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, 2020
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 (State or other jurisdiction of incorporation or organization)	**16-1630142** (I.R.S. Employer Identification No.)
1120 S. Capital of Texas Highway, Building 1, Suite #300, Austin, Texas (Address of principal executive offices)	78746 (Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of Exchange on which registered
Common Stock, $0.001 par value per share	APEN	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 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 $1.64 as reported on the Nasdaq Global Market on June 30, 2020 is $34,656,093.

As of January 31, 2021, there were 25,983,847 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 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on 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, 2020.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES

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

In this Annual Report on Form 10-K, references to U.S. dollars, 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.

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.

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 Endoscopy product portfolio consists of the OverStitch™ Endoscopic Suturing System, X-Tack™ Endoscopic HeliX Tacking System and Orbera® Intragastric Balloon.

Our products are used by gastroenterologists and bariatric surgeons in a variety of settings to treat multiple gastrointestinal ("GI") conditions including closure of acute perforations and chronic fistulas; tissue closure after the removal of abnormal lesions in the esophagus, stomach or colon (also known as endoscopic submucosal dissections, endoscopic mucosal resections and endoscopic full thickness resections); the treatment of swallowing disorders (peroral endoscopic myotomy, or "POEM"); esophageal stent fixation and obesity.

Corporate Background

Apollo was founded in 2005 and is 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. The assets acquired were the Lap-Band® System and related laparoscopic surgery accessories (the Surgical product line) and the Orbera Intragastric Balloon System. 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 capabilities.

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, which consisted of the Lap-Band® System and related laparoscopic accessories for $10.0 million in cash and future cash consideration of $7.0 million. 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, we ceased sales of ReShape's intragastric balloon product and have since withdrawn its premarket approval ("PMA").

"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.

Today, we have offices in the United Kingdom and Italy that oversee regional sales and distribution activities outside the U.S. and a manufacturing facility in Costa Rica. All other activities are managed and operated from our facilities in Austin, Texas.

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 VP, Legal and 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

Our Endoscopy products are designed to treat a variety of gastrointestinal conditions including closure of gastrointestinal defects, managing gastrointestinal complications and the treatment of obesity.

Interventional and therapeutic gastroenterology is a high growth area within medicine and our suturing products are used in both the upper and lower GI tract. Examples of upper GI applications include fistula closure, esophageal stent fixation, and tunnel closure for POEM. Fistulas are chronic or acute defects that can form between two sites in the GI tract, cavity or skin, often occurring as a result of abdominal surgery. Esophageal stents are often used as part of the treatment of esophageal blockage from cancers or benign scarring and fixation is designed to prevent the premature migration of the stent, especially in benign conditions, which is common and costly. 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, saving an average of $860 per patient by preventing repeat 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 the POEM procedure. Suturing of the tunnel following the esophageal muscle dissection and release during a POEM secures a quick and low profile solution for the patient.

In the lower GI tract, there are over 20 million colonoscopies performed annually in the United States alone. Cancer screening followed by the endoscopic resection of complex flat and large polyps can provide patients with an alternative to surgical resections. Delayed bleeding is a general risk of endoscopic resection and patients over the age of 50 are more often on anti-thrombotic (blood thinning) medications which carry a higher risk of bleeding. 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 93 million adults are obese or clinically obese with a body mass index ("BMI") of 30 or more. Worldwide, over 650 million people are considered obese. Traditional obesity intervention has been bariatric surgery (gastric bypass, sleeve gastrectomy and gastric banding), which is mostly performed laparoscopically. Today, based on U.S. population demographics and physician society reported bariatric procedure volumes, less than 1% of the population eligible for bariatric surgery elect to have a procedure each year. Based on published surveys, the eligible patient's primary detraction from bariatric surgery is fear of surgery in general, but more specifically fear associated with the invasive nature of bariatric surgery, permanent anatomical alteration, potential for non-permanent results and the post-operative severe complications that have been reported with bariatric surgery.

Apollo's Strategy

Our objective is to provide products that advance endoscopic solutions for a wide range of patient needs ranging from gastrointestinal defect and stent management to the treatment of obesity. Our "Endoscopy" products allow these solutions to be delivered endolumenally by an endoscopist using a flexible endoscope, thus providing patients with treatment options that remove or defer the need for traditional surgery.

The key elements of our strategy include:

- ***Support the adoption of our Endoscopy products*** - We accomplish this today through our medical education activities, field sales support, and clinical investments that support product adoption and use. Our most important clinical study currently is the Multi-center ESG Randomized Intervention Trial ("MERIT") study, which is expected to support future payor reimbursement decision-making for the endoscopic sleeve gastroplasty procedure for obesity.
- ***Continue to deliver innovative products and broaden the product portfolio*** - In December 2020, we received 510(k) clearance from the FDA for our X-Tack Endoscopic HeliX Tacking System. The X-Tack system expands the use of our suturing technology to a larger population of gastrointestinal procedures in the lower GI tract. In late 2018, we also introduced the OverStitch Sx Endoscopic Suturing System which enabled our full thickness suturing technology to be used with multiple manufacturers' single-channel flexible endoscopes, representing the majority of flexible endoscopes in use today. We intend to continue 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 in key international markets where we believe there is strong market demand for our products.

Apollo Products

Endoscopy

The Apollo Endoscopy products consist primarily of the OverStitch Endoscopic Suturing System, X-Tack Endoscopic HeliX Tacking System and the Intragastric Balloon System (most often branded as Orbera). For the year ended December 31, 2020, 64% of our total Endoscopy sales related to the OverStitch Endoscopic Suturing System and 36% related to the Orbera Intragastric Balloon System products. We received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for X-Tack in December 2020.

OverStitch Endoscopic Suturing System

The OverStitch and OverStitch Sx Endoscopic Suturing System ("ESS", "OverStitch", or "Sx") enables advanced endoscopic procedures from within the GI tract, or endolumenally, by allowing physicians to suture, especially full-thickness, and secure the approximation of tissue. OverStitch and OverStitch Sx are currently the only U.S. cleared flexible endoscopic suturing devices capable of full-thickness suturing of tissue. OverStitch is a single-use suturing device that is attached to a flexible endoscope. The flexible endoscope, with the OverStitch device attached, allows a physician to access a patient's upper and lower GI tract and accurately suture the tissue inside the GI tract for different clinical needs, including a range of defect repairs, esophageal stent fixation to prevent stent migration, and volumetric space reduction. The OverStitch Endoscopic Suturing System received 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 represent the majority of flexible endoscopes in hospitals and clinics around the world today.

Since its market introduction in 2008, over 60,000 OverStitch units have been sold for procedures worldwide.

We estimate that the majority of OverStitch uses, approximately 60%, were for bariatric procedures, the endoscopic sleeve gastroplasty and the revision of gastric bypass and sleeve gastrectomy anatomies to reintroduce weight loss. The other uses were for non-bariatric procedures, closure of various defects in the upper and lower GI tract and the fixation of stents in the esophagus.

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 remodel the stomach into a small diameter sleeve; similar to the goal of a surgical sleeve gastrectomy procedure but without the invasiveness and need for amputation of a significant portion of the patient's stomach. The advantages of the ESG as compared to a surgical sleeve gastrectomy include keeping the original structural and functional integrity of the stomach, lower procedure adverse events, reversibility, relative ease of revision or maintenance, reduced recovery time, avoidance of surgical incisions, 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 does not include a claim for weight-loss. The first ESG multi-center study was presented in May 2016 at Digestive Disease Week which was later updated as a 24-month follow-up study that was published in April 2017 in *Obesity Surgery*, the Journal of Metabolic Surgery and Allied Care.

Subsequently, there have been numerous published investigator-initiated ESG studies conducted by a variety of physicians around the world. In 2019, four separate meta-analyses were published that pooled the results from eight published ESG studies involving more than 1,700 patients. These four meta-analyses demonstrated between 15% to 20% total body weight loss measured at periods between 6 to 24 months and low adverse event rates.

In 2017, we entered into a clinical trial agreement with The Mayo Clinic in Rochester, Minnesota to undertake the 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 range of 30 to 45.

The MERIT-Trial was designed to enroll two hundred patients, stratified into three groups (Obesity, Obesity with hypertension, Obesity with diabetes). The trial has 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. The MERIT trial subsequently received an Investigational Device Exemption from the FDA in 2019. The primary outcomes for the first level procedures of the study are measured after a one-year follow-up period. The final enrolled patient completed their 12-month follow-up during the fourth quarter of 2020. Primary outcomes data is expected in mid-2021. Crossover patients and first level procedure recipients will continue to be followed through 2021 to measure the study's secondary outcomes. Final secondary outcomes data is expected to be available in the first half of 2022.

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 collect real-world evidence related to the safety and efficacy of a number of flexible endoscopic suturing-enabled procedures, including the revision of gastric bypass (known as an outlet revision) who have experienced weight regain after their initial bariatric surgery; the fixation of esophageal stents to prevent migration; and other suturing procedures currently in practice. The resulting data will be used to present the benefits of endoscopic suturing procedures relative to traditional therapies. Enrollment for the endoscopic revision of a gastric bypass procedure has concluded and the follow up will continue into the fourth quarter of 2021. Data from other endoscopic suturing procedures which have been collected in the registry has been analyzed and submitted to SAGES 2021 and DDW 2021.

During 2018, we established a European multi-center, longitudinal data repository for ESG and outlet revision procedures. This registry will collect outcomes across participating European centers related to procedure safety and effectiveness. 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 when OverStitch is used during various non-bariatric 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 payors in making informed decisions. Both registries are expected to 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.

X-Tack Endoscopic HeliX Tacking System

The X-Tack Endoscopic HeliX Tacking System (“X-Tack”) is a novel, through-the-scope, suture-based device designed specifically for closing and healing defects in the lower gastrointestinal tract. It is expected also to have application in the upper gastrointestinal tract. The X-Tack device enables physicians to easily address the challenges commonly encountered when closing large or irregularly shaped defects. The procedure involves suture-tethered HeliX Tacks, independently positioned into healthy tissue adjacent to a defect, then cinched to close the construct. X-Tack fulfills a long-expressed need for advanced closure devices to improve healing and address potential adverse events that can occur following standard colonic polypectomy

and endoscopic mucosal resection of complex polyps, such as delayed bleeding or perforation. X-Tack received FDA clearance on December 15, 2020 and the first clinical cases were successfully completed in January 2021.

The endoscopic removal of upper gastrointestinal and colorectal neoplasia has a 2% risk of perforation and 8% risk of delayed bleeding. These two serious adverse events often result in additional endoscopic as well as surgical interventions, hospitalizations, expanded health care costs, and significant distress for both patients and their physicians. The closure of resection sites has been reported to significantly reduce the incidence of these two adverse events and has generated growing advocacy among physician societies.

Today, closure of polyp resection sites can be accomplished by applying through-the-scope (TTS) metallic (hemostatic) clips, over-the-scope (OTSC) large metallic clips or suturing with our OverStitch device. However, clips have limited use for large or irregular shaped defects while suturing requires use of a gastroscope, limiting access to the full length of the colon and also requires removal of the scope from the patient in order to mount the suturing device.

The X-Tack closure device is intended to resolve the limitations of TTS clips, OTSC and endoscopic suturing by offering functionality through the working channel of any standard gastroscope or colonoscope with precise HeliX Tack placement and tight closure of sites of varying shapes and sizes.

Each X-Tack device enables physicians to place up to four individual HeliX Tacks into healthy tissue adjacent to a defect using a novel Persian drill handle. The HeliX Tack design includes barbs on the coil for enhanced tack fixation.

Each HeliX Tack has an eyelet tethering it to a suture. Pulling tension on the suture approximates the HeliX Tacks and, in turn, closes the tissue defect. A suture cinch is then used as the final step to secure the suture in place. Because it offers multiple points of fixation, we believe the X-Tack enhances a physician’s ability to overcome challenges of closing large or irregularly shaped defects.

Orbera Intragastric Balloon System

The intragastric balloon system ("IGB", the "Orbera System" or "Orbera") is currently marketed under three brands depending on geography: the Orbera Intragastric Balloon System, the BIB, and the Orbera365 Managed Weight Loss System ("Orbera365"). Our IGB is a non-surgical alternative for interventional weight loss. Orbera is the global market leader among intragastric balloons and is available in over 75 countries and more than 300,000 units have been sold worldwide. Our IGB is a single silicone balloon that is filled with saline after its endoscopic 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 content emptying which assists the patient in losing weight. Placement of the balloon is temporary and at the end of its indwell time it is removed endoscopically, typically, under conscious sedation.

Outside the U.S., the BIB was CE marked in May 1997 and the Orbera365 was CE marked in August 2017. In the U.S., Orbera was approved by the FDA in August 2015.

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 patients with a BMI greater than or equal to 27, and depending on the specific product 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 general surgery in order to lose weight, reduce their surgical risk and improve recovery time.

Today, IGBs are frequently used for aesthetic weight loss purposes and because of this, the IGB procedure is typically not covered by insurance and is paid for directly by the patient. While aesthetics is a significant market today for Orbera; we believe that IGB use for medical purposes is a potentially larger opportunity.

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 obesity. 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 any individual 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%.

In the January 2021 Clinical Gastroenterology and Hepatology Journal, 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; and 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 development strategy is to further establish the medical relevancy of Orbera in areas of unmet medical need such as fatty liver disease and increase clinician awareness.

As part of the FDA approval of Orbera, we were required to conduct a post-approval clinical study. The Orbera Post-Approval Study (PAS) was 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 PAS completed enrollment in September 2018 with 281 patients treated with Orbera from 11 U.S. clinical study sites. The study's primary endpoint was a serious adverse event rate of less than 15% and secondary endpoint was total body weight loss of at least 7.5% at the time of Orbera's removal. All study endpoints were met and our PAS obligation is complete.

As part of the CE mark approval for Orbera 365, we committed to perform a post-approval clinical study. The Orbera 365 CE post approval study will enroll 100 patients at four to five centers in different European countries who will be followed for 24 months. The start of this study was delayed by the COVID-19 pandemic. However, the first clinical site began enrollment in February 2021.

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 well as the physician training material to provide 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 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. In the period from January 1, 2008 through March 30, 2020, there were 31 reported deaths of patients while they had an Orbera which is an incident rate of less than 0.02% based on the more than 165,000 Orbera balloons distributed during that same time period.

In April 2020, the FDA issued a fourth update to healthcare providers upon the successful completion of the Orbera PAS. The FDA advised physicians to consider the PAS results and emphasized that patients should be instructed to recognize the symptoms of potentially life-threatening conditions.

In the U.S., we also offer Apollo Care, a professional nutritionist support service for Orbera patients and non-Orbera patients who are trying to lose weight.

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 continued to distribute the products in markets outside the U.S. for up to 12 months and continued to manufacture the Surgical product line for up to two years. As of December 31, 2020, Apollo's transition, distribution and manufacturing obligations are complete.

Competition

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 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.

We face competition from other interventional therapies for the treatment of obesity. These other 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 alters the stomach although weight regain after a few years is common. Gastric bypass surgery refers to a surgical procedure in which the stomach is divided into a small upper pouch excluding the much larger lower residual stomach 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 and ability to influence physicians and policy makers than we do.

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., Australia and certain countries in Europe. In addition, we sell products to third party distributors in certain markets where we have regulatory clearance for our products but do not have employees. In total, our products are offered in over 75 countries.

Obesity procedures that utilize our Endoscopy products are often cash pay procedures which means the patient must pay for the procedures out of pocket, although there are exceptions. Revisions of prior bariatric surgery using endoscopic suturing are routinely receiving reimbursement from select payors for patients treated at specific hospitals in the U.S. Some of these same hospitals have also established relationships with select payors for the reimbursement of ESG procedures. Other times, reimbursement occurs on a case-by-case basis following a review of the patient's specific situation. Medical procedures that utilize endoscopic suturing products in the treatment of GI complications generally receive reimbursement, but coverage can vary by country, state and procedure performed. IGB treatment is reimbursed in some countries for patients who meet certain criteria.

Manufacturing and Product Supply

We operate a manufacturing facility in the Coyol Free Trade Zone in Alajuela, Costa Rica that performs assembly of select components of the OverStitch system, and final assembly of our new X-Tack System and IGB products. We also have the ability to manufacture select product components and sub-assemblies at our engineering facility in Austin, Texas. We manage all aspects of product supply through our operations team based in Austin, Texas and in our Costa Rica facility. In addition, we rely on several third-party suppliers to provide other OverStitch system components. We have identified several gross margin improvement projects intended to lower our product costs and improve capacity utilization of our manufacturing facility over the next three years.

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").

During 2020, we completed our obligation to manufacture the LapBand product pursuant to the terms of the December 2018 sale of our Surgical product line.

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.

As of December 31, 2020, we own over 105 U.S. patents and 165 foreign patents. Our U.S. patents have expiration dates ranging from 2021 to 2037 and our foreign patents have expiration dates ranging from 2022 to 2034 subject to the payment of the requisite renewal fees. We also own 20 pending U.S. patent applications and 18 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.

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 the 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 the FTE Group and Olympus Corporation under the Joint Research Agreement and retained a license granted by the FTE Group to Olympus Corporation to the inventions and related patents developed by the 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 20 U.S. and 13 foreign issued patents and 4 pending U.S. and 6 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 $0.75 million.

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. 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 balloon is a Class III device. The OverStitch and the X-Tack devices are Class II devices. 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 or a specific indication for use. 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 study or 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;
- unique device identifier and 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.

Anti-Kickback Statute

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.

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.

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.

Transparency Reporting

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 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, certain non-physician healthcare professionals 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. In addition to reporting, some states such as Massachusetts and Vermont impose an outright ban on certain gifts to physicians. Failure to report may result in civil or criminal fines and/or penalties.

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 Apollo Endosurgery’s devices comply with the Medical Device Directive. The Medical Device Directive is being replaced

by the Regulation 2017/745 on Medical Devices, or the MDR, effective May 26, 2021. The MDR contains additional requirements beyond those required to comply with the directives they replace, and often require the submission of more detailed data to support approval. Notably, the requirements for clinical evidence and postmarket surveillance are more rigorous. All affected companies must comply with the MDR by May 26, 2021, specifically the transition requirements dealing with registration, post-market surveillance, market surveillance and vigilance reporting. To support compliance under the MDR, we intend to obtain additional clinical data for Orbera 365. We are in the process of determining the regulatory pathway, including determining requisite clinical evidence requirements, for pursuing a CE mark for the X-Tack product.

In order to place a medical device in the European market, a CE mark must be obtained. To obtain a CE Mark, medical devices must meet certain minimum standards of safety and quality and, depending on which class of medical device they fall into, as such classes are defined in the MDR for the new regime, they may need to undergo an appropriate conformity assessment procedure conducted by a Notified Body. A Notified Body will, amongst other things, assess the quality management systems of the manufacturer and verify that the subject device conform to the requirements set out in the relevant legislation. Once the appropriate conformity assessment procedure for the medical device has been completed, a declaration of conformity will be created and the manufacturer will affix the CE mark to the device. The device can then be marketed throughout the European Economic Area (being the Member States of the EU, together with Norway, Iceland and Liechtenstein). Notified bodies may perform surveillance and unannounced audits at the manufacturer and critical suppliers with respect to the devices covered by the certificates issued by them. If non-conformities raised during the audits are not remedied in a timely manner by the manufacturer, the notified body may (partially or wholly) suspend or withdraw the certificate concerned.

In the EU, we are also required to maintain certain ISO certifications in order to sell products and are 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. Additionally, we are 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.

Other Regulations

We are 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.

Employees

As of December 31, 2020, we had a total of 158 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

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- Our business has been and likely will continue to be adversely affected by the ongoing COVID-19 pandemic.
- We have incurred significant operating losses since inception and may not be able to achieve profitability.
- Our long-term growth depends on our ability to successfully develop the market for our Endoscopy products.
- A weakening of U.S. and international economic conditions may reduce consumer demand for our products, causing our sales and profitability to suffer.
- Our future growth depends on physician adoption and recommendation of procedures utilizing our products.
- Our future growth depends on patient awareness of and demand for procedures that use our 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.
- We are dependent on certain suppliers, vendors and manufacturers, and supply or service disruptions could materially adversely affect our business and future growth.
- 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.
- 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.
- 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.
- If our products contribute to a serious injury or death, or malfunction in certain ways, we may be subject to liability claims and will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- If we or our suppliers fail to comply with local, state or federal laws, rules or regulations, or 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.
- Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.
- 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.
- 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.
- 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 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.
- Our business and operations would suffer in the event of system failures, security breaches or cyber-attacks.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section titled "Risk Factors" in Part II, Item 1A. and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also harm our business, financial condition, results of operations and future growth prospects.

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

Our business has been and likely will continue to be adversely affected by the ongoing COVID-19 pandemic.

The global spread of the COVID-19 pandemic and measures introduced by local, state and federal governments to contain the virus and mitigate its public health effects have significantly impacted the global economy. Given the uncertainty around the duration and extent of the COVID-19 pandemic, we expect the evolving COVID-19 pandemic to continue to adversely impact our business, results of operations, and financial condition and liquidity, but cannot accurately predict at this time the extent of the future potential impact on our business, results of operations, financial condition and liquidity.

Government authorities around the world have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions, and the perception that such orders or restrictions could occur or continue, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects. We continue to monitor our operations and government mandates and may elect or be required to temporarily close our offices to protect our employees, and limit our access to customers and limit customer use of our products as they are required to prioritize resources to address the public healthcare needs arising from the COVID-19 pandemic. The disruptions to our activities and operations have negatively impacted and will continue to negatively impact our business, operating results and financial condition. There is a risk that government actions will not be effective at containing COVID-19, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a devastating negative impact on the world economy at large, in which case the risks to our sales, operating results and financial condition described herein would be elevated significantly.

We are unable to predict the duration of COVID-19's impact on our business. The widespread pandemic has resulted, and may continue to result, in significant disruption of global financial markets, reducing our ability to access capital, which would negatively affect our liquidity. In addition, if the COVID-19 pandemic results in a prolonged economic recession, it would materially affect our sales and our ability to continue as a going concern. A prolonged economic contraction or recession may also result in employer layoffs of their employees in markets where we conduct business, which could result in lower demand for procedures that use our products. In particular, as certain of the procedures that use our products have limited reimbursement and require patients to pay for the procedures in whole or in part, reductions in employment in our target markets have reduced, and may continue to reduce, utilization and sales of our products.

Restrictions on the ability to travel, social distancing policies, orders and restriction, including those described above, and recommendations and fears of COVID-19 spreading within medical centers have caused and may continue to cause both patients and providers to delay or cancel procedures that use our devices, which has harmed our sales, results of operations and financial condition. Even as governmental restrictions begin to be relaxed or lifted and various jurisdictions gradually reopen, we are unable to accurately predict when these policies, orders and restrictions will be fully relaxed or lifted or for how long they will remain relaxed or lifted. There can be no assurances that patients or providers will restart procedures that use our devices upon the lifting, relaxation or termination of these policies, orders and restrictions, particularly if there remains any continued community outbreak of COVID-19. Our distributors have deferred and may continue to defer their purchases of our products due to the ongoing COVID-19 pandemic. Health systems and other healthcare providers in our markets that provide procedures that use our products have also suffered financially and operationally and may not be able to return to pre-pandemic levels of operations following a slowdown in the pandemic, which would harm the recovery of our sales growth as well. Further, quarantines or government reaction or shutdowns for COVID-19 could disrupt our supply chain. Travel and import restrictions may also disrupt our ability to manufacture or distribute our devices. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products would restrict our ability to manufacture and ship products and harm our business, financial condition and results of operations. Our key personnel and

other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce, including cost saving measures we have instituted to date, could reduce the efficiency of our operations or prove insufficient. We may delay or reduce certain capital spending and related projects until the travel and logistical impacts of COVID-19 are lifted, which will delay the completion of such projects.

In addition, the conduct of clinical trials required to maintain the regulatory status of certain of our products have been and may in the future be affected by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 outbreak and changing standards of care. For example, enrollment for our Orbera365 CE post approval study was delayed due to the pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. COVID-19 restrictions may also delay the timing of regulatory reviews and approvals as regulators in various jurisdictions may have reduced staffing and capability. Due to capital resource constraints resulting from our reduced sales levels, we have prioritized key growth and operational projects over others, which may harm our future growth strategies, sales, business and results of operations.

Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers which is currently restricted as many hospitals continue to restrict access to essential personnel only. These restrictions have harmed our sales and marketing efforts, and continued restrictions would have a negative impact on our sales and results of operations. An increase of COVID-19-related hospital admissions may overload hospitals with unexpected patients, thereby delaying further procedures that use our devices but that are deemed elective by the hospital. Limited supplies of personal protective equipment and COVID-19 testing supplies may further reduce onsite access for our personnel and may delay the lifting of restrictions on elective procedures, including those that use our products. In addition, in 2020, we eliminated certain employee positions and made reductions to salary and work hours and may in the future take similar actions which may negatively impact our workforce and our business.

The global outbreak of COVID-19 continues to be volatile and rapidly evolving causing our business to be highly uncertain and unpredictable. We do not yet know the full extent of any impacts on our future business or the global economy as a whole. However, these effects have harmed our business, financial condition and results of operations in the near term and could have a material and negative impact on our future operations, sales and ability to continue as a going concern.

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, 2020 and 2019, we had net losses of $22.6 million and $27.4 million, respectively. As of December 31, 2020, we had an accumulated deficit of $272.8 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 Endoscopy products.

It is important to our business that we continue to build a market for therapeutic endoscopy procedures within the gastroenterology and bariatric communities. Our Endoscopy products offer non-surgical and less-invasive solutions and technology that enable new options for physicians treating their patients who suffer from a variety of gastrointestinal conditions, including 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 Endoscopy 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 physicians, payors and patients and educate them on the benefits of Endoscopy procedures;
- achieve adoption of procedures for the use of our products in a timely manner, including for procedures that may not receive third party insurance coverage or reimbursement;

- 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, product enhancements or product indications;
- market 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 our sales and marketing team to effectively support our market development efforts.

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.

A weakening of 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, including the economic contraction resulting in part from the COVID-19 pandemic, may negatively affect our revenues and operating results. Our Endoscopy 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, disasters or disease outbreaks, such as the COVID-19 pandemic, 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 others, such as 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 or proficiency 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.

Many of the procedures that utilize our products are 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 where allowed by local law and consistent with our product regulatory indications 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, experimental, or otherwise 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 patient outcomes and 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;
- previous long-term failure with other weight loss programs;
- reluctance of a prospective patient to commit to long-term lifestyle changes;
- out of pocket cost for an elective procedure; and
- alternative treatments that are perceived to be more effective or less expensive.

We may not be able to successfully introduce new products or indications 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, including obtaining regulatory approval for new indications for use, delays in closing acquisition transactions, or delays in receiving necessary approval from a hospital or healthcare facility to introduce a new product or procedure. The ongoing COVID-19 pandemic may contribute to such delays, particularly as research and development may be narrowed to key projects and activities. 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 product warnings, contraindications or other information provided in training materials or product labeling, fail to obtain adequate training, or fail to inform patients of the risks associated with procedures that utilize our products, potentially leading to injury and an increased risk of product liability claims. 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. Some of our products have cleared indications for general use and the FDA or foreign regulatory bodies may request clinical evidence to support a specific intended use, or determine that promotional activity, educational materials or training relating to specific intended use constitutes off-label promotion. 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.

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

If the supply of materials from our suppliers or provision of services from our vendors were to be interrupted or if we experience delays or interruptions from our manufacturers, including due to the COVID-19 pandemic, 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. If our suppliers experience unanticipated quality issues or fail to supply components that meet design specifications, or if our contract sterilizers experience delays or shutdowns, we may experience manufacturing delays or product quality issues that may erode customer confidence in our products and negatively affect our sales. As ESS product sales increase, we have experienced times of temporary supply and vendor disruption for a variety of reasons and this has caused delays in our fulfillment of customer orders. For example, we have experienced production and inventory shortages for OverStitch as a result of supply shortages from component suppliers from time to time. Continued interruptions or shortages in these inputs or services, or future unexpected interruptions and shortages, could harm our business, financial condition and results of operations. 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, or receive services, from any of our suppliers, vendors 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. We may also face disputes with our current or previous suppliers and vendors. In any of these cases, we could face a delay of several months to identify and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier or vendor transition plans. In addition, the failure of our third-party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products.

Manufacturing of our products requires capital equipment and a well-trained workforce. The sourcing of new manufacturing or supply capacity can require 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 United States, 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, changes in the market or demand for our products, the launch of new products with no sales history, as well as the ongoing COVID-19 pandemic, 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 or we may be unable to efficiently transfer divested assets.

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. In the future, should we divest assets or portions of our business, we will need to implement financial and managerial controls and procedures to efficiently manage the divestiture of such assets and the transition of such business to an acquirer. Failure to successfully manage the integration of newly acquired assets or business or to efficiently transition divested assets to an acquirer could adversely affect our business.

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 provided certain transition services, including manufacturing support, to ReShape for our divested Surgical Product line through December 2020, 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 patients and their family members, health care providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves 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.

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 expenses will increase by the same amount. 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.

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

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, including changes in our management team, likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business. For example, we recently announced a planned CEO change to be effective in early March 2021. The failure to successfully execute this leadership transition and retain key employees could negatively impact our business and results of operations.

In order to manage the impact of COVID-19, we have implemented cost reduction programs including furloughs, salary reductions and work hour reductions that have impacted all employees. The introduction of these cost reduction measures increases the likelihood the employees may voluntarily terminate employment. The impact of COVID-19 on our business has harmed our stock price and, as a result, reduced the retention value of our employee's stock-based compensation. Our future success will depend largely on our ability maintain our workforce until business conditions improve such that we can return employees to previous employment status, salary, and work hour levels. However, we cannot assure you we will be able to maintain our workforce or to replace any departing personnel on favorable or commercially reasonable terms, if at all. Loss of personnel may negatively impact our ability to support business activities in the future if and when market activities return to pre-COVID-19 levels. The cost reduction programs were implemented in multiple foreign and domestic jurisdictions and may also expose us to contract or other disputes with impacted employees that may be detrimental to our business.

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. In addition, we may change our sales approach in certain markets from direct sales to healthcare providers to sales to distributors who then resell our products. If we were to change our sales approach in a given market, our product sales price in the affected market would be reduced which would lower our revenue and gross margin and the resulting reduction in our operating expense may not be sufficient to offset this reduction in our gross margin.

We may be unable to collect future payments from ReShape related to the divestiture of our Surgical product line.

As part of the sale of the Surgical product line to ReShape, we are owed a future payment of $3.0 million in December 2021. Any failure of ReShape to timely pay the remaining future payment will adversely affect our business and financial position.

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.

If our internal controls over financial reporting are found to be insufficient, our independent registered public accounting firm, which audits our financial statements, may issue an adverse opinion on the effectiveness of internal control over financial reporting.

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. In the event that a material weakness is identified, we cannot assure you that we will be able to identify and implement measures that will be sufficient to remediate any such material weakness or that future material weaknesses will not occur.

If we fail to remediate an identified 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 exit from the EU could lead to increased market access issues, legal issues, and economic conditions which could adversely impact our business.

Following the result of a referendum in 2016, the U.K. left the E.U. on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the E.U., the U.K. was subject to a transition period until December 31, 2020, or the Transition Period, during which E.U. rules continued to apply. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

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 based in the U.K., which will no longer have standing in the EU as a notified body. We subsequently transferred our notified body to BSI in the Netherlands which required that we change product labeling and packaging for all our products and may have 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 transaction or translation risks. 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.

While the Trade and Cooperation Agreement provides for the tariff-free trade of certain products between the U.K. and the E.U., there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the U.K. diverge from the E.U. from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could harm our business and results of operations. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. There may continue to be economic uncertainty surrounding the consequences of Brexit which could negatively impact our financial condition, results of operations and cash flows.

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. 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. Of our products, Orbera is a class III product and has been approved through the FDA's PMA process and our suture-based products are class II products and have been cleared through the 510(k) process.

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. In addition, the FDA may deem certain uses of an existing cleared general use device, such as OverStitch, to be a high risk use and may require the submission of a PMA or a De Novo 510(k) prior to expanding the device's indication for such additional use. 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. 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. The De Novo 510(k) process is also more costly, lengthy and uncertain than the 510(k) clearance process. 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.

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 significant penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, 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 significant 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 federal false claims laws, including 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 covered healthcare providers, health plans and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors 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 healthcare providers, including 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 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 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. 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 we 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.

Patients in the U.S. and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their health care treatment. Accordingly, market acceptance of our products is dependent on the extent to which third-party coverage and reimbursement is available from third-party payors, which can differ significantly from payor to payor and may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and thereafter maintain sufficient third-party coverage and reimbursement for our products, the commercial success of our products may be limited and our financial condition and results of operations may be materially and adversely affected.

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.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action, particularly as a result of the new U.S. presidential administration.

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 and other regulatory authorities outside the United States require 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, a given regulatory authority, such as the FDA, can review a manufacturer's decision and may disagree and 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 a regulatory authority 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, re-introduce pre-modified product back into the specific market, and harm our operating results. In addition, a regulatory authority in one country may not agree with the conclusion of a regulatory authority of another country. In these circumstances, we may be subject to significant enforcement actions.

If we determine 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 we 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 sales.

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 to 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.

Expanding the indications of our marketed products may require new 510(k) or De Novo clearances or PMA approvals.

Expanding the indications for our products will require new regulatory approvals or clearances, including 510(k) or De Novo clearances or PMA approvals. We have current products such as OverStitch with clearance as a general use device but no procedure-specific indications for use. In the event that we pursue the approval of expanded indications for a product, the FDA may require a separate 510(k) or De Novo submission or may deem the desired indication for use to be of high enough risk to require a PMA submission. For example, the investigators conducting the MERIT trial sought and received an Investigational Device Exemption following communication from the FDA which indicated that the FDA considered the ESG procedure for weight loss to be a high risk use. Obtaining clearances and approvals for expanded uses can be a time consuming and costly process and could adversely affect our ability to market our products or delay efforts to obtain reimbursement coverage from payors.

If our products contribute to a serious injury or death, 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 serious injury or death or has malfunctioned in a way that would likely cause or contribute to serious injury or death 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 or for which we cannot confirm whether or not our product caused or contributed to the adverse event 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. In April 2020, the FDA issued a new update to Health Care Providers following the completion of the Orbera post approval study, which may further subject us to adverse publicity and harm our business. The FDA has full authority to issue these updates or letters and to choose to include or exclude key context and facts based solely on their regulatory discretion and may from time to time issue new letters or updates in the future. These types of letters, and updates to existing letters, can be reviewed by regulatory authorities worldwide, who may then require formal Field Safety Notices to communicate labeling updates to customers. Making these notifications requires significant time and resources, distract from other projects, and may harm our reputation.

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., Costa Rica, Australia and various European countries and our products are approved for sale in over 75 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 and differing reimbursement regimes 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.

We may, under our own initiative, recall a product if any material deficiency in a device is found. In addition, the FDA and similar foreign governmental authorities can 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 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. 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 voluntary 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.

Moreover, organizational 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 and was scheduled to become effective on May 26, 2020. On April 17, 2020, the European Parliament approved the delay of the effectiveness of MDR 2017 until May 26, 2021. MDR 2017 repeals and replaces the EU Medical Devices Directive ("MDD") and changes certain obligations of medical device manufacturers with product in the EU and subjects higher risk medical devices to additional scrutiny during the conformity assessment process. The new regulations will among other things:

- add new rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on 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 (EUDAMED) 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;
- modify or increase clinical evidence requirements necessary to maintain existing CE marks

Accordingly, we are required to update our quality system to conform to the requirements of MDR 2017 by May 2021. However, only one of the six EUDAMED modules is fully operational at this time, with the European Commission stating that the EUDAMED database is now not expected to be fully operational until May 2022. As such, the quality system updates required for us to comply with MDR 2017 cannot be fully operable by May 2021.

Additionally, existing regulatory filings must be reviewed again by Notified Bodies as part of the transition of CE Mark certificates from the current MDD to the new MDR 2017 requirements. Industry-wide, Notified Bodies are experiencing much longer review times on these files and this creates additional uncertainty over the timely transition to MDR 2017. Our CE certificates under MDD are valid through November 2022 and we aim to have our MDR 2017 documentation available for Notified Body review by the end of 2021. But there are no assurances that our Notified Body will be able to conduct a timely review of this documentation nor that they will conclude our documentation is sufficient. Depending on the timing of the

Notified Body review, we may not be able to supplement or correct our documentation prior to the expiration of our CE certificates.

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 the MDR 2017. Our failure to continue to comply with applicable foreign regulatory requirements, including meeting additional clinical evidence requirements and complying with regulatory requirements 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.

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. A number of countries outside of Europe consider the CE Mark status of a medical device when making their decisions to grant a license for said product. In many countries, we rely significantly on independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products.

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 or obtain reimbursement 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 or CE Mark post-approval studies required to keep our market approvals in good standing as well as clinical studies designed to obtain the clinical data necessary to garner reimbursement from private and government payors. 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, fail to obtain desired regulatory approvals or fail to obtain reimbursement for our products or the procedures that use our products, 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 may 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 often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

Furthermore, we do not have patent rights in certain foreign countries in which a market may exist in the future, and the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the 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"). We used $22.4 million of the proceeds to repay the existing senior secured credit facility. In April, July and December 2020, we entered into amendments to this agreement to allow us to enter into a loan under PPP, provide revenue covenant relief for the remainder of 2020 due to the impact of COVID-19, decrease the minimum liquidity requirement from $20.0 million to $12.5 million and extend the maturity date and interest-only payment period. 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 requirements and pay interest and principal when due. Furthermore, under the Solar Debt Facility our interest rate is tied to LIBOR. We do not hedge this variable rate exposure to LIBOR and in the event of an increase in the LIBOR rate, we will be required to pay greater interest expenses, which may be material and have an adverse effect on our net loss 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 our 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.

In April 2020, we were granted a loan of $2.8 million under the PPP of the CARES Act, or the PPP Loan, all or a portion of which may be forgiven dependent on our use of proceeds. The PPP Loan matures on February 27, 2023 and bears interest at a rate of 1.0% per annum. Commencing September 27, 2021, we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by February 27, 2023 any principal amount outstanding on the PPP Loan as of August 24, 2021. All or a portion of the PPP Loan may be forgiven by the SBA. In December 2020, we applied for forgiveness of the full amount of the loan from the SBA. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan.

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.

We may need to raise substantial additional capital to fund our operations, including:

- 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 or enforce, in litigation or otherwise, our patent and other intellectual property rights and any claims that we infringe on third-party patents or 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.

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, defending and enforcing our patent or other intellectual property rights, in litigation or otherwise and 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. In particular, the impact of the COVID-19 pandemic is highly uncertain as to the availability of additional funding and the underlying terms of such funding. 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, including due to the COVID-19 pandemic;

- 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 and convertible securities 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 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 also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, 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 require significant legal and financial compliance costs and 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 amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are 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.

The conversion or exercise of some or all of our outstanding convertible debt and pre-funded warrants, respectively, may also dilute the ownership interests of existing stockholders. Any sales in the public market of any shares of our common stock issuable upon such conversion or exercise, as applicable, including pursuant to our registration statements on Form S-3 with respect to shares underlying these convertible securities, could negatively impact prevailing market prices of our common stock. In addition, the anticipated conversion of the convertible debt or exercise of the pre-funded warrants into shares of our common stock or a combination of cash and shares of our common stock could depress the price of our common stock.

We also expect that additional capital may be needed in the future to fund our operations. To raise capital, we may sell common stock, preferred stock, convertible securities or such 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 limited public float and trading volume for our common stock may have an adverse impact and cause significant fluctuation of market price.

As of December 31, 2020, the majority of the outstanding shares of our common stock was held by a relatively small number of stockholders. In addition, 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.

Our amended and restated certificate of incorporation and amended and restated bylaws designate the Court of Chancery of the State of Delaware and, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders, which will restrict our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws each provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, or other employee of the corporation to the corporation or the corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine.

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our stockholders cannot waive compliance with the federal securities laws and

the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find the exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

General Risk Factors

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 on 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. Information technology systems are also critical to enabling employees to work remotely. 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 and our various third-party providers make investments and take measures to protect our systems and data, but 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 violate or subject us to remediation and liability under federal, state and foreign laws that protect personal data, resulting in increased costs or loss of revenue.

In addition, future interpretations and applications of consumer and data protection laws in the U.S., Europe and elsewhere, such as the EU General Data Protection Regulation ("GDPR") and the California Consumer Privacy Act (the "CCPA"), may be inconsistent with our data practices. If so, this could result in government-imposed fines, orders or guidance requiring that we change our data practices, which could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

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 September 30, 2028. Additionally, we have a research and development facility in Austin, Texas and sales and marketing offices in Italy 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.

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 January 31, 2021, there were approximately 103 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 as defined by Rule 12b-2 of the Exchange Act.

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™, X-Tack™, 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 therapeutic endoscopy. We develop and distribute devices that are used by gastroenterologists and surgeons for a variety of procedures related to closing gastrointestinal defects and managing surgical or endoscopic adverse events or bariatric (weight loss) intervention.

Our core products are the OverStitch Endoscopic Suturing System ("ESS") and Intragastric Balloon ("IGB") (most often branded as Orbera). In December 2020, we received 510(k) approval for the X-Tack Endoscopic HeliX Tacking System. In December 2018, we divested our Surgical product line, which consisted of the Lap-Band® System and related laparoscopic accessories.

We have offices in the United Kingdom and Italy that oversee commercial activities outside the U.S. ("OUS") and a products manufacturing facility in Costa Rica. All other activities are managed and operated from facilities in Austin, Texas.

Impact of COVID-19 on Our Business

Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted our business, financial condition, and results of operations. The United States and other countries implemented a variety of public health interventions to reduce the risk of disease transmission and conserve healthcare resources for addressing the community health needs of COVID-19. This resulted in an unprecedented decline in global healthcare resources available for procedures that use our products. Following sales growth in the months of January and February 2020 that were consistent with management's pre-COVID-19 expectations, our sales results in the months of March and April declined commensurate with the global decline in elective procedures and reduced patient access to treatments by shelter in place and social distancing rules, which resulted in cancellation or postponement of procedures that use our products. Beginning in May 2020, our sales began to recover primarily as certain public health interventions implemented by various countries to reduce COVID-19 transmission risks were eased and procedures that use our products increased. As a result, our sales for the six months ended December 31, 2020 have exceeded those in the same period of 2019. Demand for our products and our business showed recovery in the third and fourth quarters of 2020 as hospitals began to accept patients for elective procedures though there can be no assurance that this recovery will continue.

The COVID-19 pandemic remains active and continues to represent high uncertainty concerning our sales outlook and risk to our business operations. Business challenges and periodic disruption resulting from COVID-19 will likely continue for the duration of the pandemic, which is uncertain. We cannot assure you that our recent recovery during the second half of 2020 will be indicative of future results or that we will not experience future sales or business disruptions due to COVID-19, which could be significant. See Item 1A. Risk Factors—Risks Related to Our Business—Our business will be adversely affected by the effects of the recent COVID-19 outbreak.

Due to the business disruptions stemming directly from the COVID-19 pandemic, we took several actions to preserve our liquidity during 2020. In March and April 2020, we reduced 2019 cash bonuses, implemented reductions in compensation across our workforce including a $100,000 salary cap for all employees, furloughed 57 U.S. employees and reduced the employment arrangements of an additional 34 employees outside the United States. In September, the employee furlough program was discontinued and 35 employees were not recalled. The annual compensation costs associated with these positions were approximately $5.0 million. Finally, in November 2020, we completed a salary restoration plan to restore employee salaries to pre-reduction levels.

On April 27, 2020, the Company was granted a loan of $2.8 million under the Small Business Administration's ("SBA") Paycheck Protection Program ("PPP") established under the CARES Act. The PPP loan matures on February 27, 2023 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on September 27, 2021. In December 2020, we applied for forgiveness for the full amount of the loan from the SBA. We will continue to include this PPP loan within our long-term debt until we receive confirmation of forgiveness from the SBA.

Divestiture of the Surgical Product Line

In December 2018, we entered into an Asset Purchase Agreement ("Purchase Agreement") and sold our Surgical product line to ReShape Lifesciences Inc. ("ReShape"). Our goal with this transaction was to increase our focus on our Endoscopy products and monetize a non-strategic asset.

ReShape agreed to pay $17.0 million in cash, of which the last $3.0 million is due to us in December 2021.

Upon completion of the ReShape transaction, the parties entered into a transition services agreement, supply agreement and distribution agreement. Apollo's transition, distribution, and manufacturing services obligations were completed as of December 31, 2020.

Financial Operations Overview

Revenues

Our principal source of revenues are sales of our Endoscopy 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 the continuing COVID-19 pandemic, 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.

Under the ReShape distribution agreement, we agreed to sell Surgical products to customers OUS up to one year. Product sales in 2019 include sales from these serviced markets.

Other revenue includes amounts recognized for our digital aftercare support program, transition and manufacturing services we provided to ReShape and freight charged to customers.

Cost of Sales

Our ESS products, representing the majority of our Endoscopy product sales, have historically been purchased from third-party manufacturers, and our cost of sales for these products has consisted of the actual purchase price from these manufacturers plus an allocation of our internal manufacturing overhead cost. Cost of sales for products we manufacture include raw materials, labor, and manufacturing overhead. 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 royalties, shipping, excess and obsolete inventory charges, inspection and related costs incurred in making our products available for sale or use. In periods of reduced production volume, unabsorbed manufacturing overhead costs are charged to expense when incurred.

Our gross margin comparability between periods has been impacted by the shift in our revenue mix from Surgical to Endoscopy products. Demand for our divested Surgical products historically were declining but Surgical product sales realized a higher gross margin compared to our Endoscopy products, which have been growing in demand. In addition, manufacturing overhead as a percentage of revenue between periods can fluctuate as a result of manufacturing rates and the degree to which manufacturing overhead is allocated to production during the period. We expect to continue to improve gross margins as we complete certain identified 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 sales, marketing and medical education. In addition, our sales and marketing expense includes costs associated with physician training, industry events, advertising 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 resources. General and administrative expense also includes facility costs, insurance, audit fees, legal fees, bad debt expense and costs to develop and maintain 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, 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 depending on the activity associated with our various product development and clinical obligations.

Amortization of Intangible Assets

Definite-lived intangible assets primarily consist 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, valuation of intangible assets, long-lived assets and goodwill, going concern assessment, allowance for doubtful accounts, and inventory valuation. 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 OUS markets. 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.

In connection with the December 2018 sale of the Surgical product line, we entered into a transition services agreement, supply agreement and distribution agreement which obligated us to provide specific services for designated periods of time for each service and manufacture Surgical products through December 2020. Transition service revenue is recognized as the support is provided in accordance with the prices established in the transition services agreement. Supply agreement revenue is recognized when products are shipped at the net amount earned based upon the prices established in the supply agreement less the cost to produce the product. Transition service and supply agreement revenue are included in other revenue.

Inventory Valuation

Inventory is stated at the lower of cost or net realizable value. 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.

Non-GAAP Financial Measures

To supplement our financial results, we are providing a non-GAAP financial measure, Endoscopy product sales percentage change in constant currency, which removes the impact of changes in foreign currency exchange rates that affect the comparability and trend of our Endoscopy product sales. Endoscopy product sales percentage change in constant currency is calculated by translating current foreign currency sales using last year's exchange rate. This supplemental measure of our performance is not required by, and is not determined in accordance with GAAP.

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.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Year Ended December 31, 2020		Year Ended December 31, 2019	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	$ 42,048	100.0 %	$ 50,713	100.0 %
Cost of sales	19,806	47.1 %	25,038	49.4 %
Gross margin	22,242	52.9 %	25,675	50.6 %
Operating expenses:				
Sales and marketing	17,355	41.3 %	28,730	56.7 %
General and administrative	11,062	26.3 %	13,588	26.8 %
Research and development	7,670	18.2 %	10,384	20.5 %
Amortization of intangible assets	1,949	4.6 %	2,095	4.1 %
Settlement gain	—	— %	(5,609)	(11.1)%
Total operating expenses	38,036	90.4 %	49,188	97.0 %
Loss from operations	(15,794)	(37.6)%	(23,513)	(46.4)%
Interest expense, net	5,251	12.5 %	4,052	8.0 %
Other (income) expense	1,424	3.4 %	(408)	(0.8)%
Net loss before income taxes	(22,469)	(53.5)%	(27,157)	(53.6)%
Income tax expense	142	0.3 %	275	0.5 %
Net loss	$ (22,611)	(53.8)%	$ (27,432)	(54.1)%

Revenues

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

	Year Ended December 31, 2020			Year Ended December 31, 2019			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 15,774	$ 9,955	$ 25,729	$ 14,944	$ 13,365	$ 28,309	5.6 %	(25.5)%	(9.1)%
IGB	5,045	9,739	14,784	5,162	11,678	16,840	(2.3)%	(16.6)%	(12.2)%
Total Endoscopy	20,819	19,694	40,513	20,106	25,043	45,149	3.5 %	(21.4)%	(10.3)%
Surgical	—	—	—	—	3,712	3,712	— %	(100.0)%	(100.0)%
Other [1]	1,453	82	1,535	1,815	37	1,852	(19.9)%	121.6 %	(17.1)%
Total revenues	$ 22,272	$ 19,776	$ 42,048	$ 21,921	$ 28,792	$ 50,713	1.6 %	(31.3)%	(17.1)%
% Total revenues	53.0 %	47.0 %		43.2 %	56.8 %				

[1] Other U.S. revenue includes $0.9 million and $1.3 million of transition and manufacturing services provided for the years ended December 31, 2020 and 2019, respectively.

Non-GAAP Endoscopy product sales percentage changes in constant currency for the year ended December 31, 2020 were as follows:

	% Increase/Decrease in Constant Currency	
	OUS	Total Revenues
ESS	(24.0)%	(8.4)%
IGB	(16.9)%	(12.4)%
Total Endoscopy	(20.7)%	(9.9)%

Total revenues in 2020 were $42.0 million, compared to $50.7 million in 2019, a decrease of 17.1%. The decline in total revenues was due to the impact of the COVID-19 pandemic and related shelter-in-place restrictions and diversion of healthcare resources that began in March of 2020. Total Endoscopy product sales decreased 10.3% to $40.5 million in 2020 from $45.1 million in 2019. During the second quarter of 2020, total Endoscopy product sales declined $6.8 million compared to the same period in 2019 due to the impact of the COVID-19 pandemic. In the second half of 2020, Endoscopy procedures and product utilization in the U.S. recovered while OUS markets continued to be slowed periodically from sporadic COVID-19 resurgence. Direct markets accounted for 82.8% and 79.3% of total Endoscopy product sales in 2020 and 2019, respectively.

Sales also declined $3.7 million in 2020 due to the previously described divestiture of our Surgical products. Included in other revenues was $0.9 million and $1.3 million of transition and manufacturing services provided in 2020 and 2019, respectively.

Cost of Sales

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

	Year Ended December 31, 2020		Year Ended December 31, 2019	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	13,366	31.8 %	$ 17,160	33.8 %
Overhead	4,562	10.8 %	4,990	9.9 %
Other indirect costs	1,878	4.5 %	2,888	5.7 %
Total cost of sales	$ 19,806	47.1 %	$ 25,038	49.4 %

Gross Margin

Gross margin was 52.9% for 2020 compared to 50.6% for 2019. The increase in gross margin as a percentage of revenue was from implemented gross margin improvement projects, an increase in direct market sales as a percentage of total revenues in 2020, and a higher proportion of IGB product sales in 2020. These improvements were partially offset by a $0.5 million charge in the second quarter of 2020 for unabsorbed overhead costs associated with reduced manufacturing activity as a result of the COVID-19 pandemic.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense decreased $11.4 million in 2020 as compared to 2019 primarily due to lower compensation, reduction in marketing spend, suspension of medical education activities and reduced travel as a result of cost saving actions we initiated in response to the COVID-19 pandemic. In early 2020, we also ceased direct market operations in Brazil.

General and Administrative Expense. General and administrative expense decreased $2.5 million in 2020 as compared to 2019 primarily due to cost savings actions initiated in response to the COVID-19 pandemic and lower professional service fees.

Research and Development Expense. Research and development expense decreased $2.7 million in 2020 as compared to 2019 primarily due to lower clinical trial spend in 2020 as enrollment milestones were achieved in 2019 and due to cost saving actions initiated in response to the COVID-19 pandemic.

Amortization of Intangible Assets. Amortization of intangible assets was largely unchanged in 2020 as compared to 2019.

Settlement Gain. Settlement gain of $5.6 million in 2019 resulted from the resolution of a dispute with Allergan Inc. at a lower amount than previously accrued in connection with disputed inventory purchases and transition services provided by Allergan through 2016.

Loss from Operations.

Loss from operations in 2020 was $15.8 million compared to $23.5 million in 2019. Excluding the settlement gain in 2019 of $5.6 million, our loss from operations improved $13.3 million primarily due to the cost reduction actions implemented.

Other Expenses

Interest Expense, net. Net interest expense increased $1.2 million in 2020 primarily due to the non-cash interest on the Convertible Debt issued in August 2019.

Other (Income) Expense. Other (income) expense primarily consists of realized and unrealized foreign exchange gains or losses. The decrease of $1.8 million in 2020 compared to 2019 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 2020, unrealized exchange rate losses on these intercompany loans were $1.2 million compared to unrealized gains of $0.2 million in 2019.

Income Tax Expense. Income tax expense related to foreign income taxes on income generated in our OUS tax jurisdictions was $0.1 million in 2020 compared to $0.3 million in 2019.

Comparison of the Years Ended December 31, 2019 and 2018

	Year Ended December 31, 2019		Year Ended December 31, 2018	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues [1]	$ 50,713	100.0 %	$ 60,854	100.0 %
Cost of sales	25,038	49.4 %	27,660	45.5 %
Gross margin	25,675	50.6 %	33,194	54.5 %
Operating expenses:				
Sales and marketing	28,730	56.7 %	32,831	54.0 %
General and administrative	13,588	26.8 %	13,436	22.1 %
Research and development	10,384	20.5 %	12,176	20.0 %
Amortization of intangible assets	2,095	4.1 %	7,074	11.6 %
Settlement gain	(5,609)	(11.1)%	—	— %
Loss on divestiture	—	— %	7,770	12.8 %
Total operating expenses	49,188	97.0 %	73,287	120.5 %
Loss from operations	(23,513)	(46.4)%	(40,093)	(66.0)%
Interest expense, net	4,052	8.0 %	4,063	6.7 %
Other (income) expense	(408)	(0.8)%	1,440	2.4 %
Net loss before income taxes	(27,157)	(53.6)%	(45,596)	(75.1)%
Income tax expense	275	0.5 %	191	0.3 %
Net loss	$ (27,432)	(54.1)%	$ (45,787)	(75.4)%

[1] Revenue between periods declined $13.7 million due to the divestiture of the Surgical product line in December 2018. See the product sales table under "Revenues" for additional information for product group and geographic market.

Revenues

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

	Year Ended December 31, 2019			Year Ended December 31, 2018			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 14,944	$ 13,365	$ 28,309	$ 11,016	$ 12,364	$ 23,380	35.7 %	8.1 %	21.1 %
IGB	5,162	11,678	16,840	5,400	12,339	17,739	(4.4)%	(5.4)%	(5.1)%
Total Endoscopy	20,106	25,043	45,149	16,416	24,703	41,119	22.5 %	1.4 %	9.8 %
Surgical	—	3,712	3,712	10,795	7,913	18,708	(100.0)%	(53.1)%	(80.2)%
Other [1]	1,815	37	1,852	995	32	1,027	82.4 %	15.6 %	80.3 %
Total revenues	$ 21,921	$ 28,792	$ 50,713	$ 28,206	$ 32,648	$ 60,854	(22.3)%	(11.8)%	(16.7)%
% Total revenues	43.2 %	56.8 %		46.4 %	53.6 %				

[1] Other U.S. revenue includes $1.3 million of transition and manufacturing services provided for the year ended December 31, 2019.

Non-GAAP Endoscopy product sales percentage change in constant currency for the year ended December 31, 2019 were as follows:

	% Increase/Decrease in Constant Currency	
	OUS	Total Revenues
ESS	12.5 %	23.4 %
IGB	(1.6)%	(2.5)%
Total Endoscopy	5.5 %	12.3 %

Total revenues in 2019 were $50.7 million, compared to $60.9 million in 2018, a decrease of 16.7%. The decline in total revenues was the result of divesting our Surgical products in December 2018.

Total Endoscopy product sales increased 9.8% to $45.1 million in 2019 from $41.1 million in 2018. In constant currency, Endoscopy sales increased 12.3% when compared to 2018. Direct markets accounted for 79.3% and 81.6% of total Endoscopy product sales in 2019 and 2018, respectively.

Total ESS product sales increased $4.9 million, or 21.1%, in 2019 when compared to 2018. In constant currency, total ESS product sales increased 23.4%. U.S. ESS product sales increased $3.9 million, or 35.7%, compared to 2018. OUS ESS product sales increased $1.0 million, or 8.1%, compared to 2018. In constant currency, OUS ESS product sales increased 12.5% when compared to 2018. Worldwide, ESS growth is due to increased sales volume from new user adoption, greater product utilization in our existing customer base and growth in distributor market sales.

Total IGB product sales decreased $0.9 million, or 5.1%, in 2019 when compared to 2018. In the U.S., IGB product sales decreased $0.2 million, or 4.4%, in 2019 when compared to 2018 due to lower consumer demand in the first half of 2019 followed by a 23.2% increase in sales for the fourth quarter of 2019. We believe IGB product sales will continue to fluctuate quarter over quarter in the near term. OUS IGB product sales decreased $0.7 million, or 5.4%, in 2019 when compared to 2018 due to lower sales from lost market share in Brazil. In constant currency, OUS IGB product sales decreased 1.6% in 2019 when compared to 2018.

Included in other revenues for 2019 is $1.3 million of transition and manufacturing services provided to ReShape.

Cost of Sales

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

	Year Ended December 31, 2019		Year Ended December 31, 2018	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 17,160	33.8 %	$ 18,009	29.6 %
Overhead	4,990	9.9 %	6,670	11.0 %
Other indirect costs	2,888	5.7 %	2,981	4.9 %
Total cost of sales	$ 25,038	49.4 %	$ 27,660	45.5 %

Gross Margin

Gross margin was 50.6% for 2019 compared to 54.5% for 2018. The decline in gross margin is primarily due to a greater proportion of our overall product sales coming from our ESS products, which have experienced higher sales growth but have lower gross margins. Additionally, gross margin realized on remaining OUS Surgical product sales declined in 2019 as a result of the terms of the ReShape supply and distribution agreements. Gross margin for our Endoscopy products increased to 49.5% for 2019 compared to 44.2% for 2018 due to implementation of our gross margin improvement projects.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense decreased $4.1 million in 2019 as compared to 2018 primarily due to lower U.S. direct consumer advertising costs, lower sales compensation, and cost savings from insourcing our customer service operation at the end of 2018.

General and Administrative Expense. General and administrative expense increased $0.2 million in 2019 as compared to 2018 primarily due to higher internal control audit fees incurred in the first quarter of 2019 required for our 2018 Annual Report on Form 10-K.

Research and Development Expense. Research and development expense decreased $1.8 million in 2019 as compared to 2018 primarily due to lower clinical trial spend in 2019 as we completed the Orbera post-approval study.

Amortization of Intangible Assets. Amortization of intangible assets decreased $5.0 million in 2019 as compared to 2018 due to the disposition of intangible assets associated with the Surgical business in December 2018.

Settlement Gain. Settlement gain of $5.6 million in 2019 resulted from the resolution of a dispute with Allergan Inc. at a value less than amounts previously accrued for disputed inventory purchases and transition services provided by Allergan through 2016.

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

Loss from Operations.

Loss from operations in 2019 was $23.5 million compared to $40.1 million in 2018. Excluding the settlement gain and loss on divestiture, the loss from operations was $29.1 million in 2019 compared to $32.3 million in 2018. The decreased loss from operations, after excluding the one-time settlement gain and loss on divestiture, was primarily due to lower operating expenses offsetting the reduction in gross margin from the divestiture of our Surgical product line.

Other Expenses

Interest Expense, net. Net interest expense remained unchanged at $4.1 million in 2019 and 2018.

Other (Income) Expense. Other (income) expense primarily consists of realized and unrealized foreign exchange gains or losses. The decrease of $1.8 million in 2019 compared to 2018 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 2019, unrealized exchange rate gains on these intercompany loans were $0.2 million compared to unrealized losses of $1.2 million in 2018.

Income Tax Expense. Income tax expense was $0.3 million in 2019 compared to $0.2 million in 2018. Tax expense in 2019 and 2018 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 $272.8 million as of December 31, 2020. To date, we have funded our operating losses and acquisitions through equity offerings and the issuance of debt instruments. We have occasionally been out of compliance with our debt covenants which resulted in amendments to the terms of our debt instruments. Our ability to fund future operations and meet debt covenant requirements will depend upon our level of future revenue and operating cash flow and our ability to access additional funding through either equity offerings, issuances of debt instruments or both.

In July 2020, we issued shares of our common stock and pre-funded warrants for aggregate proceeds of approximately $25.0 million and entered into the Sixth Amendment to our loan and security agreement with Solar Capital, Ltd. that waived the minimum covenant requirements for 2020 and decreased our minimum liquidity requirements from $20.0 million to $12.5 million. In December 2020, the Seventh Amendment to our loan and security agreement with Solar Capital, Ltd. extended the interest only period until March 1, 2022 (or September 1, 2022 if certain revenue milestones are achieved in 2021) and extended the maturity date to September 1, 2024 (or March 1, 2025 if certain revenue milestones are achieved in 2021). The deferral of principal repayments resulting from the Seventh Amendment improves our 2021 liquidity by approximately $12.0 million.

Management believes its existing cash and cash equivalents, expected product revenues, and available debt and equity financing arrangements will be sufficient to meet covenant, liquidity and capital requirements for at least the next twelve months. Management periodically evaluates our liquidity requirements, alternative uses of capital, capital needs and available resources. As a result of this process, we have in the past, and may in the future, explore alternatives to finance our business plan, including, but not limited to, sales of common stock, preferred stock, convertible securities or debt financings, reduction of planned expenditures, or other sources, although there can be no assurances that such additional funding could be obtained.

Term Loan Facility

In March 2019, we entered into a term loan facility agreement with Solar Capital, Ltd. to borrow $35.0 million (the "Credit Agreement"). The Credit Agreement, as amended by the Seventh Amendment, matures on September 1, 2024, with principal payments beginning in March 2022, and bears interest at LIBOR, subject to a minimum floor, plus 7.5%. Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 7.0% of the outstanding amount will be due at end of the loan term and an additional 5.5% fee will be due at the earlier of an Exit Event (as defined in the Credit Agreement) or if we achieve trailing twelve-month revenue of $100.0 million before December 4, 2030. The Credit Agreement includes customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity requirement and minimum product revenues. We used $22.4 million of the proceeds of the Credit Agreement to repay our previous senior secured credit agreement in full, including interest.

The Credit Agreement was amended in March 2020, April 2020, July 2020 and December 2020. These amendments, among other things, (i) waived the trailing six-month Endoscopy revenue requirements through the end of 2020, (ii) reduced the minimum liquidity requirement to $12.5 million, (iii) extended the interest only period until March 1, 2022 (or September 1, 2022 if certain revenue milestones are achieved in 2021) and extended the maturity date to September 1, 2024 (or March 1, 2025 if certain revenue milestones are achieved in 2021), (iv) permitted us to enter into a loan under the SBA's PPP established under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, (v) increased the final fee due at the end of the loan term to 7.0% from 4.9%, (vi) increased the fee due at certain exit or trigger events from 4.5% to 5.5%, (vii) waived the financial statement covenant default associated with the going concern opinion of our independent registered public accounting firm for the year ended December 31, 2019, and (viii) established a minimum LIBOR interest rate.

In February 2021, we entered into the Eighth Amendment to the Credit Agreement which established the revenue covenant requirements for 2021 (see Note 18).

Convertible Senior Debt

In August 2019, we issued $20.0 million aggregate principal amount of Convertible Debt. Interest on the Convertible Debt will be payable semi-annually in shares of our common stock on January 1 and July 1 of each year, beginning on January 1, 2020, at a rate of 6.0% per year. The number of shares of common stock required to settle the amount of interest payable will be based on the volume-weighted average price ("VWAP"), of our common stock for the 10 consecutive trading days immediately preceding the applicable interest payment date. The Convertible Debt will mature on August 12, 2026, unless earlier converted or repurchased in accordance with its terms.

The Convertible Debt converts, at the option of the holders, into shares of our common stock at an initial conversion price of $3.25 per share, subject to adjustment. If the VWAP of our common stock has been at least $9.75 (subject to adjustment) for at least 20 trading days during any 30 consecutive trading day period, we may force the conversion of all or any part of the outstanding principal amount of the Convertible Debt, accrued and unpaid interest and any other amounts then owing, subject to certain conditions.

As of December 31, 2020, $20.5 million aggregate principal amount was outstanding under the Convertible Debt. In July 2020, $0.6 million of interest due for the six-month period ended June 30, 2020 accreted into principal outstanding under the Convertible Debt. In December 2020, $0.1 million of the Convertible Debt was converted into shares of common stock at a holder's election.

CARES Act

On March 27, 2020, the CARES Act was signed into law providing certain economic aid packages for qualified entities. In April 2020, we were granted a loan of $2.8 million under the PPP established under the CARES Act. The Loan matures on February 27, 2023 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on September 27, 2021.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of payroll costs, rent, utilities, and interest on debt. The terms of any forgiveness may also be subject to further requirements in any regulations and guidelines the SBA may adopt.

On June 5, 2020, the PPP Flexibility Act was signed into law which, among other things, (i) extended the covered period from 8 weeks after the date of PPP funding to 24 weeks after the date of PPP funding, (ii) reduced the required amount of payroll expenditures from 75% to 60%, (iii) removed the prior ban on borrowers taking advantage of payroll tax deferral after loan forgiveness and (iv) extended the repayment deferral period to be the earlier of (a) the date forgiveness funds are received or (b) 10 months from the end of the covered period.

In December 2020, we applied for forgiveness of the full amount of the $2.8 million loan from the SBA. We will continue to include this PPP loan within our long-term debt until we receive confirmation of forgiveness from the SBA.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

	2020	2019
Net cash used in operating activities	$ (20,812)	$ (25,622)
Net cash provided by investing activities	1,370	1,038
Net cash provided by financing activities	25,613	30,506
Effect of exchange rate changes on cash	108	(8)
Net change in cash, cash equivalents and restricted cash	$ 6,279	$ 5,914

Operating Activities

Cash used in operating activities of $20.8 million for 2020 was primarily the result of a net loss of $22.6 million plus non-cash items of $9.3 million primarily related to depreciation, amortization, non-cash interest, foreign currency on intercompany payables, and stock-based compensation. Net loss, after adjustment for non-cash items, improved $12.9 million compared to the same period in 2019 due to lower operating expenses, primarily due to cost reduction actions we initiated to preserve our liquidity during the COVID-19 pandemic, which offset reduced gross margin. Additionally, cash used for accounts payable and accrued expenses of $7.1 million primarily related to clinical study payments and raw material purchases.

Cash used in operating activities of $25.6 million for 2019 was primarily the result of a net loss of $27.4 million plus non-cash items of $1.3 million primarily related to the settlement gain of $5.6 million offset by depreciation, amortization, non-cash interest, and stock-based compensation. The increase in net loss after adjustment for non-cash items is primarily due to the divestiture of our Surgical product line in December of 2018. Additionally, cash provided by operating assets and liabilities of $0.6 million related to working capital changes primarily from accounts receivable collections and reduction in inventory levels offset by higher accounts payable payments.

Investing Activities

Cash provided by investing activities in both 2020 and 2019 was related to installment payments received from the sale of the Surgical product line partially offset by investments in property and equipment and in our intellectual property portfolio.

Financing Activities

Cash provided by financing activities of $25.6 million for 2020 primarily related to proceeds received from the issuance of common stock and pre-funded warrants to purchase common stock in July 2020 of $23.3 million and the PPP Loan granted in April 2020 of $2.8 million.

Cash provided by financing activities of $30.5 million for 2019 primarily related to the $13.3 million in net proceeds from the Term Loan Facility refinancing and proceeds from the issuance of $20.0 million aggregate principal amount of Convertible Debt offset by deferred financing costs of $2.9 million.

Future Funding Requirements

As of December 31, 2020, we had cash, cash equivalents and restricted cash balances totaling $37.2 million. We believe our existing cash and cash equivalents, product revenues, and available debt and equity financing arrangements will be sufficient to meet covenant, liquidity and capital requirements for at least the next twelve months, although there can be no assurances that we will be able to do so.

Any future capital requirements will depend on many factors including market acceptance of our products, the costs of our research and development activities, the cost and timing of additional regulatory clearance and approvals, the cost and timing of identified gross margin improvement projects, the cost and timing of clinical programs, the ability to maintain covenant compliance with our lending facility, and the costs and timing of sales, marketing, distribution and manufacturing activities. 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 U.S. Securities and Exchange Commission ("SEC").

Recent Accounting Pronouncements

See Note 2(r) to the Consolidated Financial Statements in Part II, Item 8 of this Annual 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 as defined by Rule 12b-2 of the Exchange Act.

ITEM 8. FINANCIAL STATEMENTS

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors
Apollo Endosurgery, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Apollo Endosurgery, Inc. and subsidiaries (the "Company") as of December 31, 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our 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 the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventories and Valuation of Related Estimates and Obsolescence

As described in notes 2 and 4 to the consolidated financial statements, the Company's consolidated inventories balance was $10.3 million as of December 31, 2020. Inventory is stated at the lower of cost or net realizable value. The Company values inventories using the weighted average cost approach, which approximates actual costs. The Company writes down inventory based on specific identification of excess and obsolete inventory items based on estimated sales forecasts and an analysis of inventory items approaching expiration date. If factors such as future usage and forecast product demand are less favorable than those projected, additional inventory write downs may be required.

The valuation of inventories requires management to make significant assumptions and complex judgments about the future salability of the inventory and its net realizable value. These assumptions include the assessment of net realizable value by inventory category considering approaching expiration dates, future usage and forecast product demand for the Company's products. Changes in such assumptions could have a significant impact on the valuation of the Company's inventories. Additionally, management makes qualitative judgments related to discontinued, slow

moving and obsolete inventories. This leads to a high degree of auditor judgment and an increased extent of effort is required when performing audit procedures to evaluate the methodology and reasonableness of the estimates and assumptions.

The following are the most relevant procedures we performed to address this critical audit matter:

- We evaluated and tested the appropriateness of management's process for determining the valuation of inventories, including:
  - The reasonableness of the significant assumptions used by management including those related to forecasted inventory usage and backlog;
  - The completeness, accuracy, and relevance of the underlying data used in management's estimate, including inventory expiration dates;
  - The calculations related to the application of the methodology to specific inventory categories; and
  - Inquiries with appropriate non-financial personnel regarding obsolete or discontinued inventory models, cancelled sales orders and other factors to corroborate management's assertions regarding qualitative judgments about discontinued, slow moving and obsolete inventories;
- We developed an independent expectation of inventory write-downs at year end based on historical trends and compared it to management's estimate; and
- We developed an independent expectation of inventory valuation at the product level based on historical costs and current year cost increases and compared it to management's valuation.

/s/ Moss Adams LLP

Dallas, Texas
February 25, 2021

We have served as the Company's auditor since 2020.

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 sheet of Apollo Endosurgery, Inc. and subsidiaries (the "Company") as of December 31, 2019, the related consolidated statement of operations and comprehensive loss, change in stockholders' equity, and cash flows for the year 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, 2019, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2019 consolidated financial statements, the Company has suffered recurring losses from operations, cash flow deficits and debt covenant violations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 served as the Company's auditor from 2014 to 2020.

Austin, Texas
March 26, 2020

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2020 and 2019
(In thousands, except for share data)

	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 36,235	$ 29,905
Accounts receivable, net of allowance for doubtful accounts of $634 and $658, respectively	8,218	9,232
Inventory	10,306	8,865
Prepaid expenses and other current assets	3,771	2,998
Total current assets	58,530	51,000
Restricted cash	965	1,016
Property, equipment and right-of-use assets	6,221	6,612
Goodwill	5,290	5,290
Intangible assets, net of accumulated amortization of $13,231 and $11,648, respectively	6,017	7,831
Other assets	414	2,833
Total assets	$ 77,437	$ 74,582
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,675	$ 9,902
Accrued expenses	7,357	8,438
Current portion of long-term debt	636	34,449
Total current liabilities	11,668	52,789
Long-term debt	37,192	—
Convertible debt	19,387	18,554
Long-term liabilities	2,439	1,116
Total liabilities	70,686	72,459
Commitments and contingencies		
Stockholders' equity:		
Common stock; $0.001 par value; 100,000,000 shares authorized; 25,819,329 and 20,951,963 shares issued and outstanding at December 31, 2020 and 2019, respectively	26	21
Additional paid-in capital	276,569	250,634
Accumulated other comprehensive income	2,929	1,630
Accumulated deficit	(272,773)	(250,162)
Total stockholders' equity	6,751	2,123
Total liabilities and stockholders' equity	$ 77,437	$ 74,582

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2020 and 2019
(In thousands, except for share data)

	2020	2019
Revenues	$ 42,048	$ 50,713
Cost of sales	19,806	25,038
Gross margin	22,242	25,675
Operating expenses:		
Sales and marketing	17,355	28,730
General and administrative	11,062	13,588
Research and development	7,670	10,384
Amortization of intangible assets	1,949	2,095
Settlement gain	—	(5,609)
Total operating expenses	38,036	49,188
Loss from operations	(15,794)	(23,513)
Other expenses:		
Interest expense, net	5,251	4,052
Other (income) expense	1,424	(408)
Net loss before income taxes	(22,469)	(27,157)
Income tax expense	142	275
Net loss	$ (22,611)	$ (27,432)
Other comprehensive income (loss):		
Foreign currency translation	1,299	(871)
Comprehensive loss	$ (21,312)	$ (28,303)
Net loss per share, basic and diluted	$ (0.99)	$ (1.27)
Shares used in computing net loss per share, basic and diluted	22,756,167	21,542,284

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2020 and 2019
(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, 2018	21,899,522	$ 22	$ 249,115	$ 2,501	$ (222,808)	$ 28,830
Adoption of ASU 2016-02, *Leases*	—	—	—	—	78	78
Exercise of common stock options	17,158	—	31	—	—	31
Exchange of common stock for warrants	(1,000,000)	(1)	1	—	—	—
Issuance of restricted stock units	35,283	—	—	—	—	—
Stock-based compensation	—	—	1,487	—	—	1,487
Foreign currency translation	—	—	—	(871)	—	(871)
Net loss	—	—	—	—	(27,432)	(27,432)
Balances at December 31, 2019	20,951,963	$ 21	$ 250,634	$ 1,630	$ (250,162)	$ 2,123
Exercise of common stock options	5,982	—	14	—	—	14
Exercise of common stock warrants	2,105,836	2	(2)	—	—	—
Issuance of restricted stock units	85,223	—	—	—	—	—
Issuance of common stock for convertible debt interest	164,797	—	467	—	—	467
Issuance of common stock, net of issuance costs of $1,721	2,480,000	3	23,259	—	—	23,262
Conversion of convertible debt	25,528	—	83	—	—	83
Stock-based compensation	—	—	2,114	—	—	2,114
Foreign currency translation	—	—	—	1,299	—	1,299
Net loss	—	—	—	—	(22,611)	(22,611)
Balances at December 31, 2020	25,819,329	$ 26	$ 276,569	$ 2,929	$ (272,773)	$ 6,751

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
Years Ended December 31, 2020 and 2019
(In thousands)

	2020	2019
Cash flows from operating activities:		
Net loss	$ (22,611)	$ (27,432)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,730	4,060
Amortization of deferred financing costs	656	620
Non-cash interest	1,501	540
Provision for doubtful accounts receivable	52	212
Inventory impairment	50	162
Stock-based compensation	2,114	1,487
Unrealized foreign exchange on intercompany payables	1,208	(214)
Settlement gain	—	(5,609)
Changes in operating assets and liabilities:		
Accounts receivable	1,079	1,852
Inventory	(1,559)	872
Prepaid expenses and other assets	56	(120)
Accounts payable and accrued expenses	(7,088)	(2,052)
Net cash used in operating activities	(20,812)	(25,622)
Cash flows from investing activities:		
Purchases of property and equipment	(486)	(805)
Purchases of intangibles and other assets	(144)	(175)
Proceeds from sale of equipment	—	18
Divestiture of Surgical product line	2,000	2,000
Net cash provided by investing activities	1,370	1,038
Cash flows from financing activities:		
Proceeds from exercise of stock options	14	31
Proceeds from long-term debt	2,824	35,000
Proceeds from convertible debt	—	20,000
Proceeds from issuance of common stock	23,262	—
Payments of deferred financing costs	(487)	(2,857)
Payment of long-term debt	—	(21,668)
Net cash provided by financing activities	25,613	30,506
Effect of exchange rate changes on cash	108	(8)
Net increase in cash, cash equivalents and restricted cash	6,279	5,914
Cash, cash equivalents and restricted cash at beginning of year	30,921	25,007
Cash, cash equivalents and restricted cash at end of year	$ 37,200	$ 30,921
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,182	$ 3,470
Cash paid for income taxes	192	328
Right-of-use assets recognized in exchange for new lease obligations (non-cash)	1,146	2,890

See accompanying notes to the consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements
Years Ended December 31, 2020 and 2019
(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 to advance gastrointestinal therapeutic endoscopy. The Company develops and distributes devices that are used by gastroenterologists and surgeons for a variety of procedures related to closing gastrointestinal defects and managing surgical or endoscopic adverse events and obesity intervention.

The Company's core products include the OverStitch™ Endoscopic Suturing System ("ESS") and the Orbera® Intragastric Balloon System ("IGB"), which together comprise the Company's Endoscopy products. The Company also offers Apollo Care, a digital and remotely delivered aftercare program. In December 2020, the Company received 510(k) approval for the X-Tack Endoscopic HeliX Tacking System. All devices are regulated by the U.S. Food and Drug Administration (the "FDA") or an equivalent regulatory body outside the U.S.

In December 2018, we entered into an Asset Purchase Agreement ("Purchase Agreement") and sold our Lap-Band® product line ("Surgical") to ReShape Lifesciences, Inc ("ReShape"). Our goal with this transaction was to increase our focus on our Endoscopy products and monetize a non-strategic asset. ReShape agreed to pay $17,000 in cash, of which $3,000 remains payable in December 2021. Upon completion of the ReShape transaction, the parties entered into a transition services agreement, supply agreement and distribution agreement. All transition, distribution, and manufacturing services were completed as of December 31, 2020.

(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 assessment, useful lives of intangibles and long-lived assets, 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 $965 and $1,016 which are recorded in restricted cash on the consolidated balance sheet as of December 31, 2020 and 2019, 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 deemed uncollectible. Accounts receivable of $115 and $127 were written off during the years ended December 31, 2020 and 2019, respectively.

(f) Inventory

Inventory is stated at the lower of cost or net realizable value. Charges for excess and obsolete inventory are based on specific identification of obsolete inventory items and an analysis of inventory items approaching expiration date. The Company records 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, and restricted cash, 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 $41,100 and $38,000 at December 31, 2020 and 2019, respectively. The Company's convertible debt is estimated by management to approximate $20,500 and $20,000 at December 31, 2020 and 2019, respectively. 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) Leases

Lease arrangements are generally recognized at lease commitment. Operating lease right-of-use assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term, except for leases with an initial term of 12 months or less, for which lease expense is recognized as incurred over the lease term. Right-of-use assets represent the Company’s right to use an underlying asset during the reasonably certain lease term, and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Lease terms may include options to extend or terminate the lease when its reasonably certain that the Company will exercise that option. The Company primarily uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Operating lease right-of-use assets include any lease payments related to initial direct costs and prepayments and excludes lease incentives. Lease expense is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately.

(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, 2020 and 2019 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, 2020 and 2019 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 the customer, in an amount that reflects the consideration expected to be entitled to in an exchange for 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. The Company's 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 customers may receive volume rebates or discounts, which are accounted for as variable consideration. The Company estimates these amounts based on the expected amount to be provided to customers and reduces recognized revenues.

The Company records 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.

In connection with the December 2018 sale of the Surgical product line, the Company entered into a transition services agreement, supply agreement and distribution agreement. Transition service fees were recognized as revenue when the support was provided in accordance with the prices established in the transition services agreement. Product sold under the supply agreement is recognized as revenue when product is shipped at the prices established in the supply agreement net of the cost to produce the product. Transition service and supply agreement revenue are included in other revenue. All transition, distribution, and manufacturing services were completed as of December 31, 2020.

(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 $227 and $1,648 in advertising costs during the years ended December 31, 2020 and 2019, 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) Foreign 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. Exchange rate fluctuations on short-term intercompany loans are included in other expense in the consolidated statement of operations and comprehensive loss.

(r) Recent Accounting Pronouncements

In March 2020, ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, was issued to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients for contracts that reference LIBOR, if certain criteria are met, that can be applied through December 31, 2022. As reference rate reform is still an ongoing process, the Company will continue to evaluate the timing and potential impact of adoption for optional expedients when deemed necessary.

(3) 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, 2020, the Company's cash and cash equivalents and restricted cash are held in deposit accounts at five different banks totaling $37,200. 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 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 monitors the compliance of its customers with the Company's payment terms, but generally requires no collateral.

The Company had no concentrations greater than 10% of the Company's net accounts receivable balance as of December 31, 2020. There was one customer representing approximately 15% of the Company's net accounts receivable as of December 31, 2019. The Company had no single customer that comprised more than 10% of the Company's total revenues for the years ended December 31, 2020 and 2019.

(4) Inventory

Inventory consists of the following as of December 31:

	2020	2019
Raw materials	$ 2,344	$ 2,834
Work in progress	558	532
Finished goods	7,404	5,499
Total inventory	$ 10,306	$ 8,865

The Company recorded an inventory impairment charge of $50 and $162 for the years ended December 31, 2020 and 2019, respectively. Finished goods included $140 of inventory on consignment at customer locations at December 31, 2020.

(5) Property, Equipment and Right-of-Use Assets

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

	Depreciable Lives	2020	2019
Equipment	5 years	$ 7,452	$ 7,491
Right-of-use assets	1 - 5 years	4,031	2,890
Furniture, fixtures and tooling	4 - 8 years	2,156	2,233
Computer hardware	3 - 5 years	1,244	1,261
Leasehold improvements	3 - 7 years	1,744	1,671
Construction in process		466	198
		17,093	15,744
Less accumulated depreciation		(10,872)	(9,132)
Property, equipment and right-of-use assets		$ 6,221	$ 6,612

The Company recorded depreciation expense of $1,779 and $1,859 for the years ended December 31, 2020 and 2019, respectively. There were no impairment charges for the years ended December 31, 2020 or 2019. The Company disposed of $405 of fully depreciated property, equipment and right-of-use assets no longer being utilized during the year ended December 31, 2020.

The Company has operating leases for office space in Texas, the United Kingdom, and Italy, and for the manufacturing facility in Costa Rica. In September 2020, the Company extended the lease of the manufacturing facility in Costa Rica. The Company also has various operating lease agreements for equipment and vehicles.

As of December 31, 2020, the maturities of the Company's operating lease liabilities are as follows:

2021	$ 983
2022	566
2023	488
2024	424
2025	404
Thereafter	1,172
Total lease payments	4,037
Less imputed interest	(1,032)
Total operating lease liabilities	$ 3,005

Operating lease liabilities of $675 and $2,330 are included in accrued expenses and long-term liabilities, respectively, as of December 31, 2020. Operating lease expense and cash paid within operating cash flows for operating leases was $1,156 and $1,233 during 2020 and 2019, respectively. The weighted average remaining lease term was 5.0 years and the weighted average discount rate used to estimate the value of the operating lease liabilities was 8.9%.

(6) Intangible Assets

Intangible assets consist of the following as of December 31:

	Useful Life	2020	2019
Customer relationships	9 years	$ 8,301	$ 8,301
Orbera technology	12 years	4,600	4,600
Trade names	10 years	1,700	1,700
Patents and trademarks	5 years	2,597	2,453
Capitalized software	1 - 5 years	2,050	2,425
		19,248	19,479
Less accumulated amortization		(13,231)	(11,648)
Intangible assets, net		$ 6,017	$ 7,831

The Company recorded amortization expense of $1,951 and $2,201 during 2020 and 2019, respectively. Additionally, $144 and $161 related to the extension and renewal of patents and trademarks was capitalized during 2020 and 2019, respectively.

Amortization for the next five years is as follows:

2021	$ 1,851
2022	1,674
2023	908
2024	624
2025	564
Thereafter	396
Total	$ 6,017

(7) Other Assets

Included in other assets as of December 31, 2019 was $2,511 for the non-current portion of the receivable due from ReShape, which has been reclassified to other current assets as of December 31, 2020. Interest on the receivable accretes 10% annually. Imputed interest income on the ReShape receivable was $416 and $619 for the years ended December 31, 2020 and 2019, respectively, and is included within interest expense, net.

(8) Accrued Expenses

Accrued expenses consists of the following as of December 31:

	2020	2019
Accrued employee compensation and expenses	$ 3,946	$ 3,183
Lease liability	675	932
Accrued interest	616	467
Accrued professional service fees	358	653
Accrued insurance and taxes	442	271
Accrued returns and rebates	129	216
Settlement liability	—	1,625
Other	1,191	1,091
Total accrued expenses	$ 7,357	$ 8,438

In April 2019, the Company entered into a settlement agreement with Allergan, Inc. to resolve a dispute related to amounts charged for inventory purchases and transition services provided through 2016, after the Company's asset acquisition of the obesity intervention business in December 2013. The settlement agreement provided for a payment of $3,250 to completely discharge all remaining charges. The remaining payment of $1,625 was paid in 2020. The Company recognized a gain of $5,609 in 2019 as a result of this settlement agreement.

(9) Long-Term Debt

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

	2020	2019
Term loan facility	$ 35,000	$ 35,000
PPP loan	2,824	—
Deferred interest	1,217	517
Deferred financing costs	(1,213)	(1,068)
Less current portion	(636)	(34,449)
Long-term debt	$ 37,192	$ —

Term Loan Facility

In March 2019, the Company entered into a Term Loan Facility (the "Credit Agreement") with Solar to borrow $35,000. The Credit Agreement, as amended by the Seventh Amendment, matures on September 1, 2024, with principal payments beginning in March 2022, and bears interest at LIBOR, subject to a minimum floor, plus 7.5%. Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 7.0% of the outstanding amount will be due at end of the loan term and an additional 5.5% fee will be due at the earlier of an Exit Event (as defined in the Credit Agreement) or if the Company achieves trailing twelve-month revenue of $100,000 before December 4, 2030. The Credit Agreement, collateralized by substantially all of the Company's assets, includes the customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity requirement and minimum product revenues. The Company used $22,372 of the proceeds of the Credit Agreement to repay our previous senior secured credit agreement in full including interest. Unamortized deferred financing costs and discount of $388 were written off in March 2019 in connection with the repayment.

The Credit Agreement was amended in March 2020, April 2020, July 2020 and December 2020. These amendments, among other things, (i) waived the trailing six-month Endoscopy revenue requirements through the end of 2020, (ii) reduced the minimum liquidity requirement to $12,500, (iii) extended the interest only period until March 1, 2022 (or September 1, 2022 if certain revenue milestones are achieved in 2021) and extended the maturity date to September 1, 2024 (or March 1, 2025 if certain revenue milestones are achieved in 2021), (iv) permitted the Company to enter into a loan under the Small Business Administration's ("SBA") Paycheck Protection Program ("PPP") established under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, (v) increased the final fee due at the end of the loan term to 7.0% from 4.9%, (vi) increased the fee due at certain exit or trigger events from 4.5% to 5.5%, (vii) waived the financial statement covenant default associated with the going concern opinion of our independent registered public accounting firm for the year ended December 31, 2019, and (viii) established a minimum LIBOR interest rate. In connection with these amendments and concurrent with the equity raise in July 2020, the Company reclassified the term loan facility from current liabilities to the scheduled maturity of the principal payments set out in the Credit Agreement.

As of December 31, 2020, the Company was in compliance with all financial covenants. In February 2021, we entered into the Eighth Amendment to the Credit Agreement which established the revenue covenant requirements for 2021 (see Note 18).

PPP Loan

In March 2020, the CARES Act was signed into law providing certain economic aid packages for qualified entities. In April 2020, we were granted a loan of $2,824 under the PPP established under the CARES Act. The Loan matures on February 27, 2023 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on September 27, 2021.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of payroll costs, rent, utilities, and interest on debt. The terms of any forgiveness may also be subject to further requirements in any regulations and guidelines the SBA may adopt.

In June 2020, the PPP Flexibility Act was signed into law which, among other things, (i) extended the covered period from 8 weeks after the date of PPP funding to 24 weeks after the date of PPP funding, (ii) reduced the required amount of payroll expenditures from 75% to 60%, (iii) removed the prior ban on borrowers taking advantage of payroll tax deferral after loan forgiveness and (iv) extended the repayment deferral period to be the earlier of (a) the date forgiveness funds are received or (b) 10 months from the end of the covered period.

In December 2020, the Company applied for forgiveness of the full amount of the $2,824 loan from the SBA. We will continue to include this PPP loan within our long-term debt until we receive confirmation of forgiveness from the SBA.

Interest expense on the Company's long term debt was $4,212 and $4,579 for the years ended December 31, 2020 and 2019, respectively.

Principal payments of the Company's long-term debt are as follows:

2021	$	627
2022		13,550
2023		14,314
2024		9,333
2025		—
Thereafter		—
Total	$	37,824

(10) Convertible debt

Convertible debt consists of the following as of December 31:

	2020	2019
Convertible debt principal	$ 20,519	$ 20,000
Deferred financing costs	(1,132)	(1,446)
Convertible debt	$ 19,387	$ 18,554

In August 2019, the Company issued $20,000 aggregate principal amount of 6.0% convertible senior debentures (the "Convertible Debt"), primarily to existing stockholders and officers of the Company. Interest on the Convertible Debt is payable semi-annually in shares of the Company's common stock on January 1 and July 1 of each year, at a rate of 6.0% per year. The number of shares of common stock required to settle the amount of interest payable will be based on the volume-weighted average price ("VWAP") of our common stock for the 10 consecutive trading days immediately preceding the applicable interest payment date. However, in the event that the trailing 10-trading day VWAP of the Company's common stock is less than $2.50 per share, interest accrued and payable for the applicable interest payment period will accrete to the principal amount then outstanding. The Convertible Debt will mature on August 12, 2026, as amended in December 2020, unless earlier converted or repurchased in accordance with its terms.

In January 2020, we issued 164,797 shares of the Company's common stock to holders of the Convertible Debt in fulfillment of $467 of accrued interest as of December 31, 2019. In July 2020, outstanding interest of $600 was accreted to the principal amount of the Convertible Debt. As of December 31, 2020, accrued interest on the Convertible Debt was $616.

The Convertible Debt converts, at the option of the holders, into shares of our common stock at an initial conversion price of $3.25 per share, subject to adjustment. If the VWAP of our common stock has been at least $9.75 (subject to adjustment) for at least 20 trading days during any 30 consecutive trading day period, we may force the conversion of all or any part of the outstanding principal amount of the Convertible Debt, accrued and unpaid interest and any other amounts then owing, subject to certain conditions.

In December 2020, $81 of the Convertible Debt was converted into 25,528 shares of common stock.

Interest expense on the Convertible Debt was $1,531 and $588 for the years ended December 31, 2020 and 2019, respectively.

(11) 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, 2020:

Warrant Expiration Date	Number of shares	Exercise price per share
December 29, 2021	40,456	$13.70
February 27, 2022	163,915	$21.29
No expiration	16,412,964	$0.001
Total number of warrants outstanding	16,617,335	
Weighted average exercise price of warrants outstanding		$0.24

In July 2020, the Company issued and sold (i) 2,480,000 shares of common stock, par value $0.001 per share at a purchase price of $1.25 per share, or the Shares, and (ii) pre-funded warrants to purchase up to 17,520,000 shares of common stock, or the Warrant Shares, at a purchase price of $1.249 per warrant, or the Warrants, for aggregate proceeds of approximately $25,000. In October 2020, 2,107,036 of these Warrants were exercised. No warrants expired during the year ended December 31, 2020.

(12) Stock Option Plans

Plans

2017 Plan

The Company's 2017 Equity Incentive Plan (the "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.

Certain of the outstanding options were granted under prior equity incentive plans which are no longer in effect.

As of December 31, 2020, the Company has 438,581 shares of common stock reserved for issuance under the 2017 Plan.

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, 2020 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2019	1,927,194	$5.01	7.5 years	$87
Options granted	1,216,942	$2.08		
Options exercised	(5,982)	$2.31		
Options forfeited	(216,208)	$4.13		
Options outstanding, vested and expected to vest, December 31, 2020	2,921,946	$3.86	7.6 years	$1,664
Options exercisable	1,364,859	$5.17	6.0 years	$143

The fair value for options under the Equity Plans was estimated at the date of grant using the Black-Scholes option pricing model. 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:

	2020	2019
Risk free interest rate	0.4%	2.2%
Expected dividend yield	—%	—%
Estimated volatility	73.8%	64.6%
Expected life	5.8 years	6.0 years

Additional information regarding options is as follows:

	2020	2019
Stock-based compensation cost	$2,114	$1,487
Weighted-average grant date fair value of options granted during the period	$1.31	$2.08
Aggregate intrinsic value of options exercised during the period	$8	$20

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, 2020 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, 2020 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 to its sales and marketing personnel that begin to time vest only upon the individual's achievement of a certain revenue target. In 2020, no options were determined to have met the underlying conditions. The remaining performance shares were unearned and forfeited.

Unrecognized compensation expense related to unvested options was approximately $2,121 at December 31, 2020, with a remaining amortization period of less than 2.0 years.

A summary of the restricted stock unit activity under the Company's Equity Plans as of December 31, 2020 is presented below:

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested units, December 31, 2019	243,695	$4.06	$695
Restricted stock units granted	517,978	$2.08	
Restricted stock units vested	(85,223)	$4.08	
Restricted stock units forfeited	(11,784)	$2.08	
Unvested units, December 31, 2020	664,666	$2.55	$2,260

Unrecognized compensation expense related to unvested restricted stock units was approximately $1,251 at December 31, 2020, with a remaining amortization period of 2.2 years.

(13) Commitments and Contingencies

(a) 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.

(b) 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 twenty-four 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.

(c) 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.

(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 $504 and $698 for the years ended December 31, 2020 and 2019 respectively.

(15) Income Taxes

Income tax expense of $142 and $275 for the years ended December 31, 2020 and 2019, respectively is composed of foreign income taxes on earnings generated by 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:

	2020	2019
Deferred tax assets:		
Capitalized transaction costs	$ 279	$ 330
Intangible assets	1,100	1,105
Inventory valuation	28	242
Research and development credit	4,123	4,055
Interest expense carryforward	3,121	2,188
Foreign timing differences	578	238
Other	1,095	873
Net operating loss carryforwards	53,666	50,702
	63,990	59,733
Deferred tax liabilities:		
Unremitted foreign earnings	(463)	(453)
Depreciable assets	(93)	(185)
	(556)	(638)
Total net deferred tax assets	63,434	59,095
Less valuation allowance	(63,243)	(59,049)
Net deferred tax assets (included in other assets)	$ 191	$ 46

The Company has established a valuation allowance 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 $4,194 during the year ended December 31, 2020, primarily as a result of changes in net operating loss.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act was signed into law making several changes to the Internal Revenue Code; however, the tax law changes in the Act did not have a material impact on the Company’s income tax provision.

As of December 31, 2020, 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% to income before income taxes as a result of the following:

	2020	2019
Tax at U.S. statutory rate	$ (4,719)	$ (5,703)
State taxes, net of deferred benefit	(536)	(1,051)
Foreign tax rate differential	(327)	(330)
Foreign taxes	(13)	22
Permanent differences	702	442
Research and development tax credit	(313)	(408)
Other	365	478
Deferred tax adjustment	756	(1)
Unremitted foreign earnings	33	6
Valuation allowance - current year	4,194	6,820
Income tax expense	$ 142	$ 275

Income tax expense consists of the following:

	2020	2019
Current taxes:		
U.S. state	$ 11	$ —
International	279	321
Total current income tax expense	290	321
Deferred taxes:		
International	(148)	(46)
Total deferred income tax expense	(148)	(46)
Income tax expense	$ 142	$ 275

As of December 31, 2020, the Company had U.S. federal net operating loss carryforwards of approximately $223,602, of which $79,764 has an unlimited life and the remaining amount 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, 2020 were $122,777. However, the Company's deferred tax asset value for this section 382 reduction is not reflected in the table above until written off in a future tax return. There have been no additional section 382 reductions through December 31, 2020.

The deferred tax asset associated with net operating loss carryforwards has been 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 $108,111 which will begin to expire in varying amounts beginning in 2021, if not utilized. The Company had foreign net operating losses of approximately $2,382 which do not expire.

(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, convertible debt, 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 on a weighted average basis):

	Year Ended December 31	
	2020	2019
Warrants for common stock	8,068,615	590,672
Convertible debt	6,310,621	2,440,904
Common stock options	2,520,029	1,699,410
Restricted stock units	487,636	169,808
	17,386,901	4,900,794

(17) 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.

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, 2020				Year Ended December 31, 2019			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 15,774	$ 9,955	$ 25,729	61.2 %	$ 14,944	$ 13,365	$ 28,309	55.8 %
IGB	5,045	9,739	14,784	35.2 %	5,162	11,678	16,840	33.2 %
Total Endoscopy	20,819	19,694	40,513	96.4 %	20,106	25,043	45,149	89.0 %
Surgical	—	—	—	— %	—	3,712	3,712	7.3 %
Other	1,453	82	1,535	3.6 %	1,815	37	1,852	3.7 %
Total revenues	$ 22,272	$ 19,776	$ 42,048	100.0 %	$ 21,921	$ 28,792	$ 50,713	100.0 %
% Total revenues	53.0 %	47.0 %			43.2 %	56.8 %		

Total distributor sales were 35.2% and 33.9% of total OUS revenues for the years ended December 31, 2020 and 2019, respectively. Sales in the next largest individual country outside the U.S. were 7.6% for both the years ended December 31, 2020 and 2019.

The following table represents property, equipment and right-of-use assets based on the physical location of the asset:

	2020	2019
U.S.	$ 2,149	$ 2,934
Costa Rica	3,641	3,039
Other	431	639
Total property, equipment and right-of-use assets	$ 6,221	$ 6,612

(18) Subsequent Events

In February 2021, the Company entered into the Eighth Amendment to the Credit Agreement which established the revenue covenant requirements for 2021.

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

None

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, 2020 our disclosure controls and procedures were effective at a reasonable assurance level.

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, 2020 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 effective as of December 31, 2020.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Since we are a smaller reporting company and a non-accelerated filer, the rules of the Securities and Exchange Commission permits us to provide only management's report on internal controls over financial reporting in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

On February 24, 2021, the Company entered into the Eighth Amendment to the Credit Agreement which established the revenue covenant requirements for 2021.

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 2020 fiscal year pursuant to Regulation 14A for our 2021 Annual Meeting of Stockholders, (the "2021 Proxy Statement") and the information to be included in the 2021 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 2021 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in our 2021 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 2021 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 2021 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 2021 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, 2020:

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
4.6	Form of 6.0% Convertible Debenture due 2024	8-K	001-35706	4.1	August 16, 2019
4.7 *	Description of Securities				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.1	Amendment, dated as of December 4, 2020, to the Securities Purchase Agreement, dated as of August 7, 2019, by and among Apollo Endosurgery, Inc. and the purchasers named therein, and the 6.0% Convertible Debentures due 2024.	Form 8-K	001-35706	10.2	December 7, 2020
10.2	Addendum No. 2 to Office Lease Agreement dated August 7, 2014 between Apollo Endosurgery Costa Rica and BCR Fondo de Inversion Inmobiliario	10-Q	001-35706	10.1	November 5, 2020
10.3++	Securities Purchase Agreement, dated as of July 17, 2020, by and among Apollo Endosurgery, Inc. and the purchasers named therein.	Form 8-K	001-35706	10.1	July 22, 2020
10.4	Registration Rights Agreement, dated as of July 17, 2020, by and among Apollo Endosurgery, Inc. and the purchasers named therein.	Form 8-K	001-35706	10.2	July 22, 2020
10.5	Form of Pre-Funded Warrant, dated as of July 21, 2020, issued by Apollo Endosurgery, Inc.	Form 8-K	001-35706	10.3	July 22, 2020
10.6#	2020 Bonus Plan	8-K	001-35706	10.1	March 5, 2020
10.7#	Offer Letter, dated November 19, 2014, between Apollo Endosurgery, Inc. and Bret Schwartzhoff	S-4	333-214059	10.18	October 11, 2018
10.8#	Gostout offer letter, dated December 9, 2016	10-K	001-35706	10.11	March 1, 2018
10.9#	John Molesphini Offer Letter	10-Q	001-35706	10.2	May 3, 2018
10.10#	Form of Change in Control Agreement	8-K	001-35706	10.1	May 30, 2018
10.11#	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
10.12#	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
10.13	Employment Agreement Effective March 1, 2020 by and between the Company and Charles McKhann				
10.14#	Non-Employee Director Compensation Policy May 2018 amendment	10-Q	001-35706	10.5	August 8, 2018
10.15#	Form of Indemnification Agreement	10-Q	001-35706	10.6	August 8, 2018
10.16	Loan and Security Agreement, dated March 15, 2019, by and among the Company, Solar Capital, Ltd, the guarantors party thereto, and the lenders.	10-K	001-35706	10.1	March 18, 2019
10.17	Second Amendment, dated August 7, 2019, to the Loan and Security Agreement, dated March 15, 2019, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders.	8-K	001-35706	10.5	August 16, 2019
10.18	Third Amendment to Loan and Security Agreement, Waiver and First Amendment to Fee Letter	10-Q	001-35706	10.1	October 30, 2019

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.19	Fourth Amendment and Limited Waiver to Loan and Security Agreement, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders	Form 8-K	001-35706	10.1	May 4, 2020
10.20	Fifth Amendment and Limited Waiver to Loan and Security Agreement and Second Amendment to Fee Letter, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders	Form 8-K	001-35706	10.2	May 4, 2020
10.21	Sixth Amendment, dated July 17, 2020, to the Loan and Security Agreement, dated March 15, 2019, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders.	Form 8-K	001-35706	10.4	July 22, 2020
10.22	Seventh Amendment, dated December 4, 2020, to the Loan and Security Agreement, dated March 15, 2019, by and among Apollo Endosurgery, Inc., Solar Capital Ltd., the guarantors party thereto, and the lenders.	Form 8-K	001-35706	10.1	December 7, 2020
10.23	Eighth Amendment, dated February 24, 2021, to the Loan and Security Agreement, dated March 15, 2019, by and among Apollo Endosurgery, Inc., Solar Capital Ltd., the guarantors party thereto, and the lenders.				
10.24	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
10.25	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
10.26	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
10.27#	Apollo Endosurgery, Inc. 2017 Equity Incentive Plan	8-K	001-35706	10.1	June 13, 2017
10.28#	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
10.29#	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
10.30#	Apollo Endosurgery, Inc. 2016 Equity Incentive Plan and forms of agreements relating thereto	S-4	333-214059	10.2	October 11, 2016

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
10.31#	Apollo Endosurgery, Inc. 2006 Stock Option Plan and forms of agreements relating thereto	S-4	333-214059	10.1	October 11, 2016
10.32++	Securities Purchase Agreement, dated as of August 7, 2019, by and among Apollo Endosurgery, Inc. and the purchasers named therein.	8-K	001-35706	10.1	August 16, 2019
10.33	Registration Rights Agreement, dated as of August 7, 2019, by and among Apollo Endosurgery, Inc. and the purchasers named therein.	8-K	001-35706	10.2	August 16, 2019
10.34	Subsidiary Guarantee, dated as of August 12, 2019, issued by Apollo Endosurgery International, LLC, Apollo Endosurgery Costa Rica S.R.L., Apollo Endosurgery US, Inc., Lpath Therapeutics Inc. and Apollo Endosurgery UK Ltd.	8-K	001-35706	10.3	August 16, 2019
10.35	Pre-funded Warrant, dated as of August 12, 2019, issued by Apollo Endosurgery, Inc.	8-K	001-35706	10.4	August 16, 2019
21.1	List of Subsidiaries	S-4	333-214059	21.1	October 11, 2016
23.1 *	Consent of Moss Adams LLP, Independent Public Accounting Firm to Apollo Endosurgery, Inc.				
23.2 *	Consent of KPMG LLP, Independent Public Accounting Firm to Apollo Endosurgery, Inc.				
31.1 *	Certification of Chief Executive Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
31.2 *	Certification of Chief Financial Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
32.1 * †	Certification of Chief Executive Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
32.2 * †	Certification of Chief Financial Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

Management contract or compensation plan or arrangement

* Provided herewith.

† In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

+ + Pursuant to Item 601 of Regulation S-K, the schedules to the applicable exhibit (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 February 25, 2021 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 February 25, 2021.

Signature	Title	Date
/s/ Todd Newton Todd Newton	Chief Executive Officer and Director *(Principal Executive Officer)*	February 25, 2021
/s/ Stefanie Cavanaugh Stefanie Cavanaugh	Chief Financial Officer, Treasurer and Secretary *(Principal Financial Officer)*	February 25, 2021
/s/ Chrissy Citzler-Carr Chrissy Citzler-Carr	Controller *(Principal Accounting Officer)*	February 25, 2021
/s/ John Barr John Barr	Chairman of the Board	February 25, 2021
/s/ Rick Anderson Rick Anderson	Director	February 25, 2021
/s/ Julie Shimer Julie Shimer	Director	February 25, 2021
/s/ William D. McClellan, Jr. William D. McClellan, Jr.	Director	February 25, 2021
/s/ R. Kent McGaughy, Jr. R. Kent McGaughy, Jr.	Director	February 25, 2021

/s/ David C. Pacitti David C. Pacitti	Director	February 25, 2021
/s/ Bruce Robertson, PH.D. Bruce Robertson, Ph.D.	Director	February 25, 2021

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Apollo Endosurgery, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

General

The following summary of the terms of our common stock is based upon our amended and restated certificate of incorporation and our amended and restated bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which are filed as exhibits to our Annual Report on Form 10-K, of which this Exhibit 4.7 is a part, and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law, or the DGCL, for more information.

We have authorized capital stock of up to (i) 100,000,000 shares of common stock, par value $0.001 per share and (ii) 15,000,000 shares of preferred stock. As of January 31, 2021, there were 25,983,847 shares of common stock issued and outstanding, which shares were held by 103 stockholders of record, and no shares of preferred stock outstanding.

Common Stock

All outstanding shares of our common stock are fully paid and nonassessable.

Voting Rights

Holders of our common stock are entitled to one vote for each share on all matters submitted to a stockholder vote, except matters that relate only to a series of preferred stock.

In general, stockholder action (except for certain bylaw amendments and certain amendments to our amended and restated certificate of incorporation, which requires the affirmative vote of at least two-thirds of the shares entitled to vote) is based on the affirmative vote of holders of a majority of the shares of common stock represented either in person or by proxy and entitled to vote on such action. Directors are elected by majority vote, unless there is a contested election in which case the bylaws provide for plurality voting.

Dividends

Subject to limitations under Delaware law and preferences that may apply to any then-outstanding shares of preferred stock, holders of our common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by the board of directors in its discretion from funds legally available therefor.

Dividends, if any, will be contingent upon revenues and earnings, if any, and capital requirements and financial conditions. The payment of dividends, if any, will be within the discretion of the board of directors. We presently intend to retain all earnings, if any, and accordingly the board of directors does not anticipate declaring any dividends.

Liquidation

In the event of a liquidation, dissolution or winding up, the holders of common stock are entitled to share pro rata all assets remaining after payment in full of all liabilities and after providing for each class of stock, if any, having preference over the common stock, subject to the liquidation preference of any then outstanding shares of preferred stock.

Miscellaneous

Holders of common stock have no pre-emptive rights, no conversion rights and there are no redemption provisions applicable to the common stock.

Preferred Stock

Our preferred stock, par value $0.001 per share, may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the board of directors (authority to do so being hereby expressly vested in our board of directors). The issuance of preferred stock may delay, deter or prevent a change in control. The

description of preferred stock above is not complete. You should refer to any applicable certificate of designation for complete information.

Advanced Notice Requirement

Our bylaws contain advance notice requirements for business to be brought before an annual or special meeting of stockholders, including nominations of persons for election as directors. As a result, stockholders must satisfy specific timing and information requirements in order to have a proposal considered at or in order to nominate a person for election as a director at an annual or special meeting. Any proposal or nomination that fails to comply with these timing and information requirements may be disqualified.

No Cumulative Voting

Our amended and restated certificate of incorporation does not include a provision for cumulative voting for directors.

Authorized but Unissued Shares

The authorized but unissued shares our common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control by means of a proxy contest, tender offer, merger or otherwise.

Size of Board and Vacancies

Our amended and restated bylaws provide that the number of directors on the board of directors is fixed exclusively by the board of directors. Newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the board of directors resulting from death, resignation or other cause (including removal from office by a vote of the stockholders) may be filled only by (i) a majority vote of the directors based on the total number of designated directors, though less than a quorum, or by the sole remaining director or (ii) the stockholders holding a majority of the voting power of all of the then outstanding shares of capital stock of our company authorized by law or by the charter to vote on such action at a duly called annual meeting or a duly called special meeting of stockholders (including the special election meeting discussed below). The directors so chosen shall hold office for a term expiring at the next annual meeting of stockholders, and until their respective successors are elected, except in the case of the death, incapacity, resignation or removal of any director.

Amendments of Governance Documents

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the affirmative vote of the holders of at least 66 2/3% of the voting stock then outstanding is required to amend certain provisions relating to the number, term, election and removal of its directors, the filling of its board vacancies, stockholder notice procedures, the calling of special meetings of stockholders, stockholders ability to act by written consent, and the indemnification of directors.

Limitations on Liability, Indemnification of Officers and Directors and Insurance

Our amended and restated certificate of incorporation includes provisions that require us to indemnify, to the fullest extent allowable under the DGCL, our directors and officers for monetary damages for actions taken as a director or officer, or for serving at our request as a director or officer or another position at another corporation or enterprise, as the case may be. Our amended and restated certificate of incorporation also provides that we must advance reasonable expenses to directors and officers, subject to receipt of an undertaking from the indemnified party as may be required under the DGCL.

Anti-Takeover Effects of Provisions of Our Charter Documents

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of the company to first negotiate with the board of directors. The benefits of increased protection of the potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire the company because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The authority of our board of directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest or otherwise by making it more difficult

or more costly to obtain control of the company. The board of directors may issue preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Indemnification

We are also expressly authorized by the DGCL to carry directors' and officers' insurance to protect the company, its directors, officers and certain employees for some liabilities. The indemnification and advancements provisions in our amended and restated certificate of incorporation and amended and restated bylaws, respectively, may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit our company and its stockholders. The indemnification provisions will not alter the liability of directors under the federal securities laws. In addition, your investment may be adversely affected to the extent that, in a derivative or direct suit, our company pays the litigation costs of the directors and officers and the costs of settlement and damage awards against directors and officers pursuant to these indemnification and advancements provisions.

We maintain standard policies of insurance that provide coverage (i) to directors and officers against loss arising from claims made by reason of breach of duty or other wrongful act and (ii) to us with respect to indemnification and advancements payments that it may make to such directors and officers.

We have entered into indemnification agreements with each of our officers and directors. These agreements require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to our company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. The limitation of liability provision in our amended and restated certificate of incorporation and the indemnification agreements may facilitate our ability to continue to attract and retain qualified individuals to serve as directors and officers.

Insofar as the above described indemnification provisions permit indemnification of directors, officers or persons controlling our company for liability arising under the Securities Act, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 15,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least a majority of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation and amended and restated bylaws each provide that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, or other employee of the corporation to the corporation or the corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim that is governed by the internal affairs doctrine. These exclusive-forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. The Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to the foregoing forum selection provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons.

Our amended and restated certificate of incorporation does not contain a similar provision providing that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations thereunder because the provision is included in our amended and restated bylaws. If any court of competent jurisdiction were to find this exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable, including due to its absence from our amended and restated certificate of incorporation, we may incur additional costs associated with resolving such matters in other jurisdictions. For example, if the Delaware Supreme Court does not ultimately overturn the Court of Chancery's recent determination that such a provision is not enforceable, we may incur similar additional costs.

Anti-Takeover Effects of Delaware Law

Our company is subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 generally prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of either the assets or outstanding stock of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person who, together with affiliates and associates, beneficially owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in management.

It is possible that these provisions may make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

Our common stock is listed on Nasdaq under the symbol “APEN.” The transfer agent and registrar for the common stock is Nevada Agency and Transfer Company. Its address is 50 West Liberty Street, Suite 880, Reno, Nevada, 89501, and its telephone number is (775) 322-0626.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “APEN.”

EMPLOYMENT AGREEMENT

Charles McKhann

EMPLOYMENT AGREEMENT (the "***Agreement***"), by and between Apollo Endosurgery, Inc. (the "***Company***") and Charles McKhann ("***Executive***") and, together with the Company, the "***Parties***").

WHEREAS, the Company desires to employ Executive pursuant to the terms, provisions and conditions set forth in this Agreement;

WHEREAS, Executive desires to be employed on the terms hereinafter set forth in this Agreement;

WHEREAS, Executive shall commence employment and this Agreement shall be effective on March 1, 2021 (the "***Effective Date***").

NOW, THEREFORE, in consideration of the promises and the mutual covenants herein contained, the Parties hereby agree as follows:

1. At-Will Employment. Executive shall be employed by the Company on an at-will basis, meaning either the Company or Executive may terminate Executive's employment at any time, with or without Cause (as defined below) or advanced notice. Any contrary representations that may have been made to Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between Executive and the Company on the "at will" nature of Executive's Employment, which may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive). Executive's rights to any compensation following a termination of employment shall be only as set forth in Section 9 below.

2. Position and Duties. Executive shall serve as the Company's President and Chief Executive Officer and as a member of the Company's Board of Directors (the ***"Board***"). Executive shall perform duties customary to such position, as reasonably assigned to him from time to time by the Board, to whom Executive shall report. Executive shall devote Executive's full business time and attention to the performance of Executive's duties hereunder and shall comply with all applicable laws, rules and regulations of self-regulatory organization to which the Company is subject and Company policies to which Executive is subject. Executive shall not engage in any other business, profession or occupation for compensation or otherwise which would conflict or interfere with the rendition of such services; *provided, that* nothing herein shall preclude Executive from (i) with the prior written consent of the Board, serving on the board of directors of other for-profit companies that do not compete with the Company, (ii) serving on civic or charitable boards or committees, and (iii) managing personal investments, so long as all such activities described in (i) through (iii) herein do not materially interfere with the performance of Executive's duties and responsibilities under this Agreement. Executive may continue to maintain his primary residence in Minneapolis, Minnesota and, subject to the business needs of the Company and the reasonable satisfaction of the Board, perform his services remotely, travel on Company business and be on site at the Company's offices as needed.

3. Compensation, Policies and Benefits.

(a) Base Salary. The Company shall pay Executive an initial base salary for services rendered under this Agreement at an annualized rate of $450,000.00 (or $18,750 on a semi-monthly basis) (the "***Base Salary***"), less standard payroll deductions and withholdings. Executive shall be paid in accordance with Company practice and policy. Executive's Base Salary shall be reviewed and adjusted from time to time by the Board or a duly authorized committee.

(b) Annual Bonus. Subject to the achievement, as determined by the Board or a duly authorized committee thereof in good faith, of performance milestones mutually agreed upon by Executive and the Board or a duly authorized committee thereof and based on such other criteria determined by the Board or a duly authorized committee thereof in its sole discretion, Executive shall be eligible to earn an annual cash bonus ("***Annual Bonus***") in a target amount of eighty percent (80%) of Executive's then-current Base Salary ("***Bonus Target***"). Notwithstanding the foregoing, Executive shall be eligible to earn an accelerated annual bonus (a "***Bonus Accelerator***") in a target amount of up to a maximum of 200% of Executive's then-current Bonus Target amount in the event that the Company exceeds certain Company financial objectives as established and approved by the Board in its sole discretion for each year. If a Bonus Accelerator is achieved and approved by the Board in a calendar year, it will be in the Board's discretion to determine the actual amount of Executive's earned bonus for that year which will not be more than 200% of Executive's then-current Bonus Target. For calendar year 2021, Executive's bonus eligibility shall be pro-rated based on the percentage of the year he is employed. If Executive leaves the employ of the Company prior to payment of any Annual Bonus, except as set forth in Sections 9(a), 9(b) and 9(d), Executive will not have earned, and will not be eligible for, an Annual Bonus, pro-rated or otherwise. Except as set forth in Section 9(a), 9(b), and 9(d), Executive must be employed on the day the Annual Bonus (if any) is paid in order to earn the Annual Bonus. Except as set forth in Section 9(d), the Annual Bonus earned for any given year will be paid to Executive on the date on which annual bonuses are paid to all other senior executives of the Company, but in no event later than March 15 of the year following the year in which Executive's right to the Annual Bonus is no longer subject to a substantial risk of forfeiture, so as to comply with Treasury Regulation Section 1.409A-1(b)(4).

(c) Equity Grants.

(i) Time-Based Vesting Option. Executive will be issued an option (the "***Option***") to purchase 848,733 shares of the Company's common stock pursuant to a written Stock Option Agreement between Executive and the Company. The Company will use its reasonable best efforts to issue the Option as soon as possible following the Effective Date. Except as set forth in Section 9(d), the Option shall vest and become exercisable according to the following schedule: 25% of the shares will vest as of one year from Executive's initial date of employment, and the remaining 75% of the shares will vest in equal monthly installments at the end of each calendar month thereafter over the following three (3) years, subject to Executive's Continuous Service (as defined in Section 12(o) of the Company's 2017 Equity Incentive Plan) with the Company on such dates. Vesting will commence on the Effective Date. The Option will be a nonqualified stock option and will have an exercise price per share based upon the fair market value of the Company's common stock on the date of grant. The Company intends for

the Option to be a material inducement to Executive's employment by the Company within the meaning of Listing Rule 5635(c)(4) of The Nasdaq Stock Market LLC. Executive may be eligible for additional annual equity grants at the discretion of the Board and any compensation policy for directors adopted by the Board from time to time.

(ii) Performance-Based Vesting Restricted Stock Units. Executive will be issued a second grant consisting of a restricted stock unit award for 707,278 shares of the Company's common stock pursuant and subject to a written Equity Agreement between Executive and the Company (the "***Performance-Based Vesting RSU***", and together with the Option, the "***Awards***"). The Company will use its reasonable best efforts to issue the Performance-Based Vesting RSU as soon as possible following the Effective Date. The Performance-Based Vesting RSU shall vest according to the following schedule: (a) 25% of the shares subject to the Performance-Based Vesting RSU will vest upon achievement by the Company of $50 million in annual revenue; (b) 25% of the shares subject to the Performance-Based Vesting RSU will vest upon achievement by the Company of $65 million in annual revenue; (c) 25% of the shares subject to the Performance-Based Vesting RSU will vest upon achievement by the Company of $80 million in annual revenue; and (d) 25% of the shares subject to the Performance-Based Vesting RSU will vest upon achievement by the Company of $95 million in annual revenue. In the event that any shares subject to the Performance-Based Vesting RSU have not vested on the earlier of Executive's last day as an Employee, Consultant, or Non-Employee Director (in each case, as defined in the 2017 Equity Incentive Plan) and the end of the sixteenth (16^{th}) full fiscal quarter following the Effective Date, the unvested shares of the Performance-Based Vesting RSU shall expire in its entirety on that date. For purposes of determining achievement of vesting conditions of the Performance-Based RSU, annual revenue shall be calculated on the basis of the trailing completed four (4) fiscal quarters. The Company intends for the Performance-Based Vesting RSU to be a material inducement to Executive's employment by the Company within the meaning of Listing Rule 5635(c)(4) of The Nasdaq Stock Market LLC.

(iii) Acceleration. In the event of a Change in Control (as defined in the 2017 Equity Incentive Plan), one-hundred percent (100%) of the Option shall become vested and exercisable as of the date immediately prior to the effective time of the Change in Control. In addition, the vesting of shares of the Performance-Based Vesting RSUs shall accelerate as follows upon a Change in Control: (a) if the Change in Control occurs in a transaction in which the deemed value per share of the Company's common stock is at least two (2) times the last reported sale price of the Company's common stock on The Nasdaq Global Market on the grant date of the Performance-Based Vesting RSUs (the "***Closing Price***"), but less than three (3) times the Closing Price, fifty percent (50%) of the unvested shares subject to the Performance-Based Vesting RSU shall vest as of immediately prior to effectiveness of such Change in Control; (b) if the Change in Control occurs in a transaction in which the deemed value per share of the Company's common stock is at least three (3) times the Closing Price, one-hundred percent (100%) of the unvested shares subject to the Performance-Based Vesting RSU shall vest as of immediately prior to effectiveness of such Change in Control; and (c) without limiting the foregoing clauses (a) and (b), if within twenty-four (24) months following the Effective Date the Change in Control occurs in a transaction in which the deemed value per share of the Company's common stock is at least one and one-half (1½) times the Closing Price but less than two (2) times the Closing Price, twenty-five percent (25%) of the unvested shares subject to the

Performance-Based Vesting RSU shall vest as of immediately prior to effectiveness of such Change in Control. In addition, the Awards shall be subject to the vesting acceleration provision set forth in Section 9(d) below.

4. Company Policies and Benefits. The employment relationship between the Parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Executive shall be eligible to participate in the employee benefit plans of the Company on a basis no less favorable than such benefits are provided by the Company from time to time to the Company's other senior executives. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan or program. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

5. Vacation, Sick Leave and Holidays. Executive shall be eligible to accrue four (4) weeks of paid vacation and sick days during each year in accordance with the Company's vacation and sick leave policies and the restrictions on carry-over, payout and use contained therein. Executive shall also be entitled to all paid holidays given by the Company to its senior executives, administered in accordance with the Company's holiday policies.

6. Financial Planning Benefit. Executive shall be eligible to receive prompt reimbursement for personal financial planning services expenses incurred by Executive up to $4,000, subject to deductions for applicable tax withholdings, each year of his employment with the Company.

7. Expense Reimbursement. Executive shall be eligible to receive prompt reimbursement for all travel and business expenses reasonably incurred and accounted for by Executive (in accordance with the policies and procedures established from time to time by the Company) in performing services hereunder. For the avoidance of doubt, to the extent that any reimbursements (including any taxable benefits reimbursements) are subject to the provisions of Section 409A of the Code: (a) to be eligible to obtain reimbursement for such expenses Executive must submit expense reports within 30 days after the expense is incurred, (b) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (c) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (d) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

8. Indemnification; D&O Coverage. The Company, and its successors and/or assigns, will indemnify and defend Executive to the fullest extent permitted by the By-Laws and Certificate of Incorporation of the Company with respect to any claims that may be brought against Executive arising out of any action taken or not taken in Executive's capacity as an officer or director of any member of the Company pursuant to the terms and conditions of the Indemnification Agreement between the Parties of even date herewith (the "***Indemnification Agreement***"). In addition, Executive shall be covered as an insured in respect of Executive's activities as an officer of the Company by the Company's Directors and Officers liability policy

or other comparable policies obtained by the Company's successors, to the fullest extent permitted by such policies. The Company's indemnification obligations hereunder shall remain in effect following Executive's termination of employment with the Company.

9. Termination of Employment. The Parties acknowledge that as set forth in Section 1 of this Agreement, Executive's employment relationship with the Company is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause. The provisions in this Section 9 govern the amount of compensation, if any, to be provided to Executive upon termination of employment and do not alter this at-will status.

(a) Death. Executive's employment shall terminate upon Executive's death. Upon any such termination, Executive's estate shall be entitled to receive his Base Salary, accrued but unused paid vacation through the date of termination, together with any compensation and benefits payable to Executive based on his participation in any compensation or benefit plan, program or arrangement through the date of termination (together, the "***Accrued Amounts***"), plus the Annual Bonus, if any, in connection with completion of the fiscal year prior to the date of termination that would have been earned and payable to Executive under Section 3(b) had Executive remained an employee of the Company through the Annual Bonus payment date for that fiscal year (the "***Special Bonus***"). The Accrued Amounts and the Special Bonus shall be timely paid following the date of termination in accordance with applicable laws, not to exceed thirty (30) days. Any vested options will be exercisable by Executive's estate until the earlier of eighteen (18) months after his death or the expiration date of the options. All other benefits, if any, due to Executive's estate following Executive's termination due to death shall be determined in accordance with the plans, policies and practices of the Company; *provided*, *that* Executive's estate shall not be entitled to any payments or benefits under any severance plan, severance policy or similar program of the Company. Executive's estate shall not accrue any additional compensation (including any Base Salary or Annual Bonus) or other benefits under this Agreement following the effective date of the termination of employment due to Executive's death.

(b) Disability. The Company may terminate Executive's employment for Disability. "***Disability***" shall mean Executive's inability, due to physical or mental incapacity, to perform the essential functions of his position for a period of ninety (90) consecutive days or one hundred twenty (120) days during any consecutive six (6) month period, or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In conjunction with determining Disability for purposes of this Agreement, Executive hereby (i) consents to not more than two (2) reasonable medical examinations which are relevant to a determination of whether Executive is mentally and/or physically disabled, and (ii) agrees to furnish such medical information as may be reasonably requested for such determination. Upon any such termination, Executive shall be entitled to receive payment of the Accrued Amounts and the Special Bonus. All other benefits, if any, due to Executive following Executive's termination by the Company for Disability shall be determined in accordance with the plans, policies and practices of the Company; *provided*, *that* Executive shall not be entitled to any payments or benefits under any severance plan, severance policy or similar program of the Company. Executive shall not accrue

any additional compensation (including any Base Salary or Annual Bonus) or other benefits under this Agreement following the effective date of the such termination of employment.

(c) Termination for Cause; Termination by Executive without Good Reason. At any time, (i) the Company may terminate Executive's employment for Cause (as defined below) by Notice of Termination (as defined in Section 9(e)) or (ii) Executive may elect to terminate Executive's employment other than for Good Reason (as defined below); *provided*, *that* Executive shall be required to give, at least thirty (30) days in advance, a Notice of Termination, and the Company may elect to accelerate the timing of Executive's termination date upon receipt of such notice. "***Cause***" for Executive's termination will exist for a period of ninety (90) days following the Company's discovery of the happening of one or more of the following events: (i) Executive's gross negligence or willful misconduct in performance of his duties hereunder where such gross negligence or willful misconduct has resulted in or is likely to result in substantial and material damage to the Company or any of its subsidiaries; (ii) Executive's repeated absence from the Company in violation of Company policy or the written instructions of the Board, *provided*, Executive shall have a period of ten (10) days to cure such absence after receipt of written notice thereof; (iii) Executive's material and willful violation of any federal or state law that has resulted in or is likely to result in substantial and material damage to the Company or any of its subsidiaries; (iv) the commission of any act of fraud by Executive with respect to the Company; (v) Executive's conviction of a felony or a crime involving moral turpitude causing material harm to the standing and reputation of the Company; or (vi) Executive's incurable material breach of the Company's Invention, Confidential Information and Non-Competition Agreement (the ***"Non-Competition Agreement***"), including without limitation, Executive's theft or other misappropriation of the Company's proprietary information. Upon the termination of Executive's employment pursuant to this Section 9(c), Executive shall be entitled to receive payment of the Accrued Amounts. All other benefits, if any, due to Executive following Executive's termination of employment pursuant to this Section 9(c) shall be determined in accordance with the plans, policies and practices of the Company; *provided*, *that* Executive shall not be entitled to any payments or benefits under any severance plan, severance policy or similar program of the Company. Executive shall not accrue any additional compensation (including any Base Salary or Annual Bonus) or other benefits under this Agreement following the effective date of such termination of employment.

(d) Termination for Good Reason or Without Cause.

(i) Executive may terminate Executive's employment for Good Reason (as defined below), *provided* the Company has not previously notified him in writing of its intent to terminate his employment for Cause, and the Company may terminate Executive's employment without Cause (that is, other than by death, Disability or for Cause, in accordance with Section 9(a), 9(b) or 9(c), respectively). "***Good Reason***" shall mean the occurrence, without Executive's prior written consent, of any of the following events: (a) a material reduction in the nature or scope of Executive's responsibilities, duties and/or authority, including without limitation, Executive no longer being the sole CEO of the Company; (b) a change in Executive's reporting relationship such that Executive is no longer reporting directly and solely to the Board; (c) a material reduction in Executive's then-current Base Salary or Bonus Target percentage, which the Company and Executive agree is at least 10% of Executive's then-current Base Salary or Bonus Target; *provided,* that a reduction in Base Salary or target Bonus Target

percentage shall not be "Good Reason" to the extent the reduction is made as part of a broader compensation reduction program of the Company affecting a majority of similarly situated employees; (d) Executive is required to relocate from the Minneapolis, Minnesota metropolitan area; or (e) a material breach of this Agreement by the Company. No event described in clauses (a) through (e) above shall constitute Good Reason unless Executive delivers to the Company a Notice of Termination for Good Reason within ninety (90) days after the initial existence of the circumstances giving rise to Good Reason, within thirty (30) days following the receipt of such Notice of Termination for Good Reason the Company has failed to reasonably cure the circumstances giving rise to Good Reason, and Executive terminates his employment within thirty (30) days following the end of the 30 day cure period.

(ii) Upon the termination of Executive's employment hereunder pursuant to this Section 9(d), and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regarding to any alternative definitions thereunder, "***Separation from Service***"), the Company shall pay Executive the Accrued Amounts, and, subject to Executive's (a) returning all Company physical property in his possession or control; (b) complying with his post-termination obligations under this Agreement and the Non-Competition Agreement (subject to applicable materiality standards, notice and cure periods therein); (c) execution, delivery and non-revocation of a general release of all claims against the Company substantially in the form attached hereto as Exhibit A (the "***Release***") within the sixty (60) day period following the effective date of Executive's Separation from Service, (d) resigning from all positions held with the Company and any of its subsidiaries, including, but not limited to, any positions held on the Company's Board of Directors; and (e) complying with the Release including without limitation any non-disparagement and confidentiality provisions contained therein, Executive shall receive the following severance benefits (the "***Severance Benefits***"):

(1) (A) an amount equal to 12 months of Executive's then-current Base Salary, ignoring any decrease in Base Salary that forms the basis for Good Reason, paid in equal installments on the Company's normal payroll schedule over the 12 month period immediately following the date of Separation from Service, except as set forth in Section 9(d)(iii) below (the "***Salary Continuation***"), plus (B) an amount equal to the Bonus Target amount of the Annual Bonus, if any, in connection with completion of the fiscal year prior to the date of termination that would have been earned and payable to Executive under Section 3(b) had Executive remained an employee of the Company through the Annual Bonus payment date for that fiscal year plus (C) an amount equal to the Bonus Target amount of the Annual Bonus in effect in the fiscal year of Executive's Separation from Service, pro-rated for the period of time elapsed in the year of Executive's Separation from Service through such Separation from Service (e.g. 200 of 365 days);

(2) reimbursement no less frequently than monthly to Executive for amounts paid to obtain COBRA coverage for the lesser of (A) twelve (12) months from the date of Separation of Service, or (B) until such time as Executive is able to obtain health insurance from a subsequent employer;

(3) acceleration of the vesting of all time-based vesting equity awards previously granted to Executive (based upon duration of service and not the occurrence

of corporate events or milestones) as of the effective date of Separation from Service as to the number of shares that would have vested in accordance with the applicable vesting schedule as if Executive had been in service for an additional twelve (12) months after Executive's Separation from Service date. Such acceleration shall be effective as of the effective date of Executive's Separation from Service;

(4) extension of the time period in which Executive will be permitted to exercise the vested Options (and any other options subsequently granted to Executive) after his Separation from Service until the earlier of (i) the 1-year anniversary of his Separation from Service date; and (ii) the effective date of a Change in Control;

(5) extension of the time period in which shares of the Performance-Based vesting RSU may vest pursuant to the terms of Section 3(c)(ii) to the date that is the business day after the end of the day in which the Company reports its financial results for the second (2nd) completed fiscal quarter following the effective date of Executive's Separation from Service; and

(6) if such Separation from Service occurs within three (3) months prior to (contingent upon the occurrence of the Change in Control) , on or within twelve (12) months after a Change in Control, in each case (A) the shares subject to the Awards shall become vested and exercisable, as applicable, pursuant to Section 3(c)(iii), (B) one hundred percent (100%) of the shares subject to any other equity awards subsequently granted to Executive shall become vested and exercisable, in each case as of the later of (1) the date of Executive's Separation from Service and (2) immediately prior to effectiveness of such Change in Control, and (C) the Company will pay Executive an amount equal to 50% of the Bonus Target amount of the Annual Bonus in effect in the fiscal year of Executive's Separation from Service. For the avoidance of doubt, in the event Executive is eligible for receipt of Severance Benefits under this Section 9(d)(ii)(6), Executive will not receive the bonus payment for the Annual Bonus in effect in the fiscal year of the Separation of Service set forth in Section 9(d)(ii)(1)(C).

(iii) All of the Severance Benefits are subject to deductions for applicable tax withholdings. No Severance Benefits will be paid prior to the day that is sixty (60) days following the date of Separation from Service. On the sixtieth (60th) day following the date of Separation from Service, the Company shall pay in a lump sum the aggregate amount of the Salary Continuation that the Company would have paid Executive through such date had the payments commenced on the Separation from Service through such sixtieth (60th) day, with the balance paid thereafter on the applicable schedules described above.

(iv) All other benefits, if any, due Executive following a termination pursuant to this Section 9(d) shall be determined in accordance with the plans, policies and practices of the Company; *provided*, *that* Executive shall not be entitled to any payments or benefits under any other severance plan, severance policy or similar program of the Company. Payments under this Agreement are intended to fulfill any statutory obligation to provide notice or pay in lieu of notice. Executive shall not accrue any additional compensation (including any Base Salary or Annual Bonus) or other benefits under this Agreement following such the effective date of termination of employment.

(v) A material breach of the Company's obligations to pay Executive the Severance Benefits (other than as a result of a good faith dispute as to the existence of "Good Reason" or "Cause") that remains uncured for a period of thirty (30) days after written notice thereof (which written notice, if in connection with a dispute as to the existence of "Cause", shall not be delivered until at least ninety (90) days following the Company's discovery of the happening of one or more of the events set forth within the definition of "Cause" in Section 9(c) herein) shall relieve Executive of his post-employment non-competition and non-solicitation restrictions owed to the Company hereunder or in any other agreement with the Company.

(e) Notice of Termination. Any termination of Executive's employment by the Company or by Executive shall be communicated by written notice of termination to the other Party in accordance with the Notice requirements set forth in Section 11(e) of this Agreement.

(f) Taxes. Notwithstanding any other provision of this Agreement to the contrary, if payments made or benefits provided pursuant to this Section 9 or otherwise from the Company or any person or entity are considered "parachute payments" under Section 280G of the Code, then such parachute payments shall be limited to the greatest amount that may be paid to Executive under Section 280G of the Code without causing any loss of deduction to the Company under such section, but only if, by reason of such reduction, the net after tax benefit to Executive shall exceed the net after tax benefit if such reduction were not made. "***Net after tax benefit***" for purposes of this Agreement shall mean the sum of (i) the total amounts payable to Executive under Section 9, plus (ii) all other payments and benefits which Executive receives or then is entitled to receive from the Company or otherwise that would constitute a "parachute payment" within the meaning of Section 280G of the Code, less (iii) the amount of federal and state income taxes payable with respect to the foregoing calculated at the maximum marginal income tax rate for each year in which the foregoing shall be paid to Executive (based upon the rate in effect for such year as set forth in the Code at the time of termination of Executive's employment), less (iv) the amount of excise taxes imposed with respect to the payments and benefits described in (i) and (ii) above by Section 4999 of the Code. The determination as to whether and to what extent payments are required to be reduced in accordance with this Section 9(f) shall be made at the Company's expense by a nationally recognized certified public accounting firm as may be agreed to by the Company and Executive (the "***Accounting Firm***") and the Company and Executive shall take all actions reasonably available to them in accordance with the law to minimize the amount of excise taxes imposed with respect to Section 4999 of the Code. In the event of any mistaken underpayment or overpayment under this Agreement, as determined by the Accounting Firm, the amount of such underpayment or overpayment shall forthwith be paid to Executive or refunded to the Company, as the case may be, with interest at one hundred twenty (120%) of the applicable Federal rate provided for in Section 7872(f)(2) of the Code. Any reduction in payments required by this Section 9(f) shall occur in the following order: (1) any cash severance, (2) any other cash amount payable to Executive, (3) any benefit valued as a "parachute payment," (4) the acceleration of vesting of any equity awards that are options, and (5) the acceleration of vesting of any other equity awards. Within any such category of payments and benefits, a reduction shall occur first with respect to amounts that are not "deferred compensation" within the meaning of Section 409A and then with respect to amounts that are. In the event that acceleration of compensation from equity awards is to be reduced,

such acceleration of vesting shall be canceled, subject to the immediately preceding sentence, in the reverse order of the date of grant.

10. Invention, Confidential Information and Non-Competition Obligations; Non-Disparagement.

(a) Invention, Confidential Information and Non-Competition Agreement. The Parties hereto have entered into the Non-Competition Agreement, which may be amended by the Parties from time to time without regard to this Agreement. The Non-Competition Agreement contains provisions that are intended by the Parties to survive and do survive termination or expiration of this Agreement.

(b) Non-Disparagement. Each Party agrees not to disparage the other Party, any member thereof, and any of their respective officers, attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided* that a Party may respond accurately and fully to any question, inquiry or request for information when required by legal process.

11. Miscellaneous.

(a) Executive's Representations. Executive hereby represents and warrants to the Company that (i) Executive has read this Agreement in its entirety, fully understands the terms of this Agreement, has had the opportunity to consult with counsel prior to executing this Agreement, and is signing the Agreement voluntarily and with full knowledge of its significance, (ii) the execution, delivery and performance of this Agreement by Executive does not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which Executive is a party or by which he is bound, (iii) Executive is not a party to or bound by an employment agreement, non-compete agreement or confidentiality agreement with any other person or entity which would interfere in any material respect with the performance of his duties hereunder, and (iv) Executive shall not use any confidential information or trade secrets of any person or party other than the Company in connection with the performance of his duties hereunder.

(b) Waiver. Expect with respect to adjustments provided for in Section 3(a), no provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in a writing signed by Executive and an officer of the Company (other than Executive) duly authorized by the Board to execute such amendment, waiver or discharge. No waiver by either Party of any breach of the other Party of, or compliance with, any condition or provision of this Agreement shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

(c) Successors and Assigns.

(i) This Agreement is personal to Executive and without the prior written consent of the Company shall not be assignable by Executive otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by Executive's legal representatives.

(ii) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and, other than as set forth in Section 11(c)(iii), shall not be assignable by the Company without the prior written consent of Executive (which shall not be unreasonably withheld).

(iii) This Agreement shall be assignable by the Company to any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company; *provided that*, the Company shall require such successor to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. As used in this Agreement, "Company" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law or otherwise.

(d) Notice. For the purpose of this Agreement, notices and all other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally, if delivered by overnight courier service, or if mailed by registered mail, return receipt requested, postage prepaid, addressed to the respective addresses, as the case may be, as set forth below, or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notice of change of address shall be effective only upon receipt; *provided*, *however*, that (i) notices sent by personal delivery, email or overnight courier shall be deemed given when delivered, (ii) notices sent by facsimile transmission shall be deemed given upon the sender's receipt of confirmation of complete transmission, and (iii) notices sent by registered mail shall be deemed given two days after the date of deposit in the mail.

If to Executive, to such address (including Company email address) as shall most currently appear on the records of the Company.

With a copy that shall not constitute note to:

Greenstein Sellers, PLLC
825 Nicollet Mall
Suite 1648
Minneapolis, MN 55402
Attention: Justice Ericson Lindell

If to the Company, to its primary business location
Attention: Board of Directors

(e) Governing Law; Consent to Jurisdiction. THIS AGREEMENT WILL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS, WITHOUT GIVING EFFECT TO ANY CHOICE OF LAW OR CONFLICTING PROVISION OR RULE (WHETHER OF THE STATE OF TEXAS OR ANY OTHER JURISDICTION) THAT WOULD CAUSE THE LAWS OF ANY JURISDICTION OTHER THAN THE STATE OF TEXAS TO BE APPLIED. IN FURTHERANCE OF THE FOREGOING, THE INTERNAL LAW OF THE STATE OF TEXAS WILL CONTROL THE

INTERPRETATION AND CONSTRUCTION OF THIS AGREEMENT, EVEN IF UNDER SUCH JURISDICTION'S CHOICE OF LAW OR CONFLICT OF LAW ANALYSIS, THE SUBSTANTIVE LAW OF SOME OTHER JURISDICTION WOULD ORDINARILY APPLY. ANY ACTION TO ENFORCE THIS AGREEMENT MUST BE BROUGHT IN, AND THE PARTIES HEREBY CONSENT TO THE JURISDICTION OF, A COURT SITUATED IN STATE OF TEXAS. EACH PARTY HEREBY WAIVES THE RIGHTS TO CLAIM THAT ANY SUCH COURT IS AN INCONVENIENT FORUM FOR THE RESOLUTION OF ANY SUCH ACTION.

(f) Resolution of Disputes. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web addresses: (i) https://www.jamsadr.com/rules-employmentarbitration/ and (ii) https://www.jamsadr.com/rules-comprehensive-arbitration/). **Executive acknowledges that by agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"). In the event Executive intends to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that Executive or the Company would be entitled to seek in a court of law. Executive and the Company shall equally share all JAMS' arbitration

fees, or in such other manner to the extent required by, and in accordance with, applicable law to effectuate Executive's and the Company's agreement to arbitrate. Each party is responsible for its own attorneys' fees, except as expressly set forth in Executive's Invention, Confidential Information and Non-Competition Agreement. Nothing in this letter agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

(g) Compliance with Code Section 409A. It is intended that all of the payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether Severance Benefits, expense reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment under this Agreement shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments, including the Severance Benefits, upon Separation From Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation" (including as a result of the terms of Offer Letter), then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of Executive's Separation From Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided in this Agreement or in the applicable agreement. No interest shall be due on any amounts so deferred.

(h) Severability of Invalid or Unenforceable Provisions. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the Parties insofar as possible under applicable law.

(i) Advice of Counsel and Construction. Each Party acknowledges that such Party had the opportunity to be represented by counsel in the negotiation and execution of this Agreement. Accordingly, the rule of construction of contract language against the drafting party is hereby waived by each Party.

(j) Entire Agreement. This Agreement sets forth the entire agreement of the Parties in respect of the subject matter contained herein and supersedes all prior agreements, promises, covenants, arrangements, communications, representations or warranties, whether oral or written in respect of the subject matter contained herein.

(k) Withholding Taxes. The Company shall be entitled to withhold from any payment due to Executive hereunder any amounts required to be withheld by applicable tax laws or regulations.

(l) Section Headings. The headings of the Sections hereof are provided for convenience only and are not to serve as a basis for interpretation or construction, and shall not constitute a part, of this Agreement.

(m) Cooperation. During the period of Executive's employment and at any time thereafter, Executive agrees, to the extent permitted by applicable law or the rules of self-regulatory organizations, to cooperate (i) with the Company in the defense of any legal matter involving any matter that arose during Executive's employment with the Company, and (ii) with all government authorities on matters pertaining to any investigation, litigation or administrative proceeding pertaining to the Company. For a period of thirty (30) days following termination of Executive's employment for any reason, Executive shall fully cooperate with the Company in all matters relating to the winding up of Executive's pending work and the orderly transfer of any such pending work to such other employees as may be designated by the Company. Such cooperation may be performed remotely. The Company will reimburse Executive for any reasonable travel and out of pocket expenses incurred by Executive in providing such cooperation. The Company shall further reimburse Executive for any reasonable legal fees and costs incurred in complying with this provision.

(n) Survival. Sections 3(c)(iii), 8, 9(a), 9(b), 9(d), 9(f), 10 and 11 shall survive and continue in full force in accordance with their terms notwithstanding any termination of Executive's employment with the Company.

(o) Conditions. This Agreement is subject to satisfactory proof of Executive's right to work in the United States and, if requested, satisfactory completion of a Company-required background check. Executive agrees to assist as needed and to complete any documentation at the Company's request to meet these conditions.

(p) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument. This letter may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

[Signature Page Follow]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

APOLLO ENDOSURGERY, INC.

By:/s/ John Barr
John Barr
Chairman of the Board of Directors

EXECUTIVE

/s/ Charles McKhann
Charles McKhann

[Signature Page to Employment Agreement]

EIGHTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **EIGHTH AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of February 24, 2021 (the "**Amendment Effective Date**"), is made by and among Apollo Endosurgery, Inc., a Delaware corporation ("**Parent**"), Apollo Endosurgery US, Inc., a Delaware corporation ("**Apollo Endo**"), Apollo Endosurgery International LLC, a Delaware limited liability company ("**Apollo International**"), Lpath Therapeutics Inc., a Delaware corporation ("**Lpath**"; together with Parent, Apollo Endo and Apollo International, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of March 15, 2019 (as amended, by that certain First Amendment to Loan and Security Agreement, dated as of June 20, 2019, Second Amendment to Loan and Security Agreement, dated as of August 7, 2019, Third Amendment to Loan and Security Agreement, Waiver and First Amendment to Fee Letter, dated as of October 25, 2019, Fourth Amendment and Limited Waiver to Loan and Security Agreement, dated as of March 16, 2020 (as amended by the First Amendment to Fourth Amendment and Limited Waiver to Loan and Security Agreement, dated as of March 20, 2020), Fifth Amendment and Limited Waiver to Loan and Security Agreement and Second Amendment to Fee Letter, dated as of April 30, 2020, Sixth Amendment and Limited Waiver to Loan and Security Agreement, dated as of July 17, 2020, Seventh Amendment to Loan and Security Agreement, dated as of December 4, 2020, and as further amended restated, modified or supplemented from time to time, the "**Loan and Security Agreement**").

The Borrower has requested that Collateral Agent and the Lenders agree to certain amendments to the Loan and Security Agreement. Collateral Agent and the Lenders have agreed to such requests, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) Section 7.13(b) is hereby amended and restated in its entirety as follows:

7.13 (b) Minimum Specified Product Revenue. Permit Specified Product Revenue, measured on a trailing six-month basis on the last day of each month, to be lower than the following:

Month-End	Specified Product Revenue
June 2019	$22,000,000
July 2019	$22,000,000
August 2019	$21,750,000
September 2019	$22,250,000

October 2019	$22,500,000
November 2019	$22,500,000
December 2019	$22,000,000
January 2020	$19,628,818
February 2020	$20,006,809
March 2020	$22,100,000
April 2020	Not Tested
May 2020	Not Tested
June 2020	Not Tested
July 2020	Not Tested
August 2020	Not Tested
September 2020	Not Tested
October 2020	Not Tested
November 2020	Not Tested
December 2020	Not Tested
January 2021	$20,453,000
February 2021	$21,376,000
March 2021	$21,180,000
April 2021	$20,962,000
May 2021	$21,361,000
June 2021	$22,592,000
July 2021	$23,699,000
August 2021	$23,148,000
September 2021	$23,832,000
October 2021	$24,410,000
November 2021	$25,117,000
December 2021	$25,359,000
January 2022 and thereafter	80% of projected Specified Product Revenue in accordance with an annual plan submitted by Borrower to Lenders pursuant to Section 6.2(a)(iv), such plan to be approved by Borrower's board of directors and by Agent and Lenders in writing

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3. Conditions of Effectiveness. The effectiveness of this Amendment shall be subject to the satisfaction of each of the following conditions:

(a) **Fees and Expenses**. The Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 5(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, duly executed by the Borrower, in form and substance satisfactory to Collateral Agent.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4. Representations and Warranties. To induce the Lenders to enter into this Amendment, the Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Change; and (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Seventh Amendment Effective Date remains true and correct. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete in all material respects as of such earlier date).

SECTION 5. Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. The Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3 of this Amendment, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Collateral Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from

all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(d) **No Reliance**. The Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that the Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within five (5) Business Days of the Amendment Effective Date, the reasonable out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(h) **Complete Agreement; Amendments; Exit Fee Agreement**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents. For the avoidance of doubt and notwithstanding anything to the contrary in this Amendment, Borrower (a) reaffirms its obligations under the Exit Fee Agreement, including without limitation its obligation to pay the Exit Fee (as defined in the Exit Fee Agreement) if and when due thereunder, and (b) agrees that the defined term "Loan Agreement" as defined in the Exit Fee Agreement shall on and after the Amendment Effective Date mean the Loan and Security Agreement as amended by this Amendment and as may be amended, restated or modified from time to time on or after the Amendment Effective Date.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

(l) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

APOLLO ENDOSURGERY, INC.

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

APOLLO ENDOSURGERY INTERNATIONAL, LLC

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

APOLLO ENDOSURGERY US, INC.

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

LPATH THERAPEUTICS INC.

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

GUARANTOR:

APOLLO ENDOSURGERY UK LTD

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

GUARANTOR:

APOLLO ENDOSURGERY COSTA RICA S.R.L.

By /s/ Stefanie Cavanaugh
Name: Stefanie Cavanaugh
Title: Chief Financial Officer

COLLATERAL AGENT:

SOLAR CAPITAL LTD.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

LENDER:

LENDER:

SOLAR CAPITAL LTD.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME BDC SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP SF DEBT FUND L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-245652 and 333-233439) and Form S-8 (Nos. 333-215817, 333-218773, 333-223461, 333-231202, and 333-237919) of Apollo Endosurgery, Inc. (the "Company"), of our report dated February 25, 2021, relating to the consolidated financial statements of the Company, which report expresses an unqualified opinion, appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Moss Adams LLP

Dallas, Texas
February 25, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Apollo Endosurgery, Inc.:

We consent to the incorporation by reference in the registration statements of Apollo Endosurgery, Inc. on Form S-8 (Nos. 333-215817, 333-218773, 333-223461, 333-231202 and 333-237919) and on Form S-3 (Nos. 333-233439 and 333-245652), of our report dated March 26, 2020, with respect to the consolidated balance sheet of Apollo Endosurgery, Inc. and subsidiaries as of December 31, 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Apollo Endosurgery, Inc.

Our audit report dated March 26, 2020 contains an explanatory paragraph that states that the Company has suffered recurring losses from operations, cash flow deficits and debt covenant violations and has an accumulated deficit, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Austin, Texas
February 24, 2021

Exhibit 31.1

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

I, Todd Newton, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2021

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

Exhibit 31.2

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

I, Stefanie Cavanaugh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2021

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

Exhibit 32.1

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

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: February 25, 2021

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

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

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

Exhibit 32.2

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

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2020, to which this Certification is attached as Exhibit 32.2 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: February 25, 2021

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

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

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