%	—%
Estimated volatility	57.0%	81.2%
Expected life	5.5 years	6.0 years

(In thousands, except for share data)

Additional information regarding options is as follows:

	2016	2015
Stock compensation cost	$ 381	$ 472
Weighted-average grant date fair value of options granted during the period	$ 1.22	$ 2.22
Aggregate intrinsic value of options exercised during the period	$ 42	$ 48

The aggregate intrinsic value in the table above represents the total pre-tax value of the options shown, calculated as the difference between the Company's closing stock price on December 31, 2016 and the exercise prices of the options shown, multiplied by the number of in-the money options. This is the aggregate amount that would have been received by the option holders if they had all exercised their options on December 31, 2016 and sold the shares thereby received at the closing price of the Company's stock on that date. This amount changes based on the closing price of the Company's stock.

The Company has granted 139,513 options to purchase common shares that will vest upon the Company's achievement of certain global revenue and EBITDA targets for calendar years 2016 and 2017. These performance targets are not deemed probable and thus no amounts have been recognized associated with these amounts.

Unrecognized compensation expense related to unvested options was approximately $567 at December 31, 2016, with a remaining amortization period of less than four years.

(13) Commitments

(a) Lease Commitments

The Company has entered into various lease agreements for its operating facilities in Texas and California, the manufacturing facility located in Costa Rica, and for office spaces in the United Kingdom, Australia, Italy and Brazil. The Company also has various lease agreements for equipment and vehicles.

Lease expense for the years ended December 31, 2016 and 2015 was $1,120 and $930, respectively. Certain of these leases contain scheduled rent increases which are included in lease expense and recognized using the straight-line method over the term of the leases.

At December 31, 2016, minimum rental commitments under non-cancelable operating leases payable over the next five years are as follows:

2017	$ 1,505
2018	887
2019	569
2020	481
2021	384
Thereafter	—
Total	$ 3,826

(b) Risk Management

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to these risks to an acceptable level.

(c) Employment Agreements

Certain executive officers are entitled to payments if they are terminated without cause or as a result of a change in control. Upon termination without cause, and not as a result of death or disability, each of such officers is entitled to receive a payment of base salary for three to twelve months following termination of employment and such officer will be entitled to continue to receive coverage under medical and dental benefit plans for three to twelve months or until such officer is covered under a separate plan from another employer. Upon a termination other than for cause or for good reason within 12 months

(In thousands, except for share data)

following a change in control, each of such officers will be entitled to the same benefits as upon termination without cause and will also be entitled to certain acceleration of such officer's outstanding unvested options at the time of such termination.

(d) Litigation

Management believes that there are no claims or actions pending or threatened against the Company, the ultimate disposition of which would have a material impact on the Company's consolidated financial position, results of operations or cash flows. We were informed by the Department of Justice that the Company is a subject in a federal False Claims Act investigation. The government's investigation concerns whether there has been or is a violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. related to the marketing of the Lap-Band system, including the web-based physician locator provided on our website Lap-Band.com. We believe the investigation covers the period before and after our acquisition of the obesity intervention division of Allergan, Inc. in December 2013. We are cooperating fully with the investigation, but we cannot predict the outcome of the investigation or the effect of the findings of the investigation on our business, but it is possible that the foregoing matter could result in a material adverse effect on our business, reputation, results of operation and financial condition.

(14) Defined Contribution Plan

The Company sponsors a defined contribution plan for employees in the U.S. The cost of this plan, including employer contributions, was $553 and $555 for the years ended December 31, 2016 and 2015 respectively.

(15) Income Taxes

Income tax expense of $387 and $49 for the years ended December 31, 2016 and 2015, respectively is composed of foreign income taxes on earnings generated in the foreign subsidiaries.

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

	2016	2015
Deferred tax assets:		
Capitalized transaction costs	$ 686	$ 742
Intangible assets	2,794	1,741
Inventory valuation	1,371	173
Research and development credit	2,796	2,522
Foreign timing differences	117	—
Unremitted foreign earnings	100	—
Other	1,121	1,162
Net operating loss carryforwards	44,087	35,780
	53,072	42,120
Deferred tax liabilities:		
Depreciable assets	(288)	(230)
	(288)	(230)
Total net deferred tax assets	52,784	41,890
Less valuation allowance	(52,784)	(41,890)
Net deferred tax assets (liabilities)	$ —	$ —

The Company has established a valuation allowance equal to the total net deferred tax asset due to uncertainties regarding the realization of deferred tax assets based on the Company's lack of earnings history and potential limitations pursuant to changes in ownership under Internal Revenue Code Section 382. The valuation allowance increased by $10,894 during the year ended December 31, 2016, primarily as a result of changes in net operating loss.

(In thousands, except for share data)

As of December 31, 2016, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions.

The Company's provision for income taxes differs from the expected tax expense amount computed by applying the statutory federal income tax rate of 34% to income before income taxes as a result of the following:

	2016	2015
Tax at U.S. statutory rate of 34%	$ (13,865)	$ (9,327)
State taxes, net of deferred benefit	(1,061)	(628)
Foreign tax rate differential	422	775
Foreign taxes	91	49
Permanent differences	3,942	269
Contingent purchase price	—	(1,625)
Research and development tax credit	(240)	(345)
Other	204	(18)
Change in valuation allowance	10,894	10,899
Income tax expense	$ 387	$ 49

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $123,335 which will expire in varying amounts beginning in 2025 if not utilized. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards which can be used in future years. The Company had state net operating loss carryforwards of approximately $43,330 which will begin to expire in varying amounts beginning in 2019. The Company had foreign net operating losses of approximately $4,120 of which $0 have an indefinite carryforward. The remaining amount of $4,120 begin to expire in varying amounts beginning in 2020, if not utilized.

(16) Net Loss Per Share

The basic and diluted net loss per common share presented in the consolidated statement of operations and comprehensive loss is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. For the purposes of determining net loss per share in 2016, the additional common shares from the Lpath merger transaction on December 29, 2016 were weighted as outstanding for two days for the year ended December 31, 2016. Net loss attributable to common stockholders in 2015 was computed by deducting current dividends on convertible preferred stock from net loss. Potentially dilutive shares, which include convertible preferred stock in 2015, warrants for the purchase of common and preferred stock, and options outstanding under the Company's equity incentive plans, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Year Ended December 31	
	2016	2015
Preferred stock	—	6,901,130
Warrants for common and preferred stock	263,856	495,144
Common stock options	1,016,647	972,565
	1,280,503	8,368,839

(In thousands, except for share data)

(17) Related Party Transactions

Transitional services for manufacturing, distribution and technical product support were provided by Allergan (see note 3). The Company owed Allergan $1,259 and $1,205 for transitional services and $7,246 and $3,750 for purchases of inventory that are recorded in payable to related parties at December 31, 2016 and 2015, respectively. Additionally, Allergan holds 70,580 shares of the Company's common stock as of December 31, 2016.

(18) Liquidity and Capital Resources

The Company has experienced operating losses and debt covenant violations since inception and has an accumulated deficit of $149,729 as of December 31, 2016. To date, the Company has funded its operating losses and acquisitions through private equity offerings and the issuance of debt instruments. The Company's ability to fund future operations and satisfy its ongoing debt covenant requirements will depend upon its level of future operating cash flow and its ability to access additional funding through either equity offerings, issuances of debt instruments or both. On February 27, 2015, the Company entered into a Credit Facility (see note 10(a)) which requires the Company to meet minimum revenue requirements and other covenants each quarter and provides a cure provision in the event this requirement is not met. If the Company is not able to meet its ongoing quarterly covenant requirements or utilize the remaining cure provision rights, the repayment of the Credit Facility could be accelerated at the lender's discretion. The Company believes its existing cash and cash equivalents and remaining cure provision rights will be sufficient to meet liquidity and capital requirements for a reasonable period of time.

(19) Segment and Geographic Information

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company globally manages the business within one reportable segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. The Company’s products are principally sold in the U.S. No other countries are individually significant.

Product sales by product group and geographic market, based on the location of the customer, for the periods shown were as follows:

	Year Ended December 31, 2016				Year Ended December 31, 2015			
	U.S.	OUS	Total Revenue	% Total Revenue	U.S.	OUS	Total Revenue	% Total Revenue
Endo-bariatric	$ 15,525	$ 16,382	$ 31,907	49.2%	$ 9,119	$ 8,003	$ 17,122	25.3%
Surgical	21,778	10,706	32,484	50.1%	34,975	12,628	47,603	70.2%
Other	453	24	477	0.7%	425	2,640	3,065	4.5%
Total revenues	$ 37,756	$ 27,112	$ 64,868	100.0%	$ 44,519	$ 23,271	$ 67,790	100.0%
% Total revenue	58.2%	41.8%			65.7%	34.3%		

The following table represents property and equipment, net based on the physical geographic location of the asset:

	2016	2015
United States	$ 2,426	$ 3,028
Costa Rica	4,177	4,598
Other	268	346
Total property and equipment, net	$ 6,871	$ 7,972

(20) Subsequent Events

On March 7, 2017, the Company entered into a Fifth Amendment to the Credit Agreement with its lender, Athyrium Opportunities II Acquisition LP ("Athyrium"), to modify the terms of its senior secured credit facility.

Specifically, the Fifth Amendment (i) reduced the minimum cash balance requirement to $0 from $8,000, (ii) reduced the minimum quarterly revenue requirement to $13,000 from $18,000, (iii) increased the maximum debt-to-revenue ratio to 0.65 from 0.60 and (iv) required Apollo to make a principal repayment of $7,000. The minimum quarterly revenue requirement will increase by $1,000 quarterly over the remaining term of the facility, and the maximum debt-to-revenue ratio will decline gradually each quarter, from 0.65 to 0.25, over the remaining term of the facility.

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

(a) On January 18, 2017, the Audit Committee of the Board of Directors (the "Audit Committee") of Apollo Endosurgery, Inc. (the "Company") confirmed the resignation of Moss Adams LLP as its independent registered public accounting firm, effective as of January 17, 2017.

The report of Moss Adams LLP on the Company's consolidated financial statements for the years ended December 31, 2015 and 2014 did not contain an adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope, or accounting principles, other than an explanatory paragraph relating to the Company's ability to continue as a going concern. During the years ended December 31, 2015 and 2014, and the subsequent interim period through January 17, 2017 there were no: (1) disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) with Moss Adams LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement if not resolved to the satisfaction of Moss Adams LLP would have caused Moss Adams LLP to make reference thereto in its reports on the consolidated financial statements for such years, or (2) reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

(b) On January 18, 2017, the Audit Committee approved the engagement of KPMG LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2016.

On December 29, 2016, the Company completed its business combination with what was then known as "Apollo Endosurgery, Inc." ("Private Apollo") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 8, 2016, by and among the Company, Lpath Merger Sub, Inc. ("Merger Sub"), and Private Apollo (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Private Apollo, with Apollo surviving as a wholly owned subsidiary of the Company (the "Merger"). Prior to the completion of the merger KPMG LLP served as the auditor of Apollo.

During the years ended December 31, 2015 and 2014, and the subsequent interim period through December 29, 2016, neither Lpath, Inc. nor anyone on their behalf consulted with KPMG LLP, regarding either (i) the application of accounting principles to a specific transaction, completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that KPMG LLP concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

The Company delivered a copy of the above disclosures to Moss Adams LLP on January 18, 2017 and requested that a letter addressed to the Securities and Exchange Commission stating whether or not it agrees with the statements made in response to this Item and, if not, stating the respects in which it does not agree. Moss Adams LLP responded with a letter dated January 20, 2017, a copy of which is filed as Exhibit 16.1 stating that Moss Adams LLP agrees with the statements set forth above.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management evaluated, with the participation and under the supervision of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain a system of internal control that is designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Notwithstanding that we do not qualify for the relief afforded by Instruction 1 to Item 308 of Regulation S-K to newly public companies, management has not assessed nor attested to our internal control over financial reporting as is set forth in

Item 308 of Regulation S-K promulgated under the Securities Exchange Act 1934, as amended, and Section 404 of the Sarbanes-Oxley Act as of December 31, 2016, the end of our last fiscal year. We will do so initially as of December 31, 2017.

We were unable to conduct the required assessment primarily due to the Merger occurring in the fourth quarter of 2016 and the substantial change in operational focus, management and the internal control environment following the Merger. Following the Merger, our historical operations, and not that of Lpath, represent virtually the entirety of the combined business. In addition, following the Merger the accounting and financial systems of Lpath, as well as personnel, were replaced by those of Apollo. Due to the extensive changes to our internal control environment, it was impractical for us to develop, implement, refine, test, assess our internal control environment and produce management's assessment of internal control over financial reporting as required by Item 308 of Regulation S-K.

Changes in Internal Control over Financial Reporting.

Other than as discussed above, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fiscal quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2016 fiscal year pursuant to Regulation 14A for our 2017 Annual Meeting of Stockholders, (the "2017 Proxy Statement") and the information to be included in the 2017 Proxy Statement is incorporated by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be included in our 2017 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in our 2017 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in our 2017 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be included in our 2017 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will be included in our 2017 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements and Financial Statement Schedules

1. Financial Statements

The financial statements of Apollo Endosurgery, Inc. listed below are set forth in Item 8 of this report for the year ended December 31, 2016:

2. Financial Statement Schedules

All other schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(b) Exhibits

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 8, 2016, by and among Lpath, Inc., Lpath Merger Sub, Inc., and Apollo Endosurgery, Inc.	Form 8-K	001-35706	2.1	September 8, 2016
2.2	Acquisition Agreement and Plan of Merger, dated as of March 19, 2004, between Neighborhood Connections, Inc. and JCG, Inc.	Form 8-K	000-50344	2.1	March 22, 2004
2.3	Plan of Conversion, dated July 17, 2014, of Lpath, Inc.	Form 8-K	001-35706	2.1	July 21, 2014
3.1	Amended and Restated Certificate of Incorporation.	Form 8-K	001-35706	3.1	January 3, 2017
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	Form 8-K	001-35706	3.2	January 3, 2017
3.3	Certificate of Incorporation of Lpath, Inc.	Form 8-K	001-35706	3.3	July 21, 2014
3.4	Amended and Restated Bylaws of Lpath, Inc.	Form 8-K	001-35706	3.1	September 8, 2016

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
3.5	Articles of Conversion, as filed with the Secretary of State of the State of Nevada on July 17, 2014.	Form 8-K	001-35706	3.1	July 21, 2014
3.6	Certificate of Conversion, as filed with the Secretary of State of the State of Delaware on July 17, 2014.	Form 8-K	001-35706	3.2	July 21, 2014
4.1	Specimen Common Stock Certificate of Lpath, Inc.	Form 8-K	001-35706	4.1	July 21, 2014
4.2	Form of Common Stock Purchase Warrant for Investors in the Units.	Form 8-K	000-50344	4.1	March 6, 2012
4.3	Form of Common Stock Purchase Warrant for Placement Agents of the Units.	Form 8-K	000-50344	4.2	March 6, 2012
4.4	Form of Warrant for Griffin Securities, Inc.	Form 8-K	000-50344	4.3	March 6, 2012
4.5	Form of Warrant Issued to Investors in the September 2014 Offering.	Form 8-K	001-35706	4.1	September 22, 2014
4.6	Form of Warrant issued to Maxim Group LLC in the September 2014 Offering.	Form 8-K	001-35706	4.2	September 22, 2014
4.7	Form of Warrant issued to Torreya Capital.	Form S-4	333-214059	4.7	October 11, 2016
4.8	Apollo Common Stock Purchase Warrant issued to Athyrium Opportunities II Acquisition LP dated February 27, 2015.	Form S-4	333-214059	4.8	October 11, 2016
4.9	Third Amended and Restated Investors' Rights Agreement, dated as of September 8, 2016 by and among Apollo Endosurgery, Inc. and the investors listed on Exhibit A thereto.	Form S-4	333-214059	4.9	October 11, 2016
5.1	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian LLP regarding the validity of the securities.	Form S-4	333-214059	5.1	November 14, 2016
8.1	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian LLP regarding tax matters.	Form S-4	333-214059	8.1	November 14, 2016
8.2	Opinion of Cooley LLP regarding tax matters.	Form S-4	333-214059	8.2	November 14, 2016

Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		
			File Number	Exhibit	Filing Date
10.1	Form of Indemnity Agreement between Apollo Endosurgery, Inc. and its executive officers and directors.	Form 8-K	001-35706	10.1	January 3, 2017
10.2 #	Apollo Endosurgery, Inc. 2006 Stock Option Plan and forms of agreements relating thereto.	Form S-4	333-214059	10.1	October 11, 2016
10.3 #	Apollo Endosurgery, Inc. 2016 Equity Incentive Plan and forms of agreements relating thereto.	Form S-4	333-214059	10.2	October 11, 2016
10.4	Credit Agreement, dated February 27, 2015, by and among the Company, Athyrium Opportunities II Acquisition LP, as administrative agent, the guarantors party thereto, and the other lenders from time to time party thereto, as amended or supplemented on May 8, 2015, July 29, 2015, March 8, 2016,October 10, 2016 and March 7, 2017, together with the Exhibits, Schedules and Annexes thereto.	Form 8-K	001-35706	10.1	March 8, 2017
10.5	Lease dated May 31, 2011 between Sorrento Science Park, LLC and Lpath, Inc. for 4025 Sorrento Valley Blvd. San Diego, California 92121.	Form 8-K	000-50344	10.1	June 3, 2011
10.6	Research Collaboration Agreement dated August 2, 2005 between Lpath Therapeutics Inc. and AERES Biomedical Limited.	Form 8-K/A	000-50344	10.4	January 9, 2006
10.7 #	Lpath, Inc. Amended and Restated 2005 Equity Incentive Plan.	Schedule 14-A	001-35706	Appendix A	April 27, 2015
10.8	Assignment and Assumption Agreement dated December 1, 2005 by and between Lpath, Inc. and Lpath Therapeutics, Inc.	Form 10-KSB	000-50344	10.8	March 16, 2006
10.9 #	Form of Employment Agreement between Lpath, Inc. and Gary Atkinson dated as of February 6, 2006.	Form 8-K	000-50344	99.2	March 29, 2006
10.10	Form of Indemnification Agreement for directors and officers.	Form 8-K	001-35706	10.1	July 21, 2014

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.11	At-The-Market Issuance Sales Agreement, dated as of March 18, 2014 by and between MLV & Co. LLC and Lpath, Inc.	Form 10-K	001-35706	10.25	March 18, 2014
10.12 #	First Amendment to Employment Agreement, between Lpath, Inc. and Gary Atkinson, entered into as of March 17, 2014.	Form 10-K	001-35706	10.26	March 18, 2014
10.13 #	Form of Option Agreement, between the Lpath, Inc. and its officers and directors.	Form 10-K	001-35706	10.27	March 18, 2014
10.14 #	Employment Agreement, dated as of April 15, 2013 by and between Lpath, Inc. and Dario A. Paggiarino, M.D.	Form 10-K	001-35706	10.28	March 18, 2014
10.15 #	Employment Agreement, dated as of April 15, 2013 by and between Lpath, Inc. and Gary Woodnutt Ph.D.	Form 10-K	001-35706	10.29	March 18, 2014
10.16	Securities Purchase Agreement, dated September 19, 2014, between Lpath, Inc. and investors in the September 2014 Offering.	Form 8-K	001-35706	10.1	September 22, 2014
10.17	Form of Registration Rights Agreement between Lpath, Inc. and investors in the September 2014 Offering.	Form 8-K	001-35706	10.2	September 22, 2014
10.18 #	Employment Agreement, dated June 1, 2006 (effective September 1, 2005), as amended September 16, 2007, July 1, 2014 and May 19, 2016, between Apollo Endosurgery, Inc. and Dennis McWilliams.	Form S-4	333-214059	10.16	October 11, 2016
10.19 #	Employment Agreement, dated June 1, 2014, as amended May 19, 2016, between Apollo Endosurgery, Inc. and Todd Newton.	Form S-4	333-214059	10.17	October 11, 2016
10.20 #	Offer Letter, dated November 19, 2014, between Apollo Endosurgery, Inc. and Bret Schwartzhoff.	Form S-4	333-214059	10.18	October 11, 2016
10.21 #	Offer Letter, dated March 2, 2015, between Apollo Endosurgery, Inc. and Stefanie Cavanaugh.	Form 8-K	001-35706	10.6	January 3, 2017

Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		
			File Number	Exhibit	Filing Date
10.22	Office Lease Agreement, dated as of July 16, 2012, between Apollo Endosurgery, Inc., as Tenant, and Aslan IV Austin, LLC as Landlord, subsequently assigned to DPF Cityview LP.	Form S-4	333-214059	10.19	October 11, 2016
10.23	Lease Agreement, dated August 7, 2014, between Apollo Endosurgery Costa Rica Sociedad de Responsabilidad Limitada and Zona Franca Coyol, S.A.	Form S-4	333-214059	10.20	October 11, 2016
10.24 ++	Intellectual Property Assignment Agreement, dated November 4, 2009, by and between Apollo Endosurgery, Inc., Olympus Corporation, the University of Texas Medical Branch, the Johns Hopkins University, the Mayo Foundation for Medical Education and Research, the Medical University of South Carolina Foundation for Research Development and the Chinese University of Hong Kong.	Form S-4	333-214059	10.21	November 14, 2016
10.25 #	Separation Agreement, dated as of October 14, 2016, by and between Gary Woodnutt, Ph.D. and Lpath, Inc.	Form 8-K	001-35706	10.1	October 14, 2016
10.26 * #	Tribie offer letter, dated March 21, 2014				
16.1	Letter dated January 20, 2017 from Moss Adams LLP to SEC	Form 8-K	001-35706	16.1	January 20, 2017
21.1	List of Subsidiaries	Form S-4	333-214059	21.1	October 11, 2016
23.1 *	Consent of KPMG LLP, Independent Public Accounting Firm to Apollo Endosurgery, Inc.				
31.1 *	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2 *	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
32.1 *	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2 *	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

———————

Management contract or compensation plan or arrangement

* Provided herewith.

++ Confidential treatment has been requested for certain provisions omitted from this Exhibit pursuant to Rule 406 promulgated under the Securities Act. The omitted information has been filed separately with the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

In accordance with the requirements of Section 13 on 15(k) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf on March 23, 2017 by the undersigned thereto.

APOLLO ENDOSURGERY, INC.

/s/ Todd Newton

Todd Newton

Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Todd Newton and Stefanie Cavanaugh, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 23, 2017.

Signature	Title	Date
/s/ Todd Newton Todd Newton	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2017
/s/ Stefanie Cavanaugh Stefanie Cavanaugh	Chief Financial Officer, Treasurer and Secretary *(Principal Financial Officer)*	March 23, 2017
/s/ Chrissy Citzler-Carr Chrissy Citzler-Carr	Controller *(Principal Accounting Officer)*	March 23, 2017
/s/ Richard J. Meelia Richard J. Meelia	Chairman of the Board	March 23, 2017
/s/ Rick Anderson Rick Anderson	Director	March 23, 2017
/s/ Matthew S. Crawford Matthew S. Crawford	Director	March 23, 2017
/s/ John Creecy John Creecy	Director	March 23, 2017
/s/ William D. McClellan, Jr. William D. McClellan, Jr.	Director	March 23, 2017

/s/ R. Kent McGaughy, Jr. R. Kent McGaughy, Jr.	Director	March 23, 2017
/s/ Jack Nielsen Jack Nielsen	Director	March 23, 2017
/s/ Bruce Robertson, PH.D. Bruce Robertson, Ph.D.	Director	March 23, 2017

March 21, 2014

Charles Tribie
5151 Edloe Street, Apt. 5101
Houston, Texas 77005

Dear Charles:

Apollo Endosurgery, Inc. ("Apollo" or the "Company") is extremely pleased to provide an offer of employment with our company in the position of Executive Vice President of Operations. This offer letter supersedes all other communications verbal or written. We expect that your employment as a full-time employee with the Company will start on or about **April 15, 2014**, subject to your approval of the terms hereof.

As an Executive Vice President of Operations, you will report to Apollo's Chief Executive Officer and you shall have duties and authority as are customarily performed by an Executive Vice President of Operations of a company similar in size and business as Apollo Endosurgery. You will be responsible for working in adherence to Apollo's quality systems including completing new hire training within 90 days of employment and additional training within the timelines and standards of Apollo's training policies. Your responsibilities may be adjusted by your supervisor from time to time.

As a full-time Apollo employee, you will receive the following:

- Salary: Upon employment, you will receive a starting salary of $11,875.00 per pay period (before applicable withholding and taxes) as your base salary to be paid on the Company's regular paydays on a semi-monthly basis.

- Annual Bonus: You will be eligible to receive an annual target bonus of up to 35% of your then current base salary, payable in accordance with the Company's standard policies and practices. Your first-year bonus will be prorated for partial year employment. In addition, you will be eligible for an accelerated bonus of up to a maximum of 70% of your base salary for exceeding corporate objectives as approved by the Board of Directors during the calendar years 2014, 2015 and 2016. Your annual bonus will be based upon mutually agreed upon milestones and other relevant criteria; however, the decision of whether or not such criteria have been achieved will be at the sole discretion of management. Please note that the determination to pay annual bonuses each year is solely within the discretion of the Board of Directors of the Company.

- Relocation and Temporary Living Expense: Your position is based in Austin, Texas, and by accepting this offer, you agree to relocate your primary residence to Austin. The Company will pay for reasonable and customary moving expenses for your household items to be relocated to Austin, Texas up to $25,000 for your household goods in Houston, Texas and one additional residence. Apollo has a relocation provider of choice and you may use Apollo's relocation provider or another moving company with a written quote approved by human resources. In addition, you will receive an additional amount of $3,500 per month for up to 6 months, net of applicable taxes and withholdings, for you to use for temporary living in Austin, Texas and expenses related to your current lease in Houston, Texas. Receipts will need to be submitted to HR for reimbursement of temporary housing. Applicable taxes and withholdings will apply for all relocation payments as required by the Internal Revenue Service.

  In the event you voluntarily terminate your employment with the Company within the first six months, 100% of the total relocation amount is due back to the Company. In the event you voluntarily terminate employment with the Company within the first twelve months, the relocation payment due back to the Company will be prorated based on the number of full months employed.

- Employment Stock Options: You will be granted an Incentive Stock Option to purchase 974,000 shares of Company Common Stock, subject to Board of Director approval. The granting of these options will be governed by the Company's --2006 Stock Option Plan and an option agreement, which the Company will provide you upon request or when you receive your grant. These documents will govern and control your options and any stock issued upon exercise of your options. You should look to these documents for a complete description of the option's terms, but, to summarize, the exercise price of your options will be equal to the fair market value per share of Company's Common Stock on the date of grant, as determined by Company's Board of Directors, and your options, after the initial vesting of 25% of the shares subject to the option at the one year anniversary of the date of your employment, will vest thereafter in equal monthly installments over thirty-six

(36) months, based on continued employment.

- Vacation: You will be eligible for the Company's vacation plan which provides that you accumulate 10 hours of vacation day per month, prorated during your first calendar year of employment. Per the company's policies, you will be entitled to ten (10) days of sick time per calendar year, which will not carry over to the next calendar year, prorated based on date of hire.

- Health Care Plan and Other Benefits. You will be entitled to participate in the Company's health care plan and all of the other Company standard benefits on the first of the month following your start date.

- Travel and Other Expenses: You will be entitled to reimbursement by the Company for all reasonable travel, lodging, and other expenses actually incurred in connection with the performance of your duties, against receipts or other appropriate written evidence of such expenditures as required by the appropriate United States Internal Revenue Service regulations and our Company's standard policies and practices.

- Severance: In no way limiting Apollo Endosurgery's policy of at-will employment (as described below), if your employment is terminated by Apollo Endosurgery other than for Cause, and other than as a result of your death or disability, and in either case such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), a "Separation from Service"), subject to your obligations set forth below, Apollo Endosurgery will provide you a one (1) month notice period and an amount equal to six (6) months of your then-current salary payable over such 6-month period immediately following the Separation from Service, on the schedule described below (the "Salary Continuation"). The Salary Continuation described above will be conditional upon (a) your compliance with your continuing obligations to the Company under your signed and Invention, Confidential Information and Non-Competition Agreement; (b) your resignation from all positions you hold with the Company; and (c) your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 30 days following your Separation from Service. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your Separation from Service; *provided, however,* that no payments will be made prior to the 30th day following your Separation from Service. On the 30th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 30th day in compliance with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"), and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled."Cause" for termination of your employment will exist if, in the reasonable good faith determination of Apollo Endosurgery, you have engaged in one of the following examples of misconduct: (i) final, non-appealable conviction of any felony crime involving moral turpitude or dishonesty; (ii) participated in a fraud or act of dishonesty which materially harms Apollo Endosurgery; (iii) willfully and materially and repeatedly breached your duties and have not cured or remedied such breach within thirty (30) days after written notice from Apollo Endosurgery of such breach; (iv) materially breached any written agreement between you and Apollo Endosurgery, including this letter agreement or the Invention, Confidential Information and Non-Competition Agreement, and have not cured or remedied such breach within thirty (30) days after written notice from the company of such breach.

  It is intended that all of the benefits and payments under this letter satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions. If not so exempt, this letter (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and payment terms. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) will be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder will at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this letter, if you are deemed by Apollo Endosurgery at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the company are deemed to be "deferred compensation", then if delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, the timing of the payments upon a Separation from Service will be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after the effective date of your Separation from Service, and (ii) the date

of the your death (such earlier date, the "Delayed Initial Payment Date"), the Company will (A) pay to you a lump sum amount equal to the sum of the payments upon Separation from Service that you would otherwise have received through the Delayed Initial Payment Date if the commencement of the payments had not been delayed pursuant to this paragraph, and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth above. The Company will indemnify and hold you harmless against any penalties or other amounts assessed on you as a result of the Company structuring payments under this letter in violation of Code Section 409A.

The Company requires all job candidates to undergo screening for the presence of illegal drugs as a condition for employment. Any candidate with positive test results will be denied employment at that time. In the event that employment commences prior to the Company receiving the drug test results, it is the understanding of the employee and the Company that the employee will be immediately discharged in the event of a positive result. In addition, the Company requires all candidates to complete a standard criminal background check as a condition of employment.

You will be required to execute the Company's standard Invention, Confidential Information and Non-Competition Agreement.

For purposes of federal immigration laws, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided within 3 business days of the effective date of your employment, or your employment relationship with the Company will be terminated.

Your employment relationship with Apollo will be what is called "at will." That is, even after accepting this employment offer, you will have the right to quit at any time, and the Company will have the right to end your employment relationship with the Company for any reason, with or without cause, or for no reason. Of course we hope everything works out for the best, but the Company wants to make sure that you understand that nothing in this letter or in any Company policy or statement (including any other written or verbal statements made to you during negotiations about working at Apollo) is intended to or does create anything but an at will employment relationship. Only the Company's Board of Directors may modify your at-will employment status, or guarantee that you will be employed for a specific period of time. Such modification must be in writing, approved by the Board of Directors, and signed by an authorized Company representative.

You agree that you will not use in the performance of your duties, nor disclose to any Apollo employee, any confidential information or trade secrets of any former employer or other person which would violate your legal obligations to those parties. Performance of your duties at Apollo will only require information and knowledge which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by Apollo.

The terms and conditions of the offer reflected will remain open until the earlier of the execution of this letter and the Invention, Confidential Information and Non-Competition Agreement or until the close of business on **March 26, 2014** unless revoked before then by the Company. Upon execution, this letter, together with the Invention, Confidential Information and Non-Competition Agreement, contains the entire agreement among the parties relating to your proposed employment with the Company and supersedes any previous agreements, including consulting agreements, communications or offers of any kind, written or verbal, between the parties.

We are excited about you joining the Apollo team. We believe that you can make a significant contribution to the success of the Company and are eager to have you join us and help us revolutionize surgery.

Sincerely,

/s/ Mary League

Mary League
Director of Human Resources

Accepted and agreed:

Charles Tribie

Employee Name - printed

/s/Charles Tribie

Employee Name - signature

Date: March 25, 2014

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Apollo Endosurgery, Inc.

We consent to the incorporation by reference in the registration statement (No. 333-215817) on Form S-8 of Apollo Endosurgery, Inc. of our report dated March 23, 2017, with respect to the consolidated balance sheets of Apollo Endosurgery, Inc. and subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, changes in redeemable preferred stock and stockholders' equity / (deficit) and cash flows for the years then ended, which report appears in the December 31, 2016 annual report on Form 10-K of Apollo Endosurgery, Inc.

/s/ KPMG LLP

Austin, Texas
March 23, 2017

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd Newton, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apollo Endosurgery, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of 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 functions):

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

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

Date: March 23, 2017

By: /s/ Todd Newton

Todd Newton

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stefanie Cavanaugh, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apollo Endosurgery, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of 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 functions):

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

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

Date: March 23, 2017

By: /s/ Stefanie Cavanaugh
Stefanie Cavanaugh
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Todd Newton, Chief Executive Officer of Apollo Endosurgery, Inc. (the "Company"), hereby certifies that:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2016, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 23, 2017

By: /s/ Todd Newton
Todd Newton
Chief Executive Officer
(Principal Executive Officer)

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Apollo Endosurgery, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Stefanie Cavanaugh, Chief Financial Officer of Apollo Endosurgery, Inc. (the "Company"), hereby certifies that:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2016, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 23, 2017

By: /s/ Stefanie Cavanaugh
Stefanie Cavanaugh
Chief Financial Officer
(Principal Financial Officer)

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Apollo Endosurgery, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.