UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018
OR

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

For the transition period from to

Commission file number: 001-35706

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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☐

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant (assuming for these purposes, but without conceding, that all executive officers and directors of the registrant are affiliates of the registrant) was computed based on the adjusted close price of $6.98 as reported on the Nasdaq Global Market on June 29, 2018 is $98,996,893.

As of February 28, 2019, there were 21,913,243 shares of the issuer's $0.001 par value common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2019 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, 2018.

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 (disclosed or undisclosed) and may be limited or incomplete, 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 as predictions of future events. 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.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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 U.S. Dollars.

Investors and others should note that we announce material financial information to our investor using our investor relations website (https://ir.apolloendo.com/). SEC filings, public conference calls and webcasts. We use these channels to communicate with our members and the public about our company, our services, and other issues. Therefore, we encourage investors, the media, and others interested in our company to review the information we provide on the channels listed above.

PART I

ITEM 1. BUSINESS

Overview

We are a medical technology company primarily focused on the design, development and commercialization of innovative medical devices to advance gastrointestinal therapeutic endoscopy.

Our strategic focus and our future revenue growth is expected to come from our Endo-bariatric product portfolio, which consists of the OverStitch™ Endoscopic Suturing System and Orbera® managed weight loss system. In the past, a portion of our product revenues has come from the Surgical product line, which consisted of the Lap-Band® System and related laparoscopic accessories but this line was divested in December 2018.

We are one of the market share leaders in less invasive devices that treat various gastrointestinal ("GI") conditions, ranging from gastrointestinal defect repairs to the interventional treatment of obesity. Our products are used by gastroenterologists and bariatric surgeons in a variety of settings to provide interventional therapy to patients who suffer from obesity and the many co-morbidities associated with obesity, other GI conditions including closure of acute perforations and chronic fistulas; inadvertent perforation of the GI tract; 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, or "POEM") as well as to suture in place esophageal stents in order to prevent their migration.

We believe that obesity is a chronic disease that places a tremendous burden on healthcare systems and their costs worldwide. The optimal clinical outcome for a substantial portion of patients suffering from obesity will require interventional treatments. As a result, our product portfolio consists of interventional devices that fill the gap between low efficacy drug treatments for obesity and highly-invasive, anatomy-altering bariatric stapling procedures.

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.

In December 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.

Following this acquisition, we established offices in England, Australia, Italy and Brazil that oversee regional sales and distribution activities outside the U.S.; 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.

In December 2016, we completed a business combination (the "Merger") with Lpath, Inc. ("Lpath"), a publicly traded company. Following the Merger, Lpath was renamed "Apollo Endosurgery, Inc." and our common stock began trading on The Nasdaq Global Market under the symbol "APEN."

In December 2018, Apollo entered into an Asset Purchase Agreement ("Purchase Agreement") with ReShape Lifesciences, Inc. ("ReShape") pursuant to which, among other things, ReShape acquired from Apollo substantially all of our assets exclusively related to the Surgical product line for $10.0 million in cash and future cash consideration. As additional consideration, we also received from ReShape substantially all of their assets exclusively related to their intragastric balloon product line. On December 31, 2018, the Company ceased sales of ReShape's intragastric balloon product.

"Orbera", "OverStitch", the Apollo logo and other trademarks or service marks of Apollo Endosurgery, Inc. appearing in this annual report are the property of Apollo Endosurgery, Inc. Other trademarks, service marks or trade names appearing in this annual report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us, by these other companies.

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/compliance 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 the Market

The majority of procedures performed using our Endo-bariatric products are either related to gastrointestinal defect and complication management or bariatric (weight loss) interventional treatment.

Interventional and therapeutic gastroenterology is a high growth area within medicine and our suturing product is used for patient treatment needs in both the upper and lower GI tract. Examples of upper GI applications include fistula closure, esophageal stent fixation, and closure for POEM. Fistulas are chronic or acute defects that can form between two cavities in the GI tract, often occurring as a result of abdominal surgery. Esophageal stents are often used as part of the treatment of esophageal cancers and premature migration of the stent is common. Clinical evidence shows that esophageal stents that are not fixed in place will have as high as a 60% migration rate. Suturing stents in place helps reduce stent migration, preventing further procedures and complications for the patient. Achalasia is a condition where a patient has difficulty swallowing. As the incidence of achalasia increases, there is growing interest in endoscopic treatment options that can be offered, such as POEM. Suturing following the esophageal muscle dissection and release during a POEM presents a quick and low profile solution for the patient.

In the lower GI tract, there are over 20 million colonoscopies performed annually. Cancer screening followed by the endoscopic resection of flat gastrointestinal tumors or polyps can provide patients with a viable option to colorectal surgery. Suturing the resection site aids in healing and helps prevent delayed bleeding following the procedure.

Obesity as a disease is increasing worldwide. In the U.S., it is estimated that 78 million adults are obese or clinically obese with a body mass index ("BMI") of 30 or more. It is further estimated that 24 million adults are severely or morbidly obese in the U.S., with a BMI greater than 40. Over 650 million people around the world are considered obese.

Traditional obesity intervention has been bariatric surgery (gastric bypass, sleeve gastrectomy and laparoscopic adjustable gastric banding), which is mostly performed laparoscopically. Today, based on U.S. population demographics and physician society 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 provide products that advance gastrointestinal therapeutic endoscopic solutions for a wide range of interventional patient needs ranging from gastrointestinal defect repairs to the interventional treatment of obesity. Our "Endo-bariatric" products allow these treatments to be delivered by an endoscopist endolumenally with a flexible endoscope and thus provide patients with therapy options other than or prior to traditional surgery.

The key elements of our strategy include:

- ***Support the adoption of our Endo-bariatric products*** - We accomplish this today through our medical education activities, field sales support, and clinical investments that support product adoption and use. In addition, when appropriate, we support adoption through patient education and outreach initiatives.
- ***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 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.

Apollo Products

Endo-bariatrics

The Apollo Endo-bariatric products consist primarily of the OverStitch Endoscopic Suturing System and the Intragastric Balloon System (most often branded as Orbera). For the year ended December 31, 2018, 68% of total revenues were from sales of the Endo-bariatric products. Of our total Endo-bariatric sales, 57% related to the OverStitch Endoscopic Suturing System and 43% related to the Orbera Intragastric Balloon System products.

OverStitch Endoscopic Suturing System

The OverStitch and OverStitch Sx Endoscopic Suturing System ("ESS", "OverStitch", or "Sx") enables advanced endoscopic procedures by allowing physicians to place full-thickness sutures and secure the approximation of tissue through a flexible endoscope. OverStitch and OverStitch Sx are currently the only U.S. cleared flexible endoscopic suturing device capable of full-thickness suturing of tissue. OverStitch is a single-use suturing device that is attached to a flexible endoscope and allows a physician to access portions of a patient's GI tract and place full thickness sutures to approximate the tissue of the GI tract. The OverStitch Endoscopic Suturing System received U.S. Food and Drug Administration ("FDA") 510(k) clearance in August 2008 and CE Mark in November 2012. The OverStitch Sx Endoscopic Suturing System received FDA 510(k) clearance in June 2018 and CE Mark in November 2018.

The OverStitch device that was 510(k) cleared in August of 2008 is compatible with a specific dual channel flexible endoscope that has limited market presence, representing less than five percent of the flexible endoscopes in hospitals and clinics around the world. Beginning in November 2018, we began the first commercial shipments of the OverStitch Sx that is compatible with four major scope manufacturers and over 20 single-channel flexible endoscopes with diameters ranging from 8.8 mm to 9.8 mm. These Sx compatible single-channel endoscopes represents the majority of flexible endoscopes in hospitals and clinics around the world today.

We believe that the functionality of the OverStitch devices allows them to be used for a broad number of gastrointestinal as well as bariatric applications. Since its market introduction in 2008, over 35,000 OverStitch units have been sold for procedures worldwide.

We estimate that approximately 40% of procedures performed with OverStitch were in connection with the treatment of GI defects and the remaining use was for the interventional treatment of obesity.

One of the most promising newly developed weight-loss procedures is commonly referred to as endoscopic sleeve gastroplasty ("ESG"), which transorally uses endoscopic suturing with OverStitch to reduce the volume of the stomach and form a small diameter sleeve, similar to the goal of a surgical sleeve gastrectomy procedure but without the invasiveness and need for amputation of the gastric remnant. The advantages of the ESG as compared to a surgical sleeve include maintenance of the structural integrity of the gastric wall, reversibility, relative ease of revision or maintenance, lower procedure adverse events, and reduced costs.

ESG is based on the placement of full-thickness sutures to secure the approximation of tissue which is the labeled indication of OverStitch. However, the labeled indication of the OverStitch device currently does not specifically identify the ESG procedure. The first multi-center study was presented in May 2016 at Digestive Disease Week which was updated to a 24-month follow-up study and was published in April 2017 in *Obesity Surgery*, the Journal of Metabolic Surgery and Allied Care. 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 endolumenally place full-thickness sutures to fold in the greater curvature of the stomach, and reduce the volumetric capacity of the stomach in order to lower a patient's caloric intake and induce weight loss.

A total of 248 patients were included in the study. Patient BMI at the start of the study was 37.8, plus or minus 5.6.

- 215 patients reached 6-months follow-up and the study reported an average percentage total body weight loss ("TBWL") of 15.2%.
- 57 patients reached 24-months follow-up and the study reported an average TBWL of 18.6%.
- There was no significant difference in weight loss between the three centers.

Five 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 five patients recovered fully. The suturing-related serious adverse events were associated by the study's authors with suturing to reduce the fundus part of the stomach and as a result, reducing the fundus is no longer part of the standard ESG technique.

In 2017, we entered into a clinical trial agreement with The Mayo Clinic in Rochester, Minnesota to undertake the Multi-center ESG Randomized Interventional Trial ("MERIT-Trial") to evaluate the long-term safety and efficacy of ESG compared to efficacy endpoints set forth in a consensus statement of the American Society for Gastrointestinal Endoscopy ("ASGE") and the American Society of Metabolic Bariatric Surgery ("ASMBS") and its impact on obesity related comorbidities in patients with obesity and BMI between 30-45.

The MERIT-Trial is expected to enroll two hundred patients, stratified into three groups (Obesity, Obesity with hypertension, Obesity with diabetes). The trial will have two levels: (1) the randomized study phase with primary outcomes for both treatment and control participants evaluated at twelve months, and (2) the crossover, non-randomized study phase with outcomes for (a) the initial treatment participants at 24 months after their ESG, and (b) the control cross-over participants evaluated at twelve months after their ESG.

During 2017, we entered into a Registry Funding Agreement with the American Gastroenterological Association ("AGA") Center for GI Innovation and Technology to develop and administer a registry (the "AGA Registry") to evaluate flexible endoscopic procedures enabled by the OverStitch Endoscopic Suturing System. The AGA Registry collects real-world evidence related to the safety and efficacy of a number of flexible endoscopic suturing-enabled procedures, including the revisions of patients after weight regain subsequent to an initial bariatric surgery; the fixation of esophageal stents to prevent migration; and data on other suturing procedures currently in practice. The resulting data will be used to present the benefits of endoscopic suturing procedures relative to traditional therapies. We expect the AGA to collect data for four years with interim reporting expected.

During 2018, in Europe we established a multi-center, longitudinal data repository for ESG and Gastrojejunal Anastomotic outlet revision procedures that will extend up to two years. This registry will collect both country specific and pan-European outcomes related to safety and effectiveness of procedures performed and will support informed decision-making throughout Europe. In addition, a second, multi-center, retrospective data repository for gastrointestinal applications performed using the OverStitch System was also created. The objective of this registry is to collect European demographic, procedural and outcome data using OverStitch for a variety of procedures including closure of full thickness and mucosal defects, post-operative leaks, perforations, stent fixation, treatment of gastrointestinal bleeding and other procedures. The goal is to support the clinical use and benefits of endolumenal suturing as well as provide real-world data on safety and effectiveness which can support physicians, patients and payers in making informed decisions. This registry could extend up to five years and both registries will provide interim reporting.

Additional applications for endoscopic suturing are emerging as physicians gain suturing proficiency and identify additional patient needs. In June 2018, Endoscopy International published for example a study of a novel resection and plication anti-reflux procedure ("RAP") using OverStitch. In this patient series, RAP was performed on 10 patients with gastroesophageal reflex disease ("GERD") and on long-term proton pump inhibitor ("PPI") therapy. All the patients underwent RAP without adverse events and were discharged on the same day. Follow-up ranged from 5 to 24 months, with the median being 9 months, and all patients were reported as having significant improvement in their GERD based quality of life scores, and 8 of the 10 patients had eliminated their daily PPI use.

Orbera Intragastric Balloon System

The intragastric balloon system ("IGB", the "Orbera System" or "Orbera") is currently marketed under three brands: the Orbera Intragastric Balloon System, the BIB, and the Orbera365 Managed Weight Loss System ("Orbera365") and are non-surgical alternatives for the treatment of overweight and obese adults. Orbera is the global market leader among intragastric balloons and is available in over 70 countries with more than 300,000 units distributed in the period from January 1, 2006 to March 31, 2018. The IGB brands each include a single silicone balloon that is filled with saline after its 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 balloon is temporary and is removed endoscopically, typically, under conscious sedation.

In the U.S., Orbera is indicated for an indwell period of up to six months 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 U.S., Orbera is generally indicated for temporary weight loss for patients with a BMI greater than or equal to 27,

and depending on the specific label, is indicated for an indwell time of six or twelve months. In some cases, generally higher BMI patients, Orbera is indicated for use prior to surgery, including obesity surgery, in order to reduce surgical risk.

Today, IGBs are most often used for aesthetic weight loss purposes rather than to specifically treat a patient's advancing comorbidity related with obesity. Because of this, the IGB procedure is typically not covered by insurance and is paid for out of pocket by the patient.

However, specific to Orbera, there is a substantial and increasing body of evidence that shows that the level of weight loss with Orbera is very effective in the treatment of comorbidities associated with being overweight or obese. The clinical effectiveness and safety profile of the Orbera System as a non-ulcerogenic weight loss device has been reported in over 250 peer reviewed publications. Although not specifically indicated for the treatment of obesity-related comorbidities, studies have consistently reported resolution or improvement in a patient's pre-existing comorbidities at the time of Orbera removal. Orbera is currently the only balloon or other endoscopic product that has been recognized in the 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 reported an estimated TBWL at six months of approximately 13.2%.

For example in June 2018 during Digestive Disease Week, physicians from Mayo Clinic presented on their prospective open-label FDA-approved study of Orbera patients with non-alcoholic steatohepatitis ("NASH"). Of the patients treated, 65% achieved resolution of NASH on biopsy; 80% had at least a two point improvement in their non-alcoholic fatty liver disease activity score; 15% had tissue evidence indicating regression of fibrosis (liver scarring). NASH is expected to become the most common cause of liver cirrhosis by 2030, leading to increased risk of liver-related death and higher rates of malignancy.

Our commercial strategy is to further establish the medical relevancy of Orbera in areas of large medical need such as fatty liver disease and increase market awareness of this relevancy.

The Orbera System was originally CE marked in May 1997. Orbera365 was CE marked in August 2017. After February 2019, only Orbera365 and BIB will be CE marked.

Orbera was approved by the FDA in August 2015. From FDA approval through the end of 2018, we have trained more than 1,000 U.S. physicians on the use of Orbera.

As part of the FDA approval of Orbera, we are required to conduct a post-approval clinical study. The Orbera Post-Approval Study is a prospective, multi-center, open-label study of the safety and effectiveness of Orbera as an adjunct to weight reduction for obese adults (22 years of age and older) with a BMI of ≥ 30 kg/m2 and BMI ≤ 40 kg/m2. The Orbera Post Approval Study completed enrollment in September 2018 with 281 patients treated with the Orbera from 11 U.S. clinical study sites. The endpoints include the patient's percentage of total body weight loss at 26 weeks and 12 months after balloon placement and the rate of adverse events at 26 weeks. Patient follow up is expected to be completed in late 2019 and final study results are expected in early 2020.

In February 2017, the FDA issued a letter to health care providers related to adverse events following placement of liquid-filled balloons which were not seen during the U.S. pivotal studies, specifically related to events of spontaneous balloon over-inflation and, separately, reports of acute pancreatitis. We subsequently developed updates to Orbera's product labeling and physician training materials, and these were approved by FDA and implemented in June 2017. The labeling changes included additions to the “Warnings” and “Possible Complications” sections and an update to the “Clinical Evaluations…” sub-section within the “Adverse Events” history for Orbera.

In August 2017, the FDA issued a second update to alert health care providers of five reports of unanticipated deaths that occurred since 2016 in patients with a liquid-filled intragastric balloon implant. Four of the deaths involved patients who had received an Orbera and had been self-reported by us to the FDA as part of our normal product surveillance process. Following this letter, we interactively worked with the FDA to provide further updates regarding the risks of gastric and esophageal perforation, aspiration, and death and updated the label disclosure for these adverse events as per the table below:

	Global Rate (as of March 31, 2017)	**Global Rate (as of March 31, 2018)**
Mortality Rate	0.01%	<0.01%
Gastric Perforation	0.01%	0.01%
Esophageal Perforation	<0.01%	<0.01%
Pancreatitis	<0.01%	<0.01%
Spontaneous Hyperinflation	0.04%	0.07%

In addition, The U.S. physician training material was updated to provide physicians with more detailed descriptions of the patient symptoms that may indicate persistent (or refractory) intolerance, methods of assessing these patients, and recommendations for the management of symptoms and removal of the device.

In June 2018, the FDA approved the new Orbera labeling and concurrent with their approval issued a third update to alert health care providers of the label updates and provide an update on new reports worldwide of unanticipated deaths that had been reported since their August 2017 letter to Health Care Providers. Four of the reported deaths in this third update involved patients who had received our IGB product. In each case, the occurrence had been self-reported by us to the FDA as part of our normal product surveillance process. As stated in the Orbera Directions For Use in the period from January 1, 2006 through March 31, 2017, there had been 21 reported deaths of patients while they had an Orbera which is an incident rate of less than 0.01% based on the more than 277,000 Orbera balloons distributed during that same time period. The FDA's letter to Health Care Providers does not indicate that the patient deaths were related to the Orbera device or the insertion procedures. While the cause of death has not been provided or determined in all cases, we have not received any communication or indication from the attending physicians or hospitals that the reported deaths were caused by the Orbera device. In total, Apollo has reported five instances of death involving patients who had received an Orbera since FDA approval in August 2015 with four of the incidents occurring outside the U.S.; the overall incident rate of patient death remains less than 0.01% (one in 10,000).

In the U.S., we also introduced Orbera Coach, an on-demand telehealth program that provides professional nutritionist support to patients who undergo the Orbera procedure for an annual fee.

Surgical

In December 2018, Apollo entered into an agreement with ReShape to divest its Surgical product line. As part of the agreement Apollo and ReShape entered into a set of transition services agreements under which Apollo will continue to distribute the products in markets outside the U.S. for up to 12 months and will continue to manufacture the Surgical product line for up to two years. Our Surgical products consisted of the Lap-Band System and accessories primarily 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 U.S. was obtained in 2001 and the Lap-Band System has been approved in many countries around the world. Nearly 900,000 Lap-Band Systems have been distributed worldwide.

The Lap-Band System was approved for use in the U.S. 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 U.S. 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.

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.

We are the only manufacturer with a cleared device for full thickness endoscopic suturing currently on the market in the U.S. or outside the U.S. Competing technologies for closure during certain GI defect applications are offered by large and established manufacturers in the GI space including Boston Scientific Corporation, Olympus Medical, Steris (US Endoscopy) and Cook Medical. Outside the U.S., there are a variety of local and regional competitive intragastric balloon manufacturers including SC MedSil, Medicone, Allurion Technologies and Spatz Laboratories. In the U.S., there is one other manufacturer with an intragastric balloon approved by the FDA at this time, Obalon Therapeutics, Inc.

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 U.S., Brazil, Australia and certain countries in Europe. As of December 31, 2018, we employed 46 sales and marketing personnel in the U.S. and another 41 employees in all of the markets outside of the U.S. In addition, we sell products to third party distributors who sell our products in approximately 65 other countries.

Obesity procedures that utilize our 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 initially performed final assembly for the Lap-Band and Orbera products. Beginning in 2016, we started to produce components related to the OverStitch system at this facility and have expanded the number and volume of OverStitch system products and components produced in Costa Rica since then and will continue to increase production in the coming year. In addition, we rely on several third-party suppliers to provide components used in existing products and we expect to continue to do so, including final assembly of the OverStitch and OverStitch Sx endoscopic suturing system.

In December 2018, Apollo and ReShape Lifesciences, Inc., entered into a set of transition services agreements under which we will continue to manufacture the Surgical product line for ReShape for up to two years and would continue distributing products in markets outside the U.S. for up to 12 months, and other specified services as part of the Purchase Agreement.

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").

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 97 U.S. patents and 115 foreign patents. Our U.S. patents have expiration dates ranging from 2019 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 40 pending U.S. patent applications and 58 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 acquired or 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 markets outside the U.S.

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. 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. In January 2018, we entered into a royalty-bearing License Agreement with Echelon Biosciences, Inc., ("Echelon") under which Echelon may manufacture and sell certain antibody products covered by the Lpath IP for non-clinical research use only, clinical diagnostics and immunohistochemistry. In January 2018 we also entered into a Technology Transfer Agreement with Resolute Pharma, Inc. (“Resolute”) whereby we transferred certain scientific and research materials to Resolute and granted Resolute a license to certain patent rights related to the Lpath IP. Under the terms of the agreement with Resolute, Resolute has obligations to develop and commercialize licensed products and we maintain rights to terminate the agreement if certain development and commercialization milestones are not met. Under the agreement, Resolute is responsible to pay for any ongoing costs and fees associated with the Lpath IP, and we are entitled to a royalty for any revenues related to the Lpath IP including sales of licensed products, and a Tech Transfer Fee of $0.5 million by July 31, 2019 which increases to $0.75 million if paid after this date. In addition, Resolute has a certain buyout option for the Licensed Patents or Licensed Products.

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 U.S. 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 premarket approval ("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.

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 Orbera intragastric balloons are Class III devices. The OverStitch device is a Class II device. We also sell accessory products, some of which are Class I.

The Investigational Device Process

In the U.S., absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an Investigational Device Exemption ("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 is to take 180 days, although the review generally takes between one and three years, or 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 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) for product modifications;
- medical device reporting ("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 U.S. Federal Food, Drug and Cosmetic Act 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;
- 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 remain 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 ("OIG") of the U.S. Department of Health and Human Services and the U.S. Department of Justice ("DOJ") 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 government healthcare programs such as 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 not treated as offenses under the federal Anti-Kickback Statute. These safe harbors exist 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 ("FCA") 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 based on FCA allegations that their financial relationships with customers "caused" these customers to submit false claims. When an entity is determined to have violated the FCA, 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 FCA 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 at this time. In addition, certain states have enacted laws modeled after the federal FCA. 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 ("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 us, 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 ("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 U.S. 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 was implemented, which suspended the medical device excise tax implemented as part of the ACA for a two-year period through December 31, 2017. In January 2018, the moratorium on the medical device tax was extended an additional two years, through the end of 2019.

The Physician Payments Sunshine Act ("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 this data to Centers for Medicare & Medicaid Services, 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 are current with all required reports under the PPSA.

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 ("EU") 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 EU, 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 EU, 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 transparency reporting obligations.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") 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 our customer relationships outside of the U.S. are, either directly or indirectly, with governmental entities and employees (such as physicians at state-owned or state-operated hospitals) 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 policies and procedures are designed to both prevent as well as detect reckless or criminal acts committed by employees, distributors, consultants, or agents, but such controls, policies, and procedures may not always protect us from violations. 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, 2018, we had a total of 215 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. 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.

Available Information

We file or furnish pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as applicable, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to those reports, proxy statements and other information electronically with the SEC. Through a link on our website, we make copies of our periodic and current reports, amendments to those reports, proxy statements and other information available, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information found on, or accessible through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

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, 2018 and 2017, we had net losses of $45.8 million and $27.3 million, respectively. As of December 31, 2018, we had an accumulated deficit of $222.8 million. To date, we have funded our operations primarily through equity offerings, the issuance of debt instruments, 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 therapeutic endoscopy market and successfully commercialize our Endo-bariatric products.

It is important to our business that we continue to build a market for therapeutic endoscopy procedures within the bariatric and gastroenterology community. Our Endo-bariatric products offer non-surgical and less-invasive 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;
- achieve 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;
- market new devices or modified products in compliance with the regulations of the FDA and other applicable regulatory authorities;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- train the sales and marketing team to effectively support our market development efforts.

We are dependent on the success of our Endo-bariatric products following the divestiture of our Surgical product line to ReShape, in December 2018. For the year ended December 31, 2018, revenues from Surgical product sales comprised 31% of total revenues. While we intend to focus our commercial efforts on our Endo-bariatric products, there can be no assurance that such product lines will be profitable in the future.

If we are unsuccessful in developing and commercializing the therapeutic endoscopy market, our ability to increase our revenue will be impaired and our business, results of operations, financial condition and prospects will be materially adversely affected.

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 Intragastric Balloon products, have limited reimbursement, and in most cases are not reimbursable by governmental or other health care plans and instead are partially or wholly paid for directly by patients. 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 products unless they determine that they have the necessary skills to use our products and based on their own experience, clinical data, communications from regulatory authorities 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, unsafe, ineffective, experimental or too expensive;
- 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; and,
- the 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 provide patient education materials 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 presents our products and related procedures as being unproven, unsafe, ineffective or experimental or otherwise 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, the scope of the indicated use for new products and the availability of coverage and reimbursement for procedures that use future products.

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, use improper techniques, ignore or disregard information provided in training or fail to obtain adequate training, 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 we could be subject 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 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.

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

If the supply of materials from our suppliers were to be interrupted or if we experience delays or interruptions from our manufacturers, replacement or alternative sources might not be readily obtainable. In particular, the products which together comprise our ESS products are sourced from a variety of suppliers and manufacturers, and these suppliers and manufacturers further depend on many component providers. As ESS product 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 or manufacturers 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 or manufacturer, labor disputes or shortages at the supplier and unexpected demands or quality issues.

Manufacturing of our products requires capital equipment and a well-trained workforce. The sourcing of new manufacturing or supply capacity can present significant lead time. If demand increases faster than we expect, or if we are unable to produce the quantity of goods that we expect with our current suppliers and manufacturers, we will not be able to adequately address demand for our products and our revenues and results of operations would suffer.

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 or manufacturer. 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 may make it difficult for us to accurately 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.

These participants 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 gastrointestinal conditions, including obesity, that is less invasive or more effective than our current product offerings, sales of our products would be significantly and adversely affected.

We may be unable to successfully integrate or expand operations and processes in connection with acquisitions.

Our Surgical product line, which we recently divested, and our IGB product line were acquired in December 2013. In the future, should we grow or acquire new assets or businesses, 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 and integrate newly acquired operations and processes.

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 contribute to, or merely appear to or are alleged to have contributed to, 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 us. Further, because we are obligated to continue providing certain transition services, including manufacturing and distribution support, to ReShape for our divested Surgical Product line, we may be subject to product liability claims from sales of Surgical products by ReShape, over which we have limited to no control. 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:

- litigation costs;
- 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.

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, potential liabilities under our transition services agreements with ReShape for the manufacture and distribution of Surgical products 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.

Our business and operations would suffer in the event of system failures, security breaches or cyber-attacks

Our computer systems, as well as those of various third-parties which we rely, including those of contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cyber criminals, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may in the future experience material system failures or security breaches that could cause interruptions in our operations or result in material disruption of our product development programs. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information we could incur liability.

If we experience significant disruptions in our or our third-party service providers' 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, inventory management and product support applications. 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, they could still occur and 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 to 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.

From time to time, we perform business improvements or infrastructure modernizations or use service providers for key systems and processes. If any of these initiatives are not successfully or efficiently implemented or maintained, they could adversely affect our business and our internal control over financial reporting.

The ability to protect our or our third-party service providers' information systems and electronic transmissions of sensitive and/or proprietary data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.

We rely on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers and prospective product end-users. A security breach of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, may cause all or portions of our or our third-party providers' systems to be unavailable, create system disruptions or shutdowns, and lead to erasure of critical data and software or unauthorized disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks, and we have implemented solutions, processes, and procedures to help mitigate these risks at various locations, such as encryption, virus protection, security firewalls and information security and privacy policies.

Nonetheless, our or our third-party service providers' information technology and infrastructure are subject to attacks by hackers and may be breached due to inadequacy of the protective measures undertaken, human errors or omissions, malfeasance, or other disruptions. The age of our or our third-party providers' information technology systems, as well as the level of protection and business continuity or disaster recovery capability, varies significantly by application software and third-party service provider, and there can be no guarantee that any such measures, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information, protected health information, or personal data of EU residents) could harm our reputation, compel us to comply with disparate federal, state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we or our third-party providers are unable to prevent security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to additional legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties, which could have a material adverse impact on our business, financial condition and results of operations. Hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend substantial additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties, impair our ability to transact business with our customers, lose access to critical data or systems, or compromise confidential information including trade secrets and other intellectual property, any of which may harm our competitive position, require us to allocate more resources to improved security technologies, or otherwise adversely affect our business.

In addition, the interpretation and application of consumer and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. For example, the EU General Data Protection Regulation ("GDPR") that became effective on May 25, 2018 imposes significant obligations on many U.S. companies, including us, to protect the personal information of European citizens. GDPR may be interpreted and applied in a manner that is inconsistent with our data practices and that our practices will be found to be non-compliant with this regulation. If so, this could result in government-imposed fines, orders or guidance requiring that we change our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

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 coverage 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.

We may fail to perform certain services under the transition services agreement with ReShape, and the performance of such services may negatively impact our business and operations.

We have entered into a transition services agreement and related supply and distribution agreements with ReShape in connection with the sale of our Surgical product line to ReShape pursuant to which we agreed, among other things, to manufacture the products for ReShape for up to two years and serve as ReShape's distributor of the product line outside of the U.S. for up to one year. If we do not satisfactorily perform our obligations under these agreements, we may be subject to liabilities to ReShape or may be required to re-perform such services at our expense.

If we fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2018, we identified a material weakness in our internal controls over financial reporting. The reported material weakness did not result in any adjustment to our financial statements or restatement of prior financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. We are implementing measures designed to improve our internal controls over financial reporting to remediate this material weakness. In addition, our independent registered public accounting firm, which audits our financial statements, issued an adverse opinion on the effectiveness of internal control over financial reporting as of December 31, 2018.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or that future material weaknesses will not occur.

If we fail to remediate our existing material weakness or identify new material weaknesses in our internal controls over financial reporting, investors may lack confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected regardless of whether material inaccuracies are determined to exist in our reported financial statements. If material inaccuracies are determined to exist in our financial statements or we are unable to report our financial statements on a timely basis, we could also become subject to investigations by Nasdaq, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

The United Kingdom's pending exit from the EU could lead to increased market access issues, legal issues, and economic conditions which could adversely impact our business.

On June 23, 2016, the electorate in the United Kingdom ("U.K.") voted in favor of leaving the EU (commonly referred to as "Brexit"). On March 29, 2017, the U.K. government delivered to the European Council notice of its intention to leave the EU and, in the absence of an executed withdrawal agreement with the EU, the effective date of the U.K.'s withdrawal from the EU will be March 29, 2019. Our subsidiary that manages our European business is located in the U.K. and, thus, there are many ways in which our business operations may be impacted by Brexit, only some of which we can identify at this time. Our notified body in Europe was BSI which is based in the U.K., which will no longer have standing in the EU as a notified body. We are transferring our notified body to BSI in the Netherlands which will require that we change product labeling and packaging for all our products and other potential implications that have yet to be identified at this time. Financial markets could experience volatility which could negatively impact currency exchange rates and therefore the translated U.S. dollar value of our local currency sales to customers in the U.K. or Europe. We do not hedge our foreign currency translation risk. Our warehousing and distribution hub for Europe is in the Netherlands and distribution of our products in the U.K. market may be slowed or disrupted and our U.K. sales may suffer as a result. Our efforts to mitigate the risk of this supply disruption to our U.K. customers may not prove sufficient. Until the final terms of Brexit are known, impacts to relevant currencies and business operations will be difficult to predict.

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 U.S. Federal Food, Drug and Cosmetic 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 rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other pre-amendment, 510(k)-exempt, 510(k) cleared products, or PMA-approved products that have subsequently been down-classified. 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 a 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.

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the device for its intended use. Of our products, Orbera is a class III product and has been approved through the FDA's PMA process and our OverStitch products are class II and have been cleared through the 510(k) process. In addition, 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.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

If we fail to comply with U.S. federal and state healthcare fraud and abuse or data privacy and security laws and regulations, 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.

Our industry is subject to numerous U.S. federal and state healthcare laws and regulations, including, but not limited to, anti-kickback, false claims, privacy and transparency laws and regulations. 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 or regulations 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 subject to evolving interpretations and enforcement discretion, and even minor irregularities can potentially give rise to claims that a statute or regulation 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 FCA, 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 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, and the federal Health Information Technology for Economic and Clinical Health Act of 2009, each as amended, and their implementing regulations, which impose requirements upon certain entities relating to the privacy, security, and transmission of health information;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the federal Foreign Corrupt Practices Act, 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

While we do not submit claims for reimbursement to payors and our customers make the ultimate decision on how to submit claims, from time-to-time, we may be asked for reimbursement guidance by our customers. Failure to comply with any of these laws, or any action against us for alleged 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 use our products and may influence the ordering and use of our products. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, should the government take the position that these transactions are prohibited arrangements that must be restructured or discontinued, we could be subject to significant penalties. The medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the 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.

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, actions to pursue claims under the FCA 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. For example, in March 2017, we were informed by the Department of Justice that we were a subject in a federal False Claims Act investigation. The government's investigation concerned whether there had been 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 cooperated fully with the investigation, and on August 21, 2017, we were notified by the Department of Justice that we were no longer a subject in such investigation.

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 Affordable Care Act's provision commonly referred to as the federal Physician Payment Sunshine Act, as well as similar state and foreign laws, impose obligations on medical device manufacturers

to annually report certain payments and other transfers of value provided, directly or indirectly, to certain physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Failure to comply with any of these state, federal, or foreign transparency and disclosure requirements could subject us to significant fines and penalties. 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 U.S. 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 our products. Therefore, coverage or reimbursement for medical devices may decrease in the future.

Federal and state governments in the U.S. and outside the U.S. may enact legislation to modify the healthcare system which may result in increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. These reform measures may 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 products 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.

Modifications to our marketed products may require new 510(k) or de novo clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) or de novo clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. For example, a manufacturer may determine that a modification does not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly de novo, down classification, or a premarket approval application. Where we determine that modifications to our products require a new 510(k) or de novo clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the EU, we must notify our EU Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

For our class III devices, new PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. There is no guarantee that the FDA will grant PMA approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

If our products contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device were to recur. As required per the FDA Code of Federal Regulations (21 CFR) Part 803 we have established procedures and processes for documentation and evaluation of all complaints relative to reporting requirements. As with all device manufacturers, we have 30 days from "becoming aware" of an incident to submit to FDA a MDR for an event that reasonably suggests that a device has or may have caused or contributed to the incident, or five work days for an event designated by the FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health. As part of this assessment we conduct a complaint investigation of each reported Adverse Event. In the event that an investigation is inconclusive (i.e., the investigation cannot confirm whether or not our product was a cause of an Adverse Event), our policy and practice is to default in favor of reporting events to the FDA. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

The FDA may issue safety alerts in response to its review of reported Adverse Events that do not require voluntary corrective actions or agency enforcement but that still negatively affect our product marketing efforts. For instance, in February of 2017, the FDA issued an update to alert health care providers of reported adverse events of liquid-filled intragastric balloons including several dozen incidents of balloon over-inflation and, separately, a set of reports of acute pancreatitis. In August of 2017 the FDA issued a second update to alert health care providers of five reports of unanticipated deaths that had been reported since 2016 in patients with liquid-filled intragastric balloons, four of which had received our IGB . In June 2018, the FDA issued a new update to alert health care providers of five additional reports worldwide of unanticipated deaths that had been reported since the August 2017 letter to Health Care Providers and also announced the approval of labeling changes for the Orbera Balloon System. Four of the additional mentioned reported deaths involved patients who had received our IGB product. In each case, the occurrence had been self-reported by us to the FDA as part of our normal product surveillance process. Neither the FDA's August 2017 letter to Health Care Providers nor the June 2018 letter to Health Care Providers indicates that the patient deaths were related to the intragastric balloon product or the insertion procedures. However, both letters to Health Care Providers subjected us to adverse publicity that harmed our business.

Our international operations must comply with local laws and regulations that 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 various European countries and our products are approved for sale in over 70 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 us include various anti-bribery laws, including the U.S. FCPA, 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 U.S. 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, importation requirements 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 U.S. 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 inspection 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 that could harm our reputation, business and financial results.

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 a 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 the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, 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 financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. 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 us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

U.S. legislative, FDA or global regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, in December 2016, the 21st Century Cures Act was enacted into law. The Act includes many provisions that impact the regulation of medical devices. For example, the Act includes provisions regarding, among other things:

- expediting the development and prioritizing FDA review of "breakthrough" technologies
- expanding the scope of diseases/conditions eligible for a humanitarian device exemption
- encouraging FDA to rely more on real-world evidence to demonstrate device safety and effectiveness
- emphasizing the least burdensome standard for device reviews

Moreover, leadership, personnel and structural changes within the FDA as well as recent and future federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In addition, on May 25, 2017, the new EU Medical Devices Regulation ("MDR 2017") was published. When it becomes effective on May 26, 2020, the MDR 2017 will change the obligations of medical device manufacturers with product in the EU and will subject high risk medical devices to additional scrutiny during the conformity assessment procedure. MDR 2017 repeals and replaces the EU Medical Devices Directive and intended to eliminate current differences in the regulation of medical devices among EEA Member States. Once applicable, the new regulations will among other things:

- add new the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on a manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- require the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- add rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market

Once applicable, the MDR 2017 may impose increased compliance obligations for us to access the EU market.

In order to continue to sell our products in Europe, we must maintain our CE marks and continue to comply with certain EU directives and, in the future with MDR 2017. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the EU, such as the departure of the United Kingdom (Brexit), may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

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 keep our PMA approvals in good standing. 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 or fail to obtain desired 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 U.S. FCPA and similar laws associated with any activities outside the U.S. could subject us to penalties and other adverse consequences.

We are subject to the U.S. 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. We may face significant risks if

we fail to comply with the FCPA and other similar foreign antibribery laws. Although we have implemented safeguards and training, including company policies requiring our employees, distributors, consultants and agents to comply with the FCPA and similar laws, our international operations nonetheless present a risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. 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 supply, 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 investors 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 and methods of using 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. We may also determine from time to time to discontinue the payment of maintenance fees, if we determine that certain patents are not material to our business.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the U.S. 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 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 U.S. 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. 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 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 and therapeutic endoscopy markets are 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. Our intellectual property has not been tested in prior litigation. If we initiate litigation to protect our rights, we run the risk of having our intellectual property rights adjudicated, invalidated, or limited in scope, which would undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, 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 held by other parties 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. 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 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 and 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 or information that is essential to our business operations, if such technologies, features or information are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or information that are important or essential to our products or business operations 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. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products and conduct business, which could have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Capital Requirements and Finances

We have substantial indebtedness which contain restrictive covenants that may limit our operating flexibility and our failure to comply with the covenants and payment requirements of our indebtedness may subject us to increased interest expenses, lender consent and amendment costs or adverse financial consequences.

In March 2019, we borrowed $35.0 million principal amount of debt under a term loan facility ("Solar Debt Facility) with Solar Capital, Ltd. ("Solar") under which we may borrow an additional $15.0 million upon our request subject to further credit approval. We cannot assure that additional funding will be received. We used $22.4 million of the proceeds to repay the existing senior secured credit facility. Our outstanding debt 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 without Solar's consent. 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 lender. In addition, we are required to prepare our financial statements and receive audits on our annual financial statements in a timely manner, meet certain financial ratio requirement and pay interest and principal when due. Furthermore, under the Solar Debt Facility our interest rate is tied to LIBOR and in the event of an increase in the LIBOR rate, we will be required to pay greater interest expenses, which will have an adverse effect on our income from operations and financial condition.

To the extent that our operating trends do not enable us to meet our financial and restrictive covenant requirements, we are unable to pay interest or principal when due or we are unable to meet other covenants and requirements contained within our credit agreements, we may default under such agreement. A default under any such agreements could result in further increases in consent or amendment fees to lender, further increases in interest costs, the imposition of additional constraints on borrowing by our lender or potentially more serious liquidity constraints and adverse financial consequences, including reductions in the value of our common stock or the necessity of seeking protection from creditors under bankruptcy laws. To remedy issues we may encounter with meeting our debt obligations, or for other purposes, we may find it necessary to seek further refinancing of our indebtedness, and may do so with debt instruments that are more costly than our existing instruments (and which will rank senior to our common shareholders), or we may issue additional securities which may dilute the ownership interests or value of our existing shareholders.

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.

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 us 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 we infringe on 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 recent sales of common stock, and available debt and equity financing arrangements will be sufficient to meet our capital requirements and fund our operations at least through the next twelve months. 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;
- the scope, rate of progress and cost to expand ongoing manufacturing activities;
- 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
- the costs of operating as a public company; and
- the ability of third-parties to pay future invoices and obligations.

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.

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 we may rely, including for the manufacture of the components for our products, 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 insurance coverage related to our products and procedures that utilize our products; 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 continue to incur significant legal, accounting and other expenses 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, service providers 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 General Corporate 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 Delaware General Corporate Law, 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 acquirers 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 is currently 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, 2018, 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 has 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 September 30, 2021. Our principal office in Austin houses research and development, sales, marketing, finance and administrative activities. We operate an approximate 18,200 square foot manufacturing facility in the Coyol Free Trade Zone in Alajuela, Costa Rica. The term of the lease for our Costa Rica facility extends through October 31, 2021. Additionally, we have a research and development facility in Austin, Texas and a device analysis lab in Carpinteria, California as well as sales and marketing offices in Australia, Italy, Brazil, and the United Kingdom. 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.

The information set forth under "Litigation" in Note 13 to the Consolidated Financial Statements in Item 8 of this Report is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is listed for trading on the Nasdaq Global Market under the symbol "APEN".

As of February 28, 2019, there were approximately 110 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.

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

This annual report ("Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Act of 1934, as amended (the "Exchange Act"). 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. In particular, statements, whether express or implied, concerning future operating results or the ability to generate sales, income or cash flow are forward-looking statements. They involve risks, uncertainties and assumptions that are beyond our ability to control or predict, including those discussed in Part II, Item 1A, of this Annual Report. 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. 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.

The following discussion should be read in conjunction with our consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. "Apollo," Orbera®, OverStitch™, the Apollo logo and other trademarks, service marks and trade names of Apollo are registered marks of Apollo Endosurgery, Inc. in the U.S. and other jurisdictions.

Overview

We are a medical technology company primarily focused on the design, development and commercialization of innovative medical devices to advance gastrointestinal endoscopy. We develop and distribute devices for minimally invasive gastrointestinal procedures that are used by surgeons and gastroenterologists for a variety of procedures related to gastrointestinal defect and complication management or bariatric (weight loss) interventional treatment.

Our core products are the OverStitch Endoscopic Suturing System ("ESS") and Intragastric Balloon ("IGB") (most often branded as Orbera). In December 2018, we divested our Surgical product line.

We have sales distribution offices in England, Australia, Italy, and Brazil that oversee regional sales and distribution activities outside the U.S., 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.

Divestiture of the Surgical Product Line

On December 17, 2018, we entered into an Asset Purchase Agreement ("Purchase Agreement") with ReShape Lifesciences Inc. pursuant to which, ReShape acquired from Apollo substantially all of our assets exclusively related to our Surgical product line. In connection with the Purchase Agreement, ReShape agreed to pay $17.0 million in cash ("Cash Purchase Price"), of which $10.0 million was paid at the closing of the transaction and an additional $2.0 million is payable on each of the first and second anniversary of the closing date and the remaining $3.0 million is payable on the third anniversary of the closing date. As additional consideration, we also received from ReShape substantially all of ReShape's assets exclusively related to their intragastric balloon product.

The parties entered into a transition services agreement, supply agreement and distribution agreement pursuant to which, among other things, we will manufacture the Surgical product for ReShape for up two years, serve as ReShape’s distributor of the Surgical product outside of the U.S. for up to one year and provide other specified services.

We and ReShape each made customary representations, warranties, covenants and indemnities in the Purchase Agreement. Subject to certain limitations, we each agreed to indemnify the other party for certain matters, including breaches of representations, warranties and covenants in the Purchase Agreement. ReShape also granted us a security interest in substantially all of ReShape’s assets as security for the payment and performance when due of all of ReShape’s obligations under the Purchase Agreement, including their remaining Cash Purchase Price obligations.

Effective December 31, 2018, we discontinued selling ReShape's intragastric balloon system.

In connection with the divestiture, on December 17, 2018, we entered into an Eighth Amendment to the Credit Agreement, originally dated February 27, 2015, with our lender, Athyrium Opportunities II Acquisition LP, or Athyrium. This amendment, among other things, (i) amends the covenants under our Credit Agreement with Athyrium to permit the transactions contemplated by the Purchase Agreement; (ii) modifies the mandatory prepayment provisions to require us to reduce our principal balance outstanding by the $17.0 million cash purchase price when each payment is received, so long as the Credit Agreement remains outstanding.

Financial Operations Overview

Revenues

Our principal source of revenues has come from sales of our Endo-bariatric products and our Surgical products however, with the divestiture of our Surgical product line and after completion of our OUS distribution service support pursuant to the distribution services agreement, future sales will come from our Endo-bariatric products. The majority of our sales come from direct markets where sales are made to the final end customers, typically healthcare providers. In other markets, we sell our products to distributors who resell our products to end users. 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. In the U.S., we also offer Orbera Coach, a digital aftercare support system for Orbera patients.

Cost of Sales

Our ESS products have historically been purchased from third-party manufacturers, and our cost of sales for these products has consisted of this purchase price. Cost of sales for our IGB and Surgical products includes raw materials, labor, and manufacturing overhead. Since 2017, we have begun to manufacture various components of the ESS system in order to improve the gross margin profile of this product. Raw materials used in our manufacturing activity are generally not subject to substantial commodity price volatility, and most of our manufacturing costs are incurred in U.S. dollars. Cost of sales also includes excess and obsolete inventory charges, royalties, shipping, inspection and related costs incurred in making our products available for sale or use.

We expect our gross margin will continue to be impacted by the shift in revenue mix from Surgical products, which have historically high gross margins with decreasing sales, to lower gross margin but high-growth Endo-bariatric products. In addition, manufacturing overhead is a significant portion of our cost of sales and can impact cost of sales 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. Comparability of cost of sales between periods could also be affected by inventory valuation allowances related to obsolete or excess inventory. We expect to improve gross margins as we complete certain identified Endo-bariatric product gross margin improvement projects and improve capacity utilization of our manufacturing facility.

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, physician training, industry events and other promotional activities.

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, information technology and human resource departments. General and administrative expense also includes facilities cost, insurance, audit fees, legal fees, bad debt expense and costs related to the development and protection of our intellectual property portfolio.

Research and Development Expense

Research and development expense includes product development, clinical trial costs, 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 compensation and stock-based compensation expense for personnel dedicated to these activities. Research and development expense may fluctuate between periods dependent on the activity in the period associated with our various product development and clinical obligations.

Amortization of Intangible Assets

Definite-lived intangible assets primarily consists of customer relationships, product technology, trade names, patents and trademarks, and capitalized software. 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, going concern, financial projections, useful lives with respect to intangible and long-lived assets, goodwill impairment, allowance for doubtful accounts, inventory valuation, stock compensation, deferred tax asset valuation and long-lived assets. 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 U.S. ("OUS"). The Company adopted the provisions of ASU 2014-09, *Revenue from Contracts with Customers* on January 1, 2018 as discussed in Note 2 to the Consolidated Financial Statements. Revenue is recognized when control of the promised goods is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in an exchange for those goods. Generally, these conditions are met upon product shipment. Customers generally have the right to return or exchange products purchased from us for up to thirty days from the date of product shipment. Distributors, who resell the products to their customers, take title to products and assume all risks of ownership at the time of shipment and are obligated to pay within specified terms regardless of when, if ever, they sell their products. At the end of each period, we determine the extent to which our revenues need to be reduced to account for expected rebates, returns and exchanges. We classify any 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 determined to be uncollectible.

Inventory

Inventory is stated at the lower of cost or net realizable value, net of any allowance for unsalable inventory. 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, and capitalized software 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 we have operations and account 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.

Non-GAAP Financial Measures

As a supplement to our financial results we are providing a non-GAAP financial measure, adjusted total revenues which exclude U.S. Orbera starter kit sales. This supplemental measure of our performance is not required by, and it not determined in accordance with GAAP.

Adjusted Total Revenues, Excluding U.S. Orbera Starter Kit Sales

Adjusted total revenues, excluding U.S. Orbera starter kit sales is our GAAP total revenues excluding U.S. Orbera starter kit sales. We believe the non-GAAP financial measure included herein is helpful in understanding our current financial performance. We use this supplemental non-GAAP financial measure internally to understand, manage and evaluate our business, and make operating decisions. We believe that making non-GAAP financial information available to investors, in addition to GAAP financial information, may facilitate more consistent comparisons between our performance over time with the performance of other companies in the medical device industry, which may use similar financial measures to supplement their GAAP financial information. However, our non-GAAP financial measure is not meant to be considered in isolation or as a substitute for the comparable GAAP metric. This measure should only be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Reconciliations for this non-GAAP financial measure to its most directly comparable GAAP financial measure is provided in this Annual Report on Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	Year Ended December 31, 2018		Year Ended December 31, 2017	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	$ 60,854	100.0 %	$ 64,310	100.0 %
Cost of sales	27,660	45.5 %	24,578	38.2 %
Gross margin	33,194	54.5 %	39,732	61.8 %
Operating expenses:				
Sales and marketing	32,831	54.0 %	32,910	51.2 %
General and administrative	13,436	22.1 %	13,722	21.3 %
Research and development	12,176	20.0 %	8,299	12.9 %
Loss on divestiture	7,770	12.8 %	—	— %
Amortization of intangible assets	7,074	11.6 %	7,240	11.3 %
Total operating expenses	73,287	120.5 %	62,171	96.7 %
Loss from operations	(40,093)	(66.0)%	(22,439)	(34.9)%
Interest expense, net	4,063	6.7 %	4,508	7.0 %
Other expense	1,440	2.4 %	41	0.1 %
Net loss before income taxes	(45,596)	(75.1)%	(26,988)	(42.0)%
Income tax expense	191	0.3 %	304	0.5 %
Net loss	$ (45,787)	(75.4)%	$ (27,292)	(42.5)%

Revenues

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

	Year Ended December 31, 2018			Year Ended December 31, 2017			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 11,016	$ 12,364	$ 23,380	$ 8,019	$ 8,462	$ 16,481	37.4 %	46.1 %	41.9 %
IGB	5,400	12,339	17,739	6,301	13,141	19,442	(14.3)%	(6.1)%	(8.8)%
Total Endo-bariatric	16,416	24,703	41,119	14,320	21,603	35,923	14.6 %	14.3 %	14.5 %
Surgical	10,795	7,913	18,708	17,366	10,227	27,593	(37.8)%	(22.6)%	(32.2)%
Other	995	32	1,027	766	28	794	29.9 %	14.3 %	29.3 %
Total revenues	$ 28,206	$ 32,648	$ 60,854	$ 32,452	$ 31,858	$ 64,310	(13.1)%	2.5 %	(5.4)%
% Total revenues	46.4 %	53.6 %		50.5 %	49.5 %				

Endoscopic Suturing System ("ESS") and Intragastric Balloon ("IGB")

Total revenues in 2018 were $60.9 million, compared to $64.3 million in 2017, a decrease of 5.4%. Foreign currency fluctuations increased total revenues $0.3 million in 2018. Direct market sales accounted for approximately 87% of total revenues for both periods presented.

ESS product sales increased 41.9% or $6.9 million in 2018 when compared to 2017. U.S. ESS product sales increased 37.4% or $3.0 million, compared to 2017 due to continued new user adoption and greater product utilization in existing accounts. OUS ESS product sales increased 46.1% or $3.9 million due to growth in Europe.

IGB product sales decreased $1.7 million or 8.8% in 2018 compared to 2017. In the U.S., IGB product sales decreased $0.9 million in 2018 when compared to 2017 primarily due to decreased consumer demand after the June 2018 FDA letter to Health Care Professionals. OUS IGB product sales decreased $0.8 million in 2018 when compared to 2017 due to lower sales in Brazil and our distributor markets which offset growth of 14.6% in Europe due to higher unit sales and average selling prices of Orbera365 in Europe.

Total Endo-bariatric product sales increased 14.5% to $41.1 million in 2018, compared to $35.9 million in 2017 comprising 67.6% of total revenues in 2018 compared to 55.9% in 2017.

Total Surgical product sales for 2018 were $18.7 million, a decrease of 32.2%, compared to $27.6 million in 2017. The decline was primarily due to reductions in gastric banding procedures being performed. Surgical product sales in the U.S., decreased 37.8% to $10.8 million in 2018 compared to $17.4 million for 2017 and OUS Surgical sales decreased 22.6% to $7.9 million in 2018 compared to $10.2 million in 2017.

Cost of Sales

Costs of product sales for the periods shown were as follow:

	Year Ended December 31, 2018		Year Ended December 31, 2017	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	18,009	29.6 %	$ 15,896	24.7 %
Overhead	6,670	11.0 %	5,416	8.4 %
Change in inventory reserve	387	0.6 %	692	1.1 %
Other indirect costs	2,594	4.3 %	2,574	4.0 %
Total cost of sales	$ 27,660	45.5 %	$ 24,578	38.2 %

Gross Margin

Gross margin as a percentage of revenues was 54.5% for 2018 compared to 61.8% for 2017, respectively. The decline in gross margin is primarily due to a shift in our product sales mix from higher margin Surgical products to Endo-bariatric products that realize lower relative gross margins. Additionally, finished goods inventory was higher at the end of 2017 as we built up inventory levels to protect against the risk of supply disruption while we completed gross margin improvement projects during 2018. With the completion of these projects in 2018, our finished goods inventory at the end of 2018 has been substantially reduced which resulted in a greater proportion of our manufacturing overhead getting charged to cost of sales during 2018 compared to 2017. Although overhead charged to cost of sales is higher in 2018 for the above reason compared to 2017, our overhead spend is materially unchanged between the years.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense of $32.8 million for 2018 decreased $0.1 million from 2017.

General and Administrative Expense. General and administrative expense decreased $0.3 million in 2018 as compared to 2017 primarily due to higher costs incurred to meet our public company filing requirements in the previous year.

Research and Development Expense. Research and development expense increased $3.9 million in 2018 compared to 2017 primarily due to higher clinical trial activities associated with our Endo-bariatric products and higher costs for new product development and product margin improvement projects.

Loss on Divestiture. Loss on divestiture of $7.8 million was due to the divestiture of our Surgical product line in December 2018.

Amortization of Intangible Assets. Amortization of intangible assets decreased $0.2 million in 2018 when compared to 2017 due to the divestiture of Surgical related intangibles.

Loss from Operations.

Loss from operations in 2018 was $40.1 million compared to $22.4 million in 2017. The increased loss from operations was primarily due to lower gross margins, higher research and development expenses, and the loss on divestiture.

Other Expenses

Interest Expense. Interest expense decreased $0.4 million, or 9.9%, in 2018 compared to 2017 due to principal payments on our senior secured credit facility.

Other Expense. Other expense primarily consists of realized and unrealized foreign exchange gains or losses. The increase of $1.4 million in 2018 compared to 2017 was primarily caused by the movement in exchange rates on short-term intercompany loans denominated in U.S dollars payable by our foreign subsidiaries. During 2018, unrealized exchange rate losses on these intercompany loans were $1.2 million compared to unrealized gains of $0.2 million in 2017.

Income Tax Expense. Income tax expense was $0.2 million in 2018 compared to $0.3 million in 2017. We established a valuation allowance equal to the total U.S. net deferred tax assets due to our lack of earnings history. Tax expense in 2018 and 2017 relates to foreign income taxes on income generated in our OUS tax jurisdictions.

Comparison of the Years Ended December 31, 2017 and 2016

	Year Ended December 31, 2017		Year Ended December 31, 2016	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	$ 64,310	100.0 %	$ 64,650	100.0 %
Cost of sales	24,578	38.2 %	25,255	39.1 %
Gross margin	39,732	61.8 %	39,395	60.9 %
Operating expenses:				
Sales and marketing	32,910	51.2 %	31,533	48.8 %
General and administrative	13,722	21.3 %	13,625	21.1 %
Research and development	8,299	12.9 %	7,805	12.1 %
Amortization of intangible assets	7,240	11.3 %	7,193	11.1 %
Total operating expenses	62,171	96.7 %	60,156	93.1 %
Loss from operations	(22,439)	(34.9)%	(20,761)	(32.2)%
Interest expense, net	4,508	7.0 %	18,168	28.1 %
Other expense	41	0.1 %	1,851	2.9 %
Net loss before income taxes	(26,988)	(42.0)%	(40,780)	(63.2)%
Income tax expense	304	0.5 %	387	0.6 %
Net loss	$ (27,292)	(42.5)%	$ (41,167)	(63.8)%

Product Sales

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

	Year Ended December 31, 2017				Year Ended Year Ended December 31,			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 8,019	$ 8,462	$ 16,481	25.6 %	$ 6,184	$ 3,004	$ 9,188	14.2 %
IGB, excluding U.S. Orbera starter kit sales	5,439	13,141	18,580	29.0 %	4,991	13,379	18,370	28.4 %
U.S. Orbera starter kit sales	862	—	862	1.3 %	4,350	—	4,350	6.7 %
Endo-bariatric	14,320	21,603	35,923	55.9 %	15,525	16,383	31,908	49.3 %
Surgical	17,366	10,227	27,593	42.9 %	21,560	10,706	32,266	49.9 %
Other	766	28	794	1.2 %	452	24	476	0.8 %
Total revenues	$32,452	$31,858	$ 64,310	100.0 %	$37,537	$27,113	$ 64,650	100.0 %
% Total revenues	50.5 %	49.5 %			58.1 %	41.9 %		

Endoscopic Suturing System ("ESS") and Intragastric Balloon ("IGB")

Reconciliation of GAAP to Non-GAAP Financial Information

The following table reconciles the most directly comparable GAAP financial measure to the non-GAAP financial measure discussed above.

	Year Ended December 31,		% Increase/ (Decrease)
	2017	2016	
Total revenues	$ 64,310	$ 64,650	0.5 %
Less: U.S. Orbera starter kit sales	(862)	(4,350)	(80.2)%
Adjusted total revenues, excluding U.S. Orbera starter kit sales	$ 63,448	$ 60,300	5.2 %

Total revenues in 2017 were $64.3 million, compared to $64.7 million in 2016, a decrease of less than 0.5%. Adjusted total revenues, excluding U.S. Orbera starter kit sales, increased 5.2%.

Total Endo-bariatric product sales increased 12.6% to $35.9 million in 2017, compared to $31.9 million in 2016 comprising 55.9% of total revenues in 2017 compared to 49.4% in 2016. Excluding U.S. Orbera starter kit sales, total Endo-bariatric sales increased 27.2% for the year. In markets outside the U.S. ("OUS"), Endo-bariatric product sales increased 31.9% or $5.2 million in 2017 compared to 2016 primarily due to higher OverStitch sales in our direct markets. OUS direct market sales were 68.5% of total OUS Endo-bariatric product sales in 2017 compared to 65.1% in 2016. Excluding U.S. Orbera starter kit sales, U.S. Endo-bariatric product sales increased 20.4% or $2.3 million in 2017 primarily due to higher OverStitch product sales and higher Orbera product sales in the first half of 2017.

Total Surgical product sales for 2017 were $27.6 million, a decrease of 14.5%, compared to $32.3 million in 2016. The decline was primarily due to reductions in gastric banding procedures being performed in the U.S. Total OUS Surgical sales decreased 4.5% to $10.2 million for 2017 compared to $10.7 million for 2016. In the U.S. Surgical sales decreased 19.5% to $17.4 million in 2017 compared to $21.6 million for 2016.

Cost of Sales

Cost of product sales for the periods shown were as follows:

	Year ended December 31, 2017		Year ended December 31, 2016	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 15,896	24.7 %	$ 14,184	22.0 %
Start-up costs	—	— %	3,384	5.2 %
Overhead	5,416	8.4 %	1,918	3.0 %
Change in inventory reserve	692	1.1 %	3,750	5.8 %
Other indirect costs	2,574	4.0 %	2,019	3.1 %
Total cost of sales	$ 24,578	38.2 %	$ 25,255	39.1 %

Gross Margin

Gross margin as a percentage of revenues was 61.8% for 2017 compared to 60.9% for 2016, respectively. Cost of sales included inventory impairment charges of $0.7 million and $3.8 million in 2017 and 2016, respectively. In 2016, we recorded an inventory impairment charge related to expiring finished good inventory and excess raw materials transferred from Allergan as required under the transition services agreement. Excluding inventory impairment charges, gross margin was 62.9% for 2017 and 66.7% for 2016. This decline in gross margin, excluding the impact of inventory impairment charges, is due to the ongoing shift in our product sales mix from higher margin Surgical products to Endo-bariatric products that realize lower relative gross margins. Additionally, higher shipping and warehousing costs and an increased mix of Apollo manufactured products sold, which currently provide lower gross margin due to economies of scale, contributed to the reduction in gross margin. The mix of Apollo manufactured products sold has increased as we deplete the buffer inventory we purchased as part of the planned transition from Allergan to Apollo.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense increased $1.4 million to 51.2% of total revenues in 2017 from 48.8% in 2016 primarily due to higher incentive compensation, Orbera consumer marketing campaigns, and OverStitch physician training program costs.

General and Administrative Expense. General and administrative expense was essentially flat in 2017 as compared to 2016 as higher costs incurred to meet our public company filing requirements offset the transactions costs associated with the Lpath merger in 2016.

Research and Development Expense. Research and development expense increased $0.5 million, or 6.3%, in 2017 compared to 2016 primarily due to higher costs for new product development.

Interest Expense. Interest expense decreased $13.7 million, or 75.2%, in 2017 compared to 2016 primarily due to the elimination of non-cash interest associated with the convertible notes that converted into common stock in December 2016, including $8.7 million related to the contingent beneficial conversion features. Cash interest on our senior secured credit facility decreased $2.0 million for the full year after principal reductions of $11.0 million in the fourth quarter of 2016 and $7.0 million in the first quarter of 2017.

Other Expense. Other expense primarily consists of realized and unrealized foreign exchange gains or losses. The decrease in other expense of $1.8 million, or 97.8%, in 2017 compared to 2016 was primarily caused by the movement in exchange rates on short-term intercompany loans denominated in U.S. dollars payable by our foreign subsidiaries. During 2017, unrealized exchange rate gains on these intercompany loans were $0.2 million compared to unrealized losses of $1.3 million in 2016.

Income Tax Expense. Income tax expense was $0.3 million in 2017 compared to $0.4 million in 2016. We established a valuation allowance equal to the total U.S. net deferred tax assets due to our lack of earnings history. Tax expense in 2017 and 2016 relates to foreign income taxes on income generated in our OUS tax jurisdictions.

Liquidity and Capital Resources

We have experienced operating losses since inception and occasional debt covenant violations and have an accumulated deficit of $222.8 million as of December 31, 2018. To date, we have funded our operating losses and acquisitions through equity offerings and the issuance of debt instruments. Our ability to fund future operations and meet debt covenant requirements will depend upon our level of future operating cash flow and our ability to access additional funding through either equity offerings, issuances of debt instruments or both. Management believes its existing cash and cash equivalents and product revenues, along with the additional cash received with the refinancing, will be sufficient to meet liquidity and capital requirements for at least the next twelve months, although there can be no assurances that the Company will be able to do so. The Company periodically evaluates its liquidity requirements, alternative uses of capital, capital needs and available resources. As a result of this process, the Company has in the past, and may in the future, explore alternatives to finance its business plan, including, but not limited to, a public offering of its common stock, private equity or debt financings, reduction of planned expenditures, or other sources.

In July 2017, the Company completed a public offering selling 6,542,453 shares at a price of $5.50 per share, including 853,363 shares sold to the underwriters upon the full exercise of their option to purchase additional shares, before the underwriting discount. The public offering generated net proceeds of approximately $33,584, after deducting the underwriting discount and related offering expenses.

In December 2017, we filed a shelf registration statement on Form S-3 with the SEC, which permits the offering, issuance and sale by us of up to $50.0 million of our common stock. In December 2017, we also entered into a sales agreement with Cantor Fitzgerald & Co. for the sale and issuance of shares of our common stock of up to $16.0 million from time to time in an "at-the-market" program.

In June 2018, we completed a public offering selling 4,309,090 shares of common stock at a price to the public of $5.50 per share, including 562,055 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares of common stock resulting in net proceeds of approximately $21.9 million, after deducting underwriting discounts and expenses. In connection with this transaction, the December 2017 "at-the-market" program was terminated but the sales agreement remains in effect.

In December 2018, we divested our Surgical Product line and received $10.0 million in cash on closing which was used to repay debt principal outstanding.

In March 2019, we entered into a Term Loan Facility with Solar Capital Partners to borrow $35.0 million of which we used $22.4 million of the proceeds to repay our senior secured credit facility (see Note 19).

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 an asset 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 a consolidated debt to revenue ratio. In the past, we have received waivers or amendments from the lender with respect to noncompliance with these financial 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 the lender's discretion.

During the year ended December 31, 2018, we prepaid $12.5 million of principal outstanding under the Credit Agreement, of which $2.5 million related to our waivers from Athyrium for noncompliance with our second and third quarter debt-to-revenue ratio requirement. In the fourth quarter, as a result of the divestiture of the Surgical product line, we paid an additional $10.0 million of the principal outstanding.

In March 2019, we entered into a Term Loan Facility with Solar Capital to borrow $35.0 million, of which we used $22.4 million of the proceeds to repay our Senior Secured Credit Facility (see Note 19).

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018 and 2017:

	2018	2017
Net cash used in operating activities	$ (23,119)	$ (13,320)
Net cash provided by/(used in) investing activities	7,119	(2,137)
Net cash provided by financing activities	9,695	26,703
Effect of exchange rate changes on cash	(106)	131
Net change in cash, cash equivalents and restricted cash	$ (6,411)	$ 11,377

Operating Activities

Cash used in operating activities of $23.1 million for 2018 was primarily the result of a net loss of $45.8 million net of non-cash charges of $21.0 million primarily related to depreciation, amortization, loss on divestiture of the Surgical product line, stock based compensation, and foreign exchange on intercompany loans. Net loss included $3.2 million of additional costs associated with clinical trial activities for our Endo-bariatric products. In addition, operating assets and liabilities provided cash of $1.6 million primarily due to reduction in inventory levels as we reduced our buffer stock in connection with completion of gross margin projects. The increase in cash for operating activities of $9.8 million primarily relates to the change in net loss, net of non-cash charges, as a result of lower gross margin and higher research and development expense each as explained above in our results of operations.

Cash used in operating activities of $13.3 million for 2017 was primarily the result of a net loss of $27.3 million net of non-cash charges of $12.1 million primarily related to depreciation, amortization, non-cash interest expense, inventory impairment and stock based compensation. Net loss included $2.8 million of costs associated with initial regulatory filings and corporate governance activities required of a new public company. Additionally, cash provided by operating assets and liabilities of $1.9 million related to the build-up of inventory supply in order to meet growing demand for our Endo-bariatric products offset by an increase in payables associated with the inventory build-up.

Investing Activities

Cash provided by investing activities of $7.1 million for 2018 was primarily related to the $10.0 million closing cash payment received upon the sale of the Surgical product line offset by $2.9 million of purchases of property and equipment associated with our manufacturing facility as we expand manufacturing capability and ongoing investments in our intellectual property portfolio.

Cash used for investing activities of $2.1 million for 2017 was primarily related to purchases of property and equipment associated with our manufacturing facility as we expand manufacturing capability and ongoing investments in our intellectual property portfolio.

Financing Activities

Cash provided by financing activities of $9.7 million for 2018 primarily relates to the $21.9 million in net proceeds from the June 2018 public offering offset by payments of $12.5 million in principal on the senior secured credit facility.

Cash provided by financing activities of $26.7 million for 2017 primarily relates to the $33.6 million in net proceeds from the July 2017 public offering of 6,542,453 shares of common stock at a price of $5.50 per share. The increase in cash was offset by a payment of $7.0 million in principal on the senior secured credit facility.

Future Funding Requirements

As of December 31, 2018, we had cash, cash equivalents and restricted cash balances totaling $25.0 million. We believe our existing cash and cash equivalents, product revenues, our current shelf and the public markets or cost reduction actions will be sufficient to meet our liquidity and capital requirements for at least the next twelve months.

In December 2017, we filed a shelf registration statement to sell up to $50.0 million of our common stock at a future date. In June 2018, we completed a public offering that generated $23.7 million in gross proceeds.

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, the cost and timing of identified gross margin improvement projects, the cost and timing of clinical programs, the ability to maintain covenant compliance of our lending facility, and the costs of establishing additional sales, marketing, distribution and manufacturing 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

To the Stockholders and Board of Directors
Apollo Endosurgery, Inc:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Apollo Endosurgery, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 18, 2019 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Austin, Texas
March 18, 2019

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Apollo Endosurgery, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited Apollo Endosurgery, Inc. and subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness, described below, on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the "consolidated financial statements"), and our report dated March 18, 2019 expressed an unqualified opinion on those consolidated financial statements.
A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness has been identified and included in management's assessment related to the transition in-house of the sales order to cash process (which includes revenue and accounts receivable) from a third-party service provider, where the Company's risk assessment was not sufficient, and therefore ineffective, to ensure controls were designed and implemented to respond to the risks in the transition and sufficient resources were not available to implement the transition in the requisite timeframe. Additionally, the communication of objectives and responsibilities for internal controls related to the transition was insufficient, and therefore ineffective. As a result, we identified control deficiencies over the verification of sales orders including price change approvals, the approval of credit memos and the verification of the application of cash to individual customer account balances.

The material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 consolidated financial statements, and this report does not affect our report on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Disclaimer on Additional Information in Management's Report

We do not express an opinion or any other form of assurance on management's statements, included in the accompanying Management's Report on Internal Control Over Financial Reporting, referring to corrective actions taken after December 31, 2018, relative to the aforementioned material weakness in internal control over financial reporting.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Austin, Texas
March 18, 2019

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2018 and 2017
(In thousands, except for share data)

	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 23,996	$ 30,513
Accounts receivable, net of allowance for doubtful accounts of $559 and $452, respectively	11,391	11,729
Inventory, net	9,932	14,343
Prepaid expenses and other current assets	2,801	1,015
Total current assets	48,120	57,600
Restricted cash	1,011	905
Property and equipment, net of accumulated depreciation of $6,692 and $6,658, respectively	5,897	6,885
Goodwill	5,290	6,828
Intangible assets, net of accumulated amortization of $9,455 and $28,415, respectively	9,859	36,421
Other assets	4,291	422
Total assets	$ 74,468	$ 109,061
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 15,292	$ 18,327
Accrued expenses	9,156	7,500
Total current liabilities	24,448	25,827
Long-term debt	21,190	33,321
Total liabilities	45,638	59,148
Commitments and contingencies		
Stockholders' equity:		
Common stock; $0.001 par value; 100,000,000 shares authorized; 21,899,522 and 17,291,209 shares issued and outstanding at December 31, 2018 and 2017, respectively	$ 22	$ 17
Additional paid-in capital	249,115	225,122
Accumulated other comprehensive income	2,501	1,795
Accumulated deficit	(222,808)	(177,021)
Total stockholders' equity	28,830	49,913
Total liabilities and stockholders' equity	$ 74,468	$ 109,061

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2018 and 2017
(In thousands, except for share data)

	2018	2017
Revenues	$ 60,854	$ 64,310
Cost of sales	27,660	24,578
Gross margin	33,194	39,732
Operating expenses:		
Sales and marketing	32,831	32,910
General and administrative	13,436	13,722
Research and development	12,176	8,299
Loss on divestiture	7,770	—
Amortization of intangible assets	7,074	7,240
Total operating expenses	73,287	62,171
Loss from operations	(40,093)	(22,439)
Other expenses:		
Interest expense, net	4,063	4,508
Other expense	1,440	41
Net loss before income taxes	(45,596)	(26,988)
Income tax expense	191	304
Net loss	(45,787)	(27,292)
Other comprehensive income:		
Foreign currency translation	706	324
Comprehensive loss	$ (45,081)	$ (26,968)
Net loss per share, basic and diluted	$ (2.31)	$ (2.01)
Shares used in computing net loss per share, basic and diluted	19,789,867	13,565,781

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2018 and 2017
(In thousands, except for share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2016	10,688,992	$ 11	$ 190,664	$ 1,471	$ (149,729)	$ 42,417
Exercise of common stock options	59,764	—	119	—	—	119
Issuance of common stock, net of issuance costs of $2,400	6,542,453	6	33,578	—	—	33,584
Stock based compensation	—	—	761	—	—	761
Foreign currency translation	—	—	—	324	—	324
Net loss	—	—	—	—	(27,292)	(27,292)
Balances at December 31, 2017	17,291,209	$ 17	$ 225,122	$ 1,795	$ (177,021)	$ 49,913
Exercise of common stock options	275,862	—	738	—	—	738
Issuance of restricted stock units	23,361	—	—	—	—	—
Issuance of common stock, net of issuance costs of $1,843	4,309,090	5	21,852	—	—	21,857
Stock based compensation	—	—	1,403	—	—	1,403
Foreign currency translation	—	—	—	706	—	706
Net loss	—	—	—	—	(45,787)	(45,787)
Balances at December 31, 2018	21,899,522	$ 22	$ 249,115	$ 2,501	$ (222,808)	$ 28,830

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
Years Ended December 31, 2018 and 2017
(In thousands)

	2018	2017
Cash flows from operating activities:		
Net loss	$ (45,787)	$ (27,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,292	9,717
Amortization of deferred financing costs	491	299
Non-cash interest expense	359	595
Provision for doubtful accounts receivable	186	180
Change in inventory reserve	387	692
Stock based compensation	1,403	761
Foreign exchange on short-term intercompany loans	1,161	(193)
Loss on divestiture	7,770	—
Changes in operating assets and liabilities:		
Accounts receivable	(162)	(916)
Inventory	3,004	(2,850)
Prepaid expenses and other assets	41	948
Accounts payable and accrued expenses	(1,264)	4,739
Net cash used in operating activities	(23,119)	(13,320)
Cash flows from investing activities:		
Purchases of property and equipment	(1,951)	(1,564)
Purchases of intangibles and other assets	(930)	(573)
Divestiture of Surgical product line	10,000	—
Net cash provided by/(used in) investing activities	7,119	(2,137)
Cash flows from financing activities:		
Proceeds from exercise of stock options	738	119
Proceeds from issuance of common stock	21,857	33,584
Payments of deferred financing costs	(400)	—
Payment of debt	(12,500)	(7,000)
Net cash provided by financing activities	9,695	26,703
Effect of exchange rate changes on cash	(106)	131
Net increase (decrease) in cash, cash equivalents and restricted cash	(6,411)	11,377
Cash, cash equivalents and restricted cash at beginning of year	31,418	20,041
Cash, cash equivalents and restricted cash at end of year	$ 25,007	$ 31,418
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,775	$ 3,775
Cash paid for income taxes	98	274

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements
Years Ended December 31, 2018 and 2017
(In thousands, except for share data)

(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. The Company's products are used by gastroenterologists and surgeons in a variety of settings to provide interventional therapy to patients who suffer from various gastrointestinal conditions including obesity and the many co-morbidities associated with obesity.

The Company's core products include the OverStitch™ Endoscopic Suturing System, the Orbera® Intragastric Balloon System, which together comprise the Company's Endo-bariatric products and the recently divested Lap-Band® adjustable gastric banding system ("Surgical" products). In the U.S., the Company offers Orbera® Coach, a digital and remotely delivered aftercare program. All devices are regulated by the U.S. Food and Drug Administration (the "FDA") or an equivalent regulatory body outside the U.S.

The Company's products are sold throughout the world with direct sales markets in the U.S., Europe, Australia, Brazil and Canada. The Company also has a manufacturing facility located in Costa Rica.

In December 2018, the Company completed an asset sale with ReShape Lifesciences, Inc ("ReShape") in which ReShape acquired substantially all of the assets exclusively related to the Surgical product line for $10,000 in cash at closing and future cash consideration. As additional consideration, the Company received from ReShape substantially all of ReShape's assets exclusively related to ReShape's intragastric balloon product line. Effective December 31, 2018, the Company ceased sales of ReShape's intragastric balloon system.

(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 U.S. ("U.S. GAAP") 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 revenue recognition, going concern, financial projections, useful lives of intangibles and long-lived assets, stock compensation, deferred tax asset valuation, long-lived asset and goodwill impairment, allowance for doubtful accounts, and valuation of inventory.

(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 are secured by cash balances totaling $1,011 and $905 which are recorded in restricted cash on the balance sheet as of December 31, 2018 and 2017, respectively.

(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 $559 and $452 as of December 31, 2018 and 2017, respectively. Accounts receivable of $101 and $238 were written off during the years ended December 31, 2018 and 2017, respectively.

(f) Inventory

Inventory is stated at the lower of cost or net realizable value, net of any allowances. Charges for excess and obsolete inventory are based on specific identification of obsolete inventory items and an analysis of inventory items approaching expiration date. We record estimated excess and 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 $21,935 at December 31, 2018 and $33,158 at December 31, 2017. 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.

(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 machinery to working condition are capitalized. Expenditures for repairs and maintenance and minor replacements are charged to expense as incurred.

(i) Purchase Accounting

Business combinations must be evaluated to determine whether it meets the definition of a business or will be accounted for as an asset acquisition. A business consists of inputs and processes that have the ability to create outputs and are accounted for using the acquisition method of accounting. Using this method, the assets acquired and liabilities assumed are recorded at their fair value with any excess going to goodwill. When a business combination is considered an asset acquisition, the cost accumulation approach is used and the total consideration is allocated to the assets acquired and liabilities assumed on a relative fair value basis.

(j) Goodwill and Other Intangible Assets

Goodwill is not amortized but is tested annually for impairment or more frequently if impairment indicators exist. For annual and interim goodwill impairment tests, the Company first assesses 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, 2018 and 2017 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. The Company's evaluation of long-lived assets for the years ended December 31, 2018 and 2017 resulted in no impairment losses.

(l) Revenue Recognition

The Company's principal source of revenues is from the sale of its products. Revenue is recognized when control of the promised goods is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in an exchange or those goods. Generally, these are met under the Company's agreements with most customers upon product shipment. This includes sales to 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.

Customers and distributors generally have the right to return or exchange products purchased from the Company for up to thirty days from the date of product shipment. At the end of each period, the Company determines the extent to which its revenues need to be reduced to account for expected returns and exchanges. Certain customer may receive volume rebates or discounts, which are accounted for as variable consideration. We estimate these amounts based on the expected amount to be provided to customers and reduce revenues recognized.

We record deferred revenues when cash payments are received in advance of the transfer of goods.

The Company accounts for taxes collected from customers and remitted to governmental authorities on a net basis. Accordingly, such amounts are excluded from revenues. 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 sales.

(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. Compensation cost is recognized on a straight-line basis over the respective vesting period of the award. 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 $3,024 and $3,295 in advertising costs during the years ended December 31, 2018 and 2017, 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 U.S. In December 2015, the medical device tax was suspended for two years and on January 22, 2018 the moratorium on this tax was extended through December 31, 2019.

(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 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. The Company does not hedge foreign currency translation risk in the net assets and income it reports 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

On January 1, 2018, the Company adopted the provisions of ASU 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), which requires an entity to recognize revenue when it transfers control of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. The Company adopted this new standard using the modified retrospective method and applied this method only to contracts that were not completed as of January 1, 2018. Prior periods were not retrospectively adjusted. There was no material impact on the Company's financial statement upon adoption of the new revenue recognition standard.

On January 1, 2018, the Company adopted the provisions of ASU 2017-01, *Business Combinations: Clarifying the Definition of a Business* ("ASU 2017-01") to clarify the definition of a business when evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses.

On January 1, 2019, the Company adopted the provisions of 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. Upon adoption, the Company used the modified retrospective approach and chose not to adjust comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. The Company recognized 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 of $2,669 on the balance sheet, thereby increasing reported assets and liabilities. The cumulative-effect adjustment made to the opening balance of retained earnings as of January 1, 2019 did not have a material impact on the Company's financial statements. The income statement recognition of lease expense is similar to the Company's current methodology.

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 two 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.

(3) Divestiture of Surgical Product Line

On December 17, 2018, the Company entered into an Asset Purchase Agreement ("Purchase Agreement") with ReShape pursuant to which, ReShape acquired substantially all of the Company's assets exclusively related to our Surgical product line for $10,000 at the closing of the transaction and future payments of an additional $2,000 on each of the first and second anniversary of the closing date and $3,000 on the third anniversary of the closing date. As additional consideration, Apollo received ReShape's assets exclusively related to their intragastric balloon product. Legal fees associated with the divestiture were $498 and are also included in loss on divestiture.

The $7,000 receivable from Reshape was discounted at 10% in order to determine the fair value for the consideration received. The current portion of this receivable is included in other current assets on the balance sheet with the long-term portion included in other assets.

A summary of the consideration received from Reshape for the divestiture and the related Surgical assets that were divested is included below:

Consideration received		
Cash	$	10,000
Receivable		5,725
Inventory		102
Intangible assets		1,781
Total consideration		**17,608**
Less: Assets divested		
Inventory		(873)
Property and equipment, net of accumulated depreciation		(478)
Intangible assets, net of accumulated amortization		(21,186)
Patents and trademarks, net of accumulated amortization		(805)
Goodwill		(1,538)
Total assets divested		**(24,880)**
Legal fees associated with divestiture		(498)
Loss on divestiture	**$**	**(7,770)**

The assets acquired from ReShape were accounted for as an asset acquisition. The Surgical product line was deemed to be a business, and thus goodwill was allocated to the Surgical product line and included in assets divested.

Apollo and ReShape each made customary representations, warranties, covenants and indemnities in the Purchase Agreement. Subject to certain limitations, each party agreed to indemnify the other party for certain matters, including breaches of representations, warranties and covenants in the Purchase Agreement. The execution of the Purchase Agreement and the closing of the transaction occurred simultaneously on December 17, 2018.

ReShape also granted the Company a security interest in substantially all of ReShape's assets as security for the payment and performance when due of all of ReShape's obligations under the Purchase Agreement, including the obligation to pay its remaining cash purchase price.

In addition, the parties entered into a transition services agreement, supply agreement and distribution agreement pursuant to which, among other things, the Company will manufacture the Surgical product for ReShape for up to two years, and will serve as ReShape's distributor of the Surgical product outside of the U.S. for up to one year.

(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, 2018, the Company's cash and cash equivalents and restricted cash are held in deposit accounts at three different banks totaling $25,007. 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 or revenues as of or for the years ended December 31, 2018 and 2017.

(5) Inventory

Inventory consists of the following as of December 31:

	2018	2017
Raw materials	$ 3,806	$ 3,764
Work in progress	352	493
Finished goods	5,774	10,086
Total inventory	$ 9,932	$ 14,343

The Company recorded an inventory impairment charge of $387 and $692 and for the year ended December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, the Company disposed of $1,419 of expired product which was fully reserved. Finished goods included $328 of consigned inventory at December 31, 2018.

(6) Property and Equipment

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

	Depreciable Lives	2018	2017
Equipment	5 years	$ 7,510	$ 5,501
Furniture, fixtures and tooling	4 - 8 years	2,223	3,524
Computer hardware	3 - 5 years	1,326	1,223
Leasehold improvements	3 - 5 years	1,400	1,424
Construction in process		130	1,871
		12,589	13,543
Less accumulated depreciation		(6,692)	(6,658)
Property and equipment, net		$ 5,897	$ 6,885

The Company recorded depreciation expense of $2,024 and $2,250 for the years ended December 31, 2018 and 2017, respectively. There were no impairment charges for the years ended December 31, 2018 or 2017. The Company disposed of $1,861 of gross property and equipment with accumulated depreciation of $1,383 related to the disposition of the Surgical product line (see Note 3) and also disposed of $608 which was fully depreciated as of December 31, 2018 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, 2018 and 2017:

December 31, 2016	$ 6,828
December 31, 2017	$ 6,828
Goodwill associated with divestiture of Surgical product line (see Note 3)	(1,538)
December 31, 2018	$ 5,290

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

	Useful Life	2018	2017
Customer relationships	9 years	$ 8,301	$ 30,300
Lap-Band technology	10 years	—	15,500
Orbera technology	12 years	4,600	4,600
Trade names	10 years	1,700	7,900
Patents and trademarks	5 years	2,292	4,579
Other	1 - 5 years	2,421	1,957
		19,314	64,836
Less accumulated amortization		(9,455)	(28,415)
Intangible assets, net		$ 9,859	$ 36,421

In connection with the Purchase Agreement (see Note 3), the Company divested of the intangibles related to the Surgical product line. Additionally, the Company obtained an independent third-party valuation to determine the value of the customer relationships purchased of $1,781.

Amortization expense related to the above intangible assets was $7,268 and $7,467 during 2018 and 2017, respectively. Additionally, we capitalized $416 and $401 related to the extension and renewal of our patents and trademarks during 2018 and 2017, respectively.

Amortization for the next five years is as follows:

2019	$ 2,181
2020	1,909
2021	1,786
2022	1,612
2023	845
Thereafter	1,526
Total	$ 9,859

(8) Accrued Expenses

Accrued expenses consist of the following as of December 31:

	2018	2017
Accrued employee compensation and expenses	$ 3,804	$ 4,243
Accrued professional service fees (including clinical trials)	2,983	522
Accrued returns and rebates	331	438
Accrued insurance and taxes	625	527
Other	1,413	1,770
Total accrued expenses	$ 9,156	$ 7,500

(9) Long-Term Debt

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

	2018	2017
Senior secured credit facility	$ 19,500	$ 32,000
Payment-in-kind interest	2,142	2,223
Discount on long-term debt	(175)	(534)
Deferred financing costs	(277)	(368)
Long-term debt	$ 21,190	$ 33,321

In February 2015, the Company entered into a senior secured credit facility (the "Credit Agreement") with Athyrium Opportunities II Acquisition LP ("Athyrium") to borrow $50,000 which is payable in a lump sum on February 27, 2020. The Credit Agreement is secured by all of the Company's assets and has priority over all other debt. The Credit Agreement bears interest at 10.5% per annum. In the first year, 7% cash interest was paid quarterly and 3.5% of payment-in-kind 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 previous outstanding long-term debt. In October 2016, the Company issued a warrant to purchase 163,915 shares of common stock with an exercise price of $21.29 per share. These warrants remain outstanding and are included in Note 10.

The Credit Agreement 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 Agreement also includes financial covenants including minimum consolidated quarterly revenue requirements and a consolidated debt to revenue ratio and provides certain limited cure provisions in the event these requirements are not met.

In February 2018, the Company entered into a Sixth Amendment to the Credit Agreement with Athyrium which removed the minimum quarterly revenue requirement and increased the maximum debt-to-revenue ratio to 0.54 from 0.49 with the maximum debt-to-revenue ratio declining gradually each quarter over the remaining term of the facility.

In July 2018, the Company entered into a waiver with Athyrium that increased the maximum debt-to-revenue ratio for the second quarter of 2018 to 0.56 from 0.53, waived the existing default under such ratio and prepaid $1,500 of the principal amount outstanding, together with accrued interest and certain fees and expenses.

In September 2018, the Company made an additional $1,000 voluntary principal payment to the lender and in November, 2018, the Company entered into a Seventh Amendment to the Credit Agreement and Waiver with Athyrium which granted a waiver for the noncompliance of the debt-to-revenue ratio for the third quarter 2018. In addition, the amendment removed the cure right provision.

In December 2018, the Company entered into an Eighth Amendment to the Credit Agreement with Athyrium which amended, among other things (i) the covenants under the Credit Agreement with Athyrium to permit the transactions contemplated by the Asset Purchase Agreement with ReShape Lifesciences Inc.; (ii) modified the mandatory prepayment

provisions and required the Company to pay Athyrium the additional cash consideration received from ReShape on the first, second and third anniversaries of the closing date, so long as the Credit Agreement remains outstanding; and (iii) required the Company to pay Athyrium the initial $10,000 received from ReShape plus accrued interest due under the Credit Agreement and certain fees and expenses.

In March 2019, the Company entered into a Term Loan Facility with Solar Capital Partners to borrow $35,000 of which $22,372 of the proceeds were used to repay our Senior Secured Credit Facility. See Note 19 for further details.

(10) Stockholders' Equity

(a) Authorized Stock

The Company's amended and restated certificate of incorporation, 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.

(b) Warrants

Warrants consist of the following as of December 31, 2018:

Warrant Expiration Date	Number of shares	Exercise price per share
September 25, 2019	46,818	$ 258.72
December 29, 2021	40,456	$ 13.70
February 27, 2022	163,915	$ 21.29
Total number of warrants outstanding	251,189	
Weighted average exercise price of warrants outstanding		$ 64.32

There were no warrants exercised in 2018 and 702 expired during the year ended December 31, 2018.

(11) Stock Option Plans

(a) Plans

2006 Plan

The Company's 2006 Equity Incentive Plan (the "2006 Plan") covers employees, consultants, and nonemployee directors of the Company and provides for the grant of 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 were 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. 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") covers employees, consultants, and nonemployee directors of the Company and provides for the grant of 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 2016 Plan was replaced by the 2017 Plan.

2017 Plan

The Company's 2017 Equity Incentive Plan ("2017 Plan") was approved in June 2017 by the Company's stockholders. The 2017 plan covers employees, consultants, and nonemployee directors of the Company and provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance stock awards, performance cash awards, 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 2017 Plan is 10 years from the date of grant. Options generally vest over a period of time, typically not more than 5 years. The plan's reserve is automatically increased by 4% of the total number of shares outstanding at the prior year end for a period of ten years. Shares subject to awards granted under the 2017 Plan which expire, are repurchased, or are canceled or forfeited will again become available for issuance under the 2017 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 2017 Plan.

The 2017 Plan replaced the Company's 2016 Plan, which was the successor to the 2006 Plan, and the Lpath Plan (collectively, the Lpath Plan, with the 2016 Plan and the 2006 Plan, the "Prior Plans"). Grants will no longer be made under the Prior Plans, but the awards that remain outstanding will continue to be governed by the terms of the applicable Prior Plan and the applicable award agreement.

As of December 31, 2018, the Company has 974,056 shares of common stock reserved for issuance under the 2017 Plan.

(b) Stock Option Activity

A summary of the stock option activity under the Company's 2017 Plan and Prior Plans (collectively, the "Equity Plans") as of December 31, 2018 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2017	1,390,428	$4.64	7.0 years	$2,432
Options granted	681,403	$6.72		
Options exercised	(275,862)	$2.68		
Options forfeited	(293,213)	$6.24		
Options outstanding, December 31, 2018	1,502,756	$5.63	7.7 years	$217
Options vested and expected to vest	1,502,756	$5.63	7.7 years	$217
Options exercisable	725,972	$4.53	6.5 years	$174

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 the stock awards. Prior to December 2016, 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 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:

	2018	2017
Risk free interest rate	2.7%	1.9%
Expected dividend yield	—%	—%
Estimated volatility	63.3%	61.7%
Expected life	5.8 years	5.4 years

Additional information regarding options is as follows:

	2018	2017
Stock compensation cost	$ 1,403	$ 761
Weighted-average grant date fair value of options granted during the period	$ 3.95	$ 3.75
Aggregate intrinsic value of options exercised during the period	$ 921	$ 231

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, 2018 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, 2018 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.

Annually the Company grants options that would vest only upon the Company's achievement of certain global revenue and EBITDA targets and in 2018, 37,500 options were determined to have met the underlying conditions. The remaining performance shares were forfeited.

Unrecognized compensation expense related to unvested options was approximately $2,579 at December 31, 2018, with a remaining amortization period of less than 2.6 years.

A summary of the restricted stock unit activity under the Company's Equity Plans as of December 31, 2018 is presented below:

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested units, December 31, 2017	61,198	$5.60	$343
Restricted stock units granted	61,220	$6.63	
Restricted stock units vested	(23,361)	$5.64	
Restricted stock units forfeited	(4,117)	$6.53	
Unvested units, December 31, 2018	94,940	$6.21	$328

Unrecognized compensation expense related to unvested restricted stock units was approximately $438 at December 31, 2018, with a remaining amortization period of 2.6 years.

(12) Commitments

(a) Lease Commitments

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

Lease expense for the years ended December 31, 2018 and 2017 was $1,290 and $1,769, 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, 2018, minimum rental commitments under non-cancellable operating leases payable over the next five years are as follows:

2019	$ 1,174
2020	965
2021	764
2022	84
2023	84
Thereafter	49
Total	$ 3,120

(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 twelve months 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 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.

(13) Contingencies

Accounts payable includes $8,505 related to inventory and transition services provided during 2015 and 2016. The payment of these charges is contingent upon resolution of audit findings related to the transition agreements in connection with a dispute with Allergan. As the dispute has not yet been resolved with Allergan, the timing and terms of final amounts payable remain uncertain.

(14) Defined Contribution Plan

The Company sponsors defined contribution plans for employees in the U.S. and Europe. The cost of these plans, including employer contributions, was $731 and $645 for the years ended December 31, 2018 and 2017 respectively.

(15) Income Taxes

Income tax expense of $191 and $304 for the years ended December 31, 2018 and 2017, 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:

	2018	2017
Deferred tax assets:		
Capitalized transaction costs	$ 385	$ 415
Intangible assets	1,321	2,418
Inventory valuation	255	506
Research and development credit	3,597	3,241
Foreign timing differences	187	(17)
Other	1,942	952
Net operating loss carryforwards	45,067	34,887
	52,754	42,402
Deferred tax liabilities:		
Unremitted foreign earnings	(461)	(438)
Depreciable assets	(64)	(47)
	(525)	(485)
Total net deferred tax assets	52,229	41,917
Less valuation allowance	(52,229)	(41,917)
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 $10,312 during the year ended December 31, 2018, primarily as a result of changes in net operating loss.

As of December 31, 2018, 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 21% for 2018 and 35% for 2017 to income before income taxes as a result of the following:

	2018	2017
Tax at U.S. statutory rate	$ (9,575)	$ (9,176)
State taxes, net of deferred benefit	(2,017)	(866)
Foreign tax rate differential	(92)	(451)
Foreign taxes	(88)	—
Permanent differences	993	726
Research and development tax credit	(362)	(444)
Other	211	1,045
Deferred tax adjustment	796	—
Unremitted foreign earnings	13	(757)
Valuation allowance - current year	10,312	9,332
Change in valuation allowance - rate change	—	(20,199)
Federal tax rate change	—	21,094
Income tax expense	$ 191	$ 304

As of December 31, 2018, the Company had federal net operating loss carryforwards of approximately $186,866 which will expire in varying amounts beginning in 2025 if not utilized. The Company’s July 2017 stock offering qualified as an ownership change under section 382 which resulted in a reduction of $100,825 in the Company’s U.S. federal net operating losses that will not be utilizable in the future, thus federal net operating loss carryforwards available to the Company as of December 31, 2018 were $86,041. In June 2018, the Company had an additional stock offering that could potentially have triggered an additional ownership change and is still being assessed.

The deferred tax asset associated with net operating loss carryforwards has been fully offset by a valuation allowance due to the uncertainty that the Company will achieve taxable income necessary to utilize the net operating loss carryforward in the future.

The Company had state net operating loss carryforwards of approximately $104,818 which will begin to expire in varying amounts beginning in 2019. The Company had foreign net operating losses of approximately $3,817 which begin to expire in varying amounts beginning in 2020, if not utilized.

New Tax Legislation

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act ("Tax Act") which makes significant changes in the U.S. tax law including a reduction in the corporate tax rates from 35% to 21%. Because the Company previously established a valuation allowance equal to its total U.S. net deferred tax assets, the enactment of the new tax law also reduced its valuation allowance and had no net impact on earnings. This adjustment was recorded in the Company's December 31, 2017 consolidated financial statements.

On December 22, 2017, Staff Accounting Bulletin No. 118 was issued to address the implication of U.S. GAAP in situations when the Company does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act and provided a one-year measurement period to complete the accounting required under ASC 740. Due to this significant tax law change, the Company recorded provisional estimates within the tax provision based on the best information available as of the filing of the financial statements ending December 31, 2017. During the fourth quarter of 2018, the Company finalized these estimates. As of the fourth quarter of 2018, there are no material impacts on tax expense with respect to the finalization of tax positions taken due to Tax Reform Legislation.

(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 by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Potentially dilutive shares, which include warrants for the purchase of common stock, restricted stock units, 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	
	2018	2017
Warrants for common stock	251,189	251,891
Common stock options	1,382,512	1,390,428
Restricted stock units	84,183	61,198
	1,717,884	1,703,517

(17) Liquidity and Capital Resources

The Company has experienced operating losses since inception and occasional debt covenant violations and has an accumulated deficit of $222,808 as of December 31, 2018. To date, the Company has funded its operating losses and acquisitions through equity offerings and the issuance of debt instruments. The Company's ability to fund future operations and meet debt covenant requirements will depend upon the level of future operating cash flow and our ability to access additional funding through either equity offerings, issuances of debt instruments or both. Management believes its existing cash and cash equivalents and product revenues, along with the additional cash received with the refinancing, will be sufficient to meet liquidity and capital requirements for at least the next twelve months, although there can be no assurances that the Company will be able to do so. The Company periodically evaluates its liquidity requirements, alternative uses of capital, capital needs and available resources. As a result of this process, the Company has in the past, and may in the future, explore alternatives to finance its business plan, including, but not limited to, a public offering of its common stock, private equity or debt financings, reduction of planned expenditures, or other sources.

In July 2017, the Company completed a public offering selling 6,542,453 shares at a price of $5.50 per share, including 853,363 shares sold to the underwriters upon the full exercise of their option to purchase additional shares, before the underwriting discount. The public offering generated net proceeds of approximately $33,584, after deducting the underwriting discount and related offering expenses.

In December 2017, the Company filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission ("SEC"), which permits the offering, issuance and sale by it of up to $50,000 of its common stock. At that time the Company also entered into a sales agreement with Cantor Fitzgerald & Co. for the sale and issuance of shares of its common stock of up to $16,000 from time to time in an "at-the-market" program.

In June 2018, the Company completed a public offering selling 4,309,090 shares of common stock at a price of $5.50 per share, including 562,055 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares of common stock resulting in net proceeds of approximately $21,857, after deducting underwriting discounts and expenses. Following the closing of this transaction, the December 2017 "at-the-market" program was terminated but the sales agreement remains in effect.

In December 2018, the Company divested its Surgical product line and received $10,000 in cash on closing which was used to repay debt principal outstanding.

In March 2019, the Company entered into a Term Loan Facility with Solar Capital Partners to borrow $35,000 of which $22,372 of the proceeds were used to repay the Company's senior secured credit facility (See Note 19). The Facility includes affirmative, negative and financial covenants, including maintenance of a minimum cash balance of $10,000 and meeting minimum product revenues which requires the Company to achieve 85% of planned revenues beginning with the first covenant compliance reporting period ending June 30, 2019. While the Company believes it will remain in compliance with these covenants, if it is unable to do so, the Company would seek covenant waivers which may not be granted or the repayment of the Term Loan Facility could be accelerated at the lender's discretion. The Company believes its existing cash and cash equivalents and product revenues, along with the additional cash received with the refinancing, will be sufficient to meet liquidity and capital requirements for at least the next twelve months.

(18) 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, whether the U.S. or outside the U.S. ("OUS") for the periods shown were as follows:

	Year Ended December 31, 2018				Year Ended December 31, 2017			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 11,016	$ 12,364	$ 23,380	38.4 %	$ 8,019	$ 8,462	$ 16,481	25.6 %
IGB	5,400	12,339	17,739	29.2 %	6,301	13,141	19,442	30.3 %
Endo-bariatric	16,416	24,703	41,119	67.6 %	14,320	21,603	35,923	55.9 %
Surgical	10,795	7,913	18,708	30.7 %	17,366	10,227	27,593	42.9 %
Other	995	32	1,027	1.7 %	766	28	794	1.2 %
Total revenues	$ 28,206	$ 32,648	$ 60,854	100.0 %	$ 32,452	$ 31,858	$ 64,310	100.0 %
% Total revenues	46.4 %	53.6 %			50.5 %	49.5 %		

Endoscopic Suturing System ("ESS") and Intragastric Balloon ("IGB")

Total distributor sales were 24.8% of total OUS revenues for both the year ended December 31, 2018 and 2017. Sales in the next largest individual country outside the U.S. were 7.6% and 8.2% for the year ended December 31, 2018 and 2017, respectively.

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

	2018	2017
U.S.	$ 2,337	$ 2,855
Costa Rica	3,347	3,748
Other	213	282
Total property and equipment, net	$ 5,897	$ 6,885

(19) Subsequent Events

In March 2019, the Company entered into a Term Loan Facility (the "Facility") with Solar Capital Ltd. ("Solar") to borrow $35,000. The Facility is due on September 1, 2023 and bears interest at LIBOR plus 7.5%. Interest only is payable in arrears until March 1, 2021 (or September 1, 2021 if certain revenue milestones are achieved). Principal payments are due on a straight-line basis after the interest-only period concludes. The Facility may provide an additional $15,000 upon the Company's request subject to further credit approval. The Facility includes the customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity of $10,000 and minimum product revenues. We used $22,372 of the proceeds of the Facility to repay our senior secured credit facility, in full. Closing fees of $263 were paid on the closing date.

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

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of 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 and design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) 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 as of December 31, 2018 our disclosure controls and procedures were not effective because of the material weakness in internal control over financial reporting discussed below.

The material weakness described below did not result in any adjustments to our consolidated financial statements for the year ended December 31, 2018 or to any previously reported interim or prior year financial statement. As a result, management has concluded that our consolidated financial statements included in this Form 10-K, are presented in conformity with U.S. generally accepted accounting principles.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act). Our management, including our Chief Executive Officer and Chief Financial Officer and oversight of our Board of Directors, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organization of the Treadway Commission ("COSO"). Based on our evaluation under the criteria set forth in Internal Control — Integrated Framework, our management concluded that our internal control over financial reporting was not effective as of December 31, 2018 due to the material weakness discussed below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

In the fourth quarter of 2018, we assumed in-house responsibility for our sales order to cash processes (which includes revenue and accounts receivable) from a third-party service provider. During the transition of these processes, our risk assessment process was not sufficient, and therefore ineffective, to ensure controls were designed and implemented to respond to the risks in the transition and sufficient resources were not available to implement the transition in the requisite timeframe. Additionally, the communication of objectives and responsibilities for internal controls related to the transition was insufficient, and therefore ineffective. As a result, we identified control deficiencies over the verification of sales orders including price change approvals, the approval of credit memos and the verification of the application of cash to individual customer account balances. The aggregation of these control deficiencies created a reasonable possibility that a material misstatement to our consolidated financial statements would not be prevented or detected on a timely basis and therefore we concluded that, the aggregation of these deficiencies represents a material weakness in our internal control over financial reporting as of December 31, 2018.

KPMG LLP, an independent registered public accounting firm, has audited the effectiveness of our internal controls over financial reporting and has issued an attestation report, which contains an adverse opinion, as of December 31, 2018. Please see their report included in our consolidated financial statements found on page 51 in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

Other than the material weakness resulting from the fourth quarter transition of our order to cash process from an external third party service provider to an internally managed process, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Remediation

Commencing in the fourth quarter of 2018 and continuing into 2019, we began our remediation efforts including, but not limited to, establishing and enhancing review procedures for sales orders, clarifying processes and controls for the approval of

credit memos, and implementing additional customer account review procedures related to the application of cash to customer accounts. Additionally, we are evaluating our procedures related to when changes in our transaction processing environment or business occur to ensure our risk assessment, communications and resources are sufficient to support our financial reporting objectives.

We believe these remediation actions will strengthen our internal control over financial reporting, but there can be no assurance that we will not conclude that additional measures are required to remediate the material weakness identified above as we test and evaluate the effectiveness of our remediation efforts, which may necessitate additional implementation and evaluation time.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive and principal financial officers, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Apollo have been detected.

ITEM 9B. OTHER INFORMATION

In March 2019, the Company entered into a Term Loan Facility (the "Facility") with Solar Capital Ltd. ("Solar") to borrow up to $50,000. The Company borrowed $35,000 on the effective date of the Facility, and the remaining $15,000 may be provided at the request of the Company subject to further credit approval. All loans under the Facility are due on September 1, 2023. The Facility bears interest at LIBOR plus 7.50% and interest is payable in arrears, with an interest-only period until March 1, 2021 (or September 1,2021 if certain revenue milestones are achieved). Principal payments are due on a straight-line basis after the interest-only period concludes. The Facility includes customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity requirement of $10,000 and minimum product revenues. We used $22,372 of the proceeds of the Facility to repay our senior secured credit facility with Athyrium Opportunities II Acquisition LP, that was previously due in February 2020, in full.

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 2018 fiscal year pursuant to Regulation 14A for our 2019 Annual Meeting of Stockholders, (the "2019 Proxy Statement") and the information to be included in the 2019 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 2019 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in our 2019 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 2019 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 2019 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 2019 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

a. Financial Statements and Financial Statement Schedules

i. 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, 2018:

ii. 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

			Incorporated by Reference		
Exhibit Number	**Description of Document**	**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.	8-K	001-35706	2.1	September 8, 2016
2.2++	Asset Purchase Agreement, dated December 17, 2018, by and between Apollo Endosurgery, Inc. and ReShape Lifesciences Inc.	8-K	001-35706	2.1	December 19, 2018
3.1	Amended and Restated Certificate of Incorporation	8-K	001-35706	3.1	June 13, 2017
3.2	Amended and Restated Bylaws	8-K	001-35706	3.2	June 13, 2017
4.1	Form of Common Stock Certificate of the registrant	10-Q	001-35706	4.1	May 4, 2017
4.2	Form of Warrant Issued to Investors in the September 2014 Offering	8-K	001-35706	4.1	September 22, 2014
4.3	Form of Warrant issued to Torreya Capital	S-4	333-214059	4.7	October 11, 2016
4.4	Apollo Common Stock Purchase Warrant issued to Athyrium Opportunities II Acquisition LP dated February 27, 2015	S-4	333-214059	4.8	October 11, 2016
4.5	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	S-4	333-214059	4.9	October 11, 2016
10.1#	2019 Bonus Plan	8-K	001-35706	10.1	March 5, 2019

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.2#	Offer Letter, dated November 19, 2014, between Apollo Endosurgery, Inc. and Bret Schwartzhoff	S-4	333-214059	10.18	October 11, 2018
10.3#	Gostout offer letter, dated December 9, 2016	10-K	001-35706	10.11	March 1, 2018
10.4#	John Molesphini Offer Letter	10-Q	001-35706	10.2	May 3, 2018
10.5#	Form of Change in Control Agreement	8-K	001-35706	10.1	May 30, 2018
10.6#	Second Amendment to Employment Agreement dated June 1, 2014 by and between the Company and Todd Newton	8-K	001-35706	10.2	May 30, 2018
10.7#	First Amendment to Employment Agreement dated March 2, 2015 by and between the Company and Stefanie Cavanaugh	8-K	001-35706	10.3	May 30, 2018
10.8#	Non-Employee Director Compensation Policy May 2018 amendment	10-Q	001-35706	10.5	August 8, 2018
10.9#	Form of Indemnification Agreement	10-Q	001-35706	10.6	August 8, 2018
10.10	Loan and Security Agreement, dated March 15, 2019, by and among the Company, Solar Capital, Ltd, the guarantors party thereto, and the lenders.				
10.11	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.	8-K	001-35706	10.1	March 8, 2017
10.12	First Amendment to Office Lease Agreement dated June 11, 2018, by and between the Company and DPF Cityview LP	10-Q	001-35706	10.4	August 8, 2018
10.13	Lease Agreement, dated August 7, 2014, between Apollo Endosurgery Costa Rica Sociedad de Responsabilidad Limitada and Zona Franca Coyol, S.A.	S-4	331-214059	10.20	October 11, 2016
10.14	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.	S-4	331-214059	10.21	November 14, 2016
10.15#	Apollo Endosurgery, Inc. 2017 Equity Incentive Plan	8-K	001-35706	10.1	June 13, 2017
10.16#	Forms of grant notice, stock option agreement and notice of exercise under the Apollo Endosurgery, Inc. 2017 Equity Incentive Plan	8-K	001-35706	10.2	June 13, 2017
10.17#	Form of restricted stock unit grant notice and award agreement under the Apollo Endosurgery, Inc. 2017 Equity Incentive Plan	8-K	001-35706	10.3	June 13, 2017

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.18#	Apollo Endosurgery, Inc. 2016 Equity Incentive Plan and forms of agreements relating thereto	S-4	333-214059	10.2	October 11, 2016
10.18#	Apollo Endosurgery, Inc. 2006 Stock Option Plan and forms of agreements relating thereto	S-4	333-214059	10.2	October 11, 2016
21.1	List of Subsidiaries	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.				
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				

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Management contract or compensation plan or arrangement

* Provided herewith.

++ Pursuant to Item 601(b)(2) of Regulation S-K, the schedules to the Purchase Agreement (identified therein) have been omitted from this report and will be furnished supplementally to the SEC upon request.

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 18, 2019 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 18, 2019.

Signature	Title	Date
/s/ Todd Newton Todd Newton	Chief Executive Officer and Director *(Principal Executive Officer)*	March 18, 2019
/s/ Stefanie Cavanaugh Stefanie Cavanaugh	Chief Financial Officer, Treasurer and Secretary *(Principal Financial Officer)*	March 18, 2019
/s/ Chrissy Citzler-Carr Chrissy Citzler-Carr	Controller *(Principal Accounting Officer)*	March 18, 2019
/s/ Richard J. Meelia Richard J. Meelia	Chairman of the Board	March 18, 2019
/s/ Rick Anderson Rick Anderson	Director	March 18, 2019
/s/ Matthew S. Crawford Matthew S. Crawford	Director	March 18, 2019
/s/ Julie Shimer Julie Shimer	Director	March 18, 2019
/s/ William D. McClellan, Jr. William D. McClellan, Jr.	Director	March 18, 2019

/s/ R. Kent McGaughy, Jr. R. Kent McGaughy, Jr.	Director	March 18, 2019
/s/ David Pacitti David Pacitti	Director	March 18, 2019
/s/ Bruce Robertson, PH.D. Bruce Robertson, Ph.D.	Director	March 18, 2019