

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, 2021  
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)

1120 S. Capital of Texas Highway, Building 1, Suite #300, Austin, Texas  
(Address of principal executive officers)

Registrant's telephone number (512) 279-5100

16-1630142  
(I.R.S. Employer  
Identification No.)

78746  
(Zip Code)

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 \$8.10 as reported on the Nasdaq Global Market on June 30, 2021 is \$192,292,615.

As of January 31, 2022, there were 39,623,333 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 2022 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, 2021.

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.

#### 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.
- Our future growth depends on developing clinical data that demonstrates the safety and efficacy of our products and the procedures that use our products.
- Our future growth depends on obtaining and maintaining adequate coverage and reimbursement for procedures performed with our products.
- 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.
- 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 and/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 and foreign regulatory authorities, 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, 510(k) clearances and foreign regulatory approvals to commercially market our products, we will continue to be subject to extensive regulatory oversight from the FDA and foreign regulatory authorities.
- 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.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a medical technology company primarily focused on the design, development and commercialization of next-generation, less invasive 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 primarily 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 neoplastic lesions in the esophagus, stomach or colon (also known as polypectomy, 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.

Beginning in 2021, we have revitalized our organization with the addition of key members to our senior leadership team, including our Chief Executive Officer, Chief Financial Officer, Vice President of U.S. Sales, Vice President of Marketing and Medical Education, and Vice President of Market Access and Reimbursement. By leveraging our team’s extensive experience to create clinically distinct solutions that improve patient lives, we have created a strong foundation for growth and believe that we are well-positioned to positively impact patient care and address substantial unmet clinical needs in gastroenterology and bariatrics. We intend to become a technology provider of choice for doctors, hospitals, healthcare systems, and payers.

## Recent Developments

In September 2021, we submitted a De Novo classification request to the FDA seeking FDA 510(k) classification and clearance for the Apollo ESG™ and Apollo REVISE™ systems, which consist of the OverStitch Endoscopic Suturing System and related components. Apollo ESG is intended for use in the endoscopic sleeve gastroplasty (“ESG”) procedure for weight loss and Apollo REVISE is intended for use in revision of bariatric surgery procedures. Pending FDA approval of the Apollo ESG and Apollo REVISE devices, we expect to begin education and marketing programs to expand visibility of the ESG procedures and thereby increase the use of OverStitch. If granted, we believe that clearance by the FDA for these weight loss indications will be a significant growth catalyst for us.

In October 2021, we completed a public offering of our common stock for aggregate gross proceeds of \$74.9 million. In December 2021, we entered into a term loan facility agreement with Innovatus Capital Partners, LLC to borrow up to \$100.0 million. We made an initial draw of \$35.0 million, which we used to repay our previous senior secured credit agreement in full. We are eligible to draw up to an additional aggregate \$40.0 million between July 1, 2023 and December 31, 2024, upon the achievement of certain minimum revenue thresholds. We are also eligible to draw an additional \$25.0 million to finance certain approved acquisitions between June 30, 2022 and June 30, 2024.

Following these financing transactions, we believe we are well-positioned to invest in our planned growth initiatives.

## 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. Our 2013 acquisition of Allergan’s obesity intervention division included their international sales distribution channel, which continues to be a strategic asset for us. In December 2018, we subsequently divested our assets related to the Surgical product line, including the LapBand system. Currently, over 45% of our revenue is derived from customers outside the United States.

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.”

“Orbera”, “OverStitch”, “X-Tack”, 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 products are offered in over 75 countries today, across a wide range of patient indications.

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](http://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](mailto: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.

## Apollo's Market and Strategy

Our vision is to be the industry leader and preferred technology partner for delivering innovative, cost-effective minimally invasive gastrointestinal and bariatric products that improve patient care. We provide products that advance endoscopic solutions for a wide range of patient needs ranging from gastrointestinal defect closure 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 are designed to remove or defer the need for traditional surgery.

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. For the year ended December 31, 2021, 63% of our total sales related to the OverStitch Endoscopic Suturing System and X-Tack Endoscopic HeliX Tacking System products and 35% related to the Orbera Intragastric Balloon System products.

Based on public research and management estimates, we believe that the historical addressable market for our endoscopy products is approximately \$215 million, consisting of a \$175 million primarily U.S. market for advanced upper gastrointestinal defect closure and a \$40 million global market for intragastric balloons. We intend to expand our future potential addressable market through new indications for our current products, new applications for existing solutions, increased clinical support and increased reimbursement.

We believe that, through the development of our current endoscopic suturing system, the advanced gastrointestinal procedures market, which includes defect closures in both the upper and lower gastrointestinal tracts, presents an aggregate global market opportunity of approximately \$850 million, including the potential U.S. market for polyp removal defect closures, which is expected to be in excess of \$500 million. Additionally, we aim to expand the indications for our Orbera and OverStitch products to continue addressing the approximately \$3.9 billion global endobariatric weight loss market.

Our development strategy is to further establish the medical relevancy of our products in areas of unmet medical need, such as addressing the needs of the approximately 10 million U.S. patients with non-alcoholic steatohepatitis, or NASH. NASH is the leading cause of liver transplants in women and patients over the age of 65. NASH treatment presents a large and growing market opportunity, having grown from \$1.9 billion in 2019 to \$2.9 billion in 2021 and projected to reach \$54 billion by 2027, representing a 59% estimated compound annual growth rate.

By leveraging our team's extensive experience to create clinically distinct solutions that improve patient lives, we have created a strong foundation for growth and believe that we are well-positioned to positively impact patient care and address substantial unmet clinical needs in gastrointestinal and weight loss applications. We intend to become a partner of choice for doctors, hospitals, healthcare systems, and payers. We are committed to attracting, engaging, and retaining the best talent in the industry.

We intend to continue to pursue regulatory clearance in key international markets where we believe there is strong market demand for our products to continue to broaden our portfolio of products through internal product development efforts, and will consider acquisitions that complement our current business.

The key elements of our strategy include:

### ***Support the continued adoption of our endoscopy products and establish Apollo as the market leader in GI defect closure and fixation.***

We intend to establish endoscopic suturing as a standard of care in GI defect closure and fixation through the continued market penetration of our flagship product, the OverStitch Endoscopic Suturing System, and the X-Tack Endoscopic HeliX Tacking System, which we launched in December 2020, expanding the clinical utility of our suturing technology to a larger population of gastrointestinal procedures in the lower GI tract.

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 peroral endoscopic myotomy, or 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 fully covered 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 by preventing repeat procedures and complications for the patient.

In the lower GI tract, there are over 21 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.

Currently, we have a presence in over 90% of the top 20 research hospitals and top 25 GI specialized hospitals in the U.S. We intend to leverage our clinical experience in these leading academic institutions and hospitals to further penetrate existing accounts, as well as expand our global user base, through clinical research, clinical selling and training, peer-to-peer education programs, industry and society collaborations, product enhancement, new product development initiatives and expanding regulatory indications and obtaining new regulatory approvals in strategic markets.

#### **Create an endoscopic weight loss franchise**

We intend to leverage our unique product portfolio to address the growing global obesity crisis. We believe that our Orbera intragastric balloon and OverStitch system provide a comprehensive set of scalable, safe, effective, organ-sparing solutions. The underlying procedures may be performed in an outpatient facility by either a gastroenterologist or a bariatric surgeon, positioning us to increase market penetration and potentially expand the market for weight loss procedures.

Worldwide obesity numbers have nearly tripled since 1975. More than 650 million people are now considered clinically obese. In the U.S., more than 100 million adults are obese, comprising in excess of 40% of the adult population. Obesity related conditions including heart disease, stroke, type 2 diabetes, liver disease, and certain types of cancer are among the leading causes of preventable, premature death. Obesity costs the U.S. health care system more than \$170 billion a year, yet, less than 1% of eligible obese patients are treated with bariatric surgical weight loss procedures each year.

Traditional obesity intervention has been bariatric surgery (typically, gastric bypass, sleeve gastrectomy or 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 elects to have a procedure each year. Based on published surveys, the eligible patients' primary resistance to bariatric surgery is fear of surgery in general, and 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.

Our Orbera intragastric balloon is currently the leading gastric weight loss balloon worldwide, with over 400,000 balloons placed globally to date. We expect to leverage recent market momentum, including clinical practice guidelines published by the American Gastroenterology Association in 2021 recommending the use of intragastric balloons for obesity management, to drive growth for our Orbera products.

One of the most promising newly developed weight-loss procedures is commonly referred to as endoscopic sleeve gastroplasty ("ESG"). ESG is a minimally-invasive (nonsurgical) weight loss procedure that uses the OverStitch Endoscopic Suturing System to transorally reduce the volume of a person's stomach; 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 potential advantages of an ESG procedure include maintaining the original structural and functional integrity of the stomach, providing clinically meaningful weight loss, low adverse events, reversibility, short recovery time, and avoidance of surgical incisions. We believe the application of OverStitch to bariatric weight loss procedures addresses many of the concerns that patients have about traditional bariatric surgeries. In addition, the ESG procedure has the potential to fill an important clinical gap between diet, exercise and medications for patients with a relatively low BMI and traditional bariatric surgeries that are often reserved for patients with a BMI > 40 kg/m<sup>2</sup>. To date, there have been more than 6,500 participants studied in ESG clinical trials. Clinically, these trials show average excess body weight loss greater than 50% and a low adverse event rate. In fact, clinical studies of the ESG procedures typically demonstrate a complication rate of less than 2%, whereas published studies of sleeve gastrectomy and RNY gastric bypass surgeries have reported complication rates ranging from 5% to 26%.

In addition, we believe that endoscopic revisions of bariatric surgeries present another potential market for application of our OverStitch products. Between 2011 and 2019, over 1.4 million laparoscopic sleeve and gastric bypasses were performed in the U.S. alone. We estimate that 30% to 50% of these are potential revision candidates. In 2019, more than 43,000 revision procedures were performed in the U.S. This revision segment is the fastest growing segment of the traditional bariatric surgery market. In a peer-reviewed study, published in 2021, that compared results at five years, endoscopic revision demonstrated equivalent efficacy and an improved safety profile as compared to surgical revision. We estimate that over 70% of our top 100 OverStitch accounts in the U.S. are already performing revision procedures.

In 2021, we announced that study investigators of the Multi-Center ESG Randomized Interventional Trial, or MERIT, presented positive outcomes evaluating the safety and effectiveness of the ESG procedure. These data, along with additional clinical evidence for ESG and revision procedures, have been submitted to the FDA through a De Novo request to create new device clearances specifically for ESG and bariatric revision procedures. If granted, we believe that clearance by the FDA for these weight loss indications will be a significant growth driver for us.

#### **Develop NASH indication and evidence**

Our development strategy is to further establish the medical relevancy of our products in areas of unmet medical need such as fatty liver disease, and to increase clinician awareness. In March 2021, the FDA granted a Breakthrough Device Designation for Orbera specifically for use in treating patients with BMI between 30-40 kg/m<sup>2</sup> with noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis.

The adult U.S. NASH population having a BMI between 30-40 kg/m<sup>2</sup> is approximately 10 million, and while there are currently no FDA approved treatments for NASH, weight loss is the recommended treatment and is essential for meaningful improvement in NASH.

Expanding the approval for Orbera, and potentially other Apollo products, will require the development of additional clinical data to support regulatory submissions to the FDA or foreign regulatory authorities. We are currently evaluating various clinical strategies to best optimize our approach to a potential treatment for NASH, which we believe has the potential to be a long-term growth driver for Apollo.

#### **Apollo Products**

The Apollo Endoscopy products consist primarily of the OverStitch Endoscopic Suturing System, X-Tack Endoscopic HeliX Tacking System (collectively “ESS”) and the IntraGastric Balloon System (most often branded as Orbera).

##### *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 one of the few 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 2008 is compatible with a specific dual channel flexible endoscope, sold by Olympus, that has limited market presence, representing less than five percent of the flexible endoscopes in hospitals and clinics around the world. We have updated the OverStitch labeling to include both Olympus and Fujinon endoscopes as compatible with OverStitch, reducing our reliance on Olympus. 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 75,000 OverStitch units have been sold for procedures worldwide. We estimate that approximately 60% of OverStitch uses in the U.S. were for advanced gastrointestinal therapies. The other uses were for endoscopic sleeve gastropasty, or ESG, approximately 25%, and bariatric revision, approximately 15%. Outside the U.S., we estimate that the majority of OverStitch uses, approximately 65%, were for ESG. The other uses outside the U.S. were for bariatric revision, approximately 20%, and for advanced gastrointestinal therapies, approximately 15%.

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. Several meta analyses have been published since 2019.



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 40.

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. In June 2021, one of the principal investigators of the MERIT trial reported that, based on a preliminary analysis, the MERIT trial had achieved its primary end points for safety and efficacy, and in October 2021, the primary investigators reported on the primary endpoints at a virtual session of the International Society for Surgery of Obesity (IFSO). We anticipate that the full trial results will be reported in 2022. The MERIT data, along with additional clinical evidence for ESGs and endoscopic revision procedures, have been submitted to the FDA through a De Novo 510(k) request to create new device clearances specifically for ESG and bariatric revision procedures.

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. Enrollment and follow up completed in 2021. The resulting data will be used to present the benefits of endoscopic suturing procedures relative to traditional therapies. Data from other endoscopic suturing procedures which have been collected in the registry has been analyzed and submitted for publication.

During 2018, we established a European multi-center, longitudinal data repository for ESG and outlet revision procedures. This registry collected outcomes for over 1,000 patients enrolled 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 endoluminal 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 publications from the data sets.

#### *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 both the lower and 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.

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 accurately closing large or irregularly shaped defects.

In December 2020, we received 510(k) clearance from the FDA for our X-Tack Endoscopic HeliX Tacking System. We commercially launched the X-Tack system in the U.S. beginning in January 2021. In 2021, we also received regulatory clearance in a limited number of markets outside the U.S., including Israel, Hong Kong, and Australia. We expect to launch X-Tack more broadly outside the U.S. following regulatory approvals, anticipated by early 2023.

The endoscopic removal of upper gastrointestinal and colorectal neoplasia has a 2% risk of perforation and 8-10% 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 wide 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.

In 2021, we announced the publication of a multi-center study of the X-Tack® System in closing challenging gastrointestinal defects. The multicenter study included 93 subjects who were treated at eight centers in the U.S., including the Mayo Clinic, Johns Hopkins Hospital, Brigham and Women's Hospital, and New York University, among others. The study focused on large, challenging defects in both the upper and lower GI tract, specifically those that would be difficult or impossible to close with alternative devices. The primary outcomes were feasibility (defined by technical success of the procedure) and safety. Technical success, defined as full closure of a defect or stent fixation as intended, was achieved in 89% of subjects. The mean defect size was 42 mm. Closure was determined not to have been possible with any device other than the X-Tack in 25% of cases studied due to size, location, or shape of the defect. No serious adverse events or deaths occurred during the follow up period of approximately 34 days.

In the first year of product adoption, physicians at a number of leading academic centers have been conducting additional clinical studies on the X-Tack device. In 2022, we anticipate multiple presentations or publications for the use of X-Tack in applications such as repair of an endoscopic mucosal resection (EMR) in the colon, repair of an EMR in the duodenum, and use in stent fixation.

#### *Orbera Intra gastric Balloon System*

The intragastric balloon system ("IGB", the "Orbera System" or "Orbera") is currently marketed under three brands depending on geography: the Orbera Intra gastric 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 400,000 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; 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 2021, the American Gastroenterology Association published clinical practice for Intra-gastric Balloons in the Management of Obesity. The guidelines suggest the use of intra-gastric balloons with lifestyle modification over lifestyle modification alone. Furthermore, the guidelines highlight the improvements in cardiovascular disease, diabetes and non-alcoholic fatty liver disease that are associated with a 10% reduction in total body weight loss.

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, and potentially other Apollo products, in areas of unmet medical need such as fatty liver disease and increase clinician awareness. In March 2021, the FDA granted a Breakthrough Device Designation for the Orbera Intra-gastric Balloon specifically for use in treating patients with BMI between 30-40 kg/m with noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis. Expanding the approval for Orbera will require the development of additional clinical data to support regulatory submissions to the FDA or foreign regulatory authorities.

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  $\geq 30$  kg/m<sup>2</sup> and BMI  $\leq 40$  kg/m<sup>2</sup>. 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 intra-gastric 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 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.

#### **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. Other 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, Endo Tools Therapeutics S.A., Steris (US Endoscopy) and Cook Medical. Outside the U.S., USGI Medical Inc. manufactures a suture anchor technology for gastric plication. 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 are two other manufacturers with an intragastric balloon approved by the FDA at this time: ReShape Lifesciences, Inc. and Spatz FGIA 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).

#### **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 Coyoil 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").

#### **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, 2021, 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 21 pending U.S. patent applications and 34 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 8 U.S. and 8 foreign issued patents and 2 pending U.S. 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.

### **Other U.S. Healthcare Laws**

Our business is regulated by laws pertaining to healthcare fraud and abuse including anti-kickback laws and false claims laws, and other healthcare laws. Violations of these laws are punishable by significant administrative, criminal and civil penalties, including, damages, disgorgement, monetary fines, possible exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid, imprisonment, and integrity oversight and reporting obligations.

#### **Anti-Kickback Statute**

The federal Anti-Kickback Statute prohibits, among other things, persons and entities 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. These exceptions and 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. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Activities and business arrangements that do not fully satisfy each applicable exception or safe harbor may result in increased scrutiny by government enforcement authorities such as the Office of the Inspector General (“OIG”).

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if “one purpose” of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (“FCA”) (discussed below).

Further, certain 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 and/or safe harbors to those provided by the federal Anti-Kickback Statute.

#### **Federal False Claims Act**

The FCA prohibits, among other things, 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 new federal crimes, including: 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, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), also protects the security and privacy of individually identifiable health information maintained or transmitted by certain 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. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. 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 ACA.

The Physician Payments Sunshine Act, which is part of the ACA, requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record payments and transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members 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.

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.

#### **Coverage, Reimbursement and Healthcare Reform**

Patients in the U.S. and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their healthcare 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 from time to time. 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.

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. In addition, consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.

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. The resulting pricing pressure from our hospital and ambulatory surgical center (“ASC”) customers due to cost sensitivities resulting from healthcare cost containment pressures and reimbursement changes could decrease demand for our products, the prices that customers are willing to pay and the frequency of use of our products, which could have an adverse effect on our business.

Moreover, in the U.S., there have been several presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Further, it is possible that additional government action will be taken in response to the COVID-19 pandemic.

### **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 was replaced by the Regulation 2017/745 on Medical Devices, or the MDR, effective as of 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 as of May 26, 2021, specifically the transition requirements dealing with registration, post-market surveillance, market surveillance and vigilance reporting. The company is scheduled to be audited by its Notified Body in February 2022 to verify that the Quality Management System meets the current requirements of the MDR. Additionally, all products have been submitted to our Notified Body for CE review against the new requirements of MDR. These reviews are ongoing and we expect initial comments on these reviews over the coming months. Our legacy products (which includes all products excluding X-Tack) are currently sold under the MDD until November 2022. X-Tack is slated to be our first product to be originally CE Marked through the MDR. To support compliance under the MDR, we intend to obtain additional clinical data for Orbera 365.

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.

### **Employee Management and Retention**

#### **Employees**

As of December 31, 2021, we had 107 employees in the U.S. and 95 outside the U.S. None of our employees are (i) represented by a labor union or (ii) are party to a collective bargaining agreement. We believe that we have good relationships with our employees.

### **Code of Business Conduct and Business Ethics**

We are dedicated to conducting our business consistent with the highest standard of business ethics. Each employee receives and agrees to follow the Apollo Endosurgery Code of Business Conduct and Ethics. Employees are encouraged to discuss any related concerns with management or report concerns anonymously through an Ethics Helpline.

### **Talent Management & Development**

We believe that our employees are the foundation of our business and we are committed to the development and retention of our workforce.

### **Compensation Philosophy**

To ensure we are able to attract, retain and develop high performing teams, we engage external compensation advisors to guide our efforts in developing cash and equity rewards programs that are competitive with our peer companies.

### **Other Benefits**

We offer competitive health and welfare programs to support our employees and their families' physical, mental, and financial well-being.

### **COVID-19 Health and Safety**

The health and safety of our employees is a key focus at our Company. In response to the COVID-19 pandemic, the Company established safety protocols, facility enhancements, and work from home strategies to protect our employees. Some of our employees continue to work remotely. Employees that work on site are required to adhere to applicable protocols and to report and document exposures, all following guidelines issued by the Centers for Disease Control or mandated by local regulations.

### **Available Information**

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

### **ITEM 1A. RISK FACTORS**

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

#### **Risks Related to Our Business**

##### ***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 and may continue to impact the global economy, our business and our industry. Given the uncertainty around the duration and extent of the COVID-19 pandemic, including due to emerging variant strains of the virus, we expect the COVID-19 pandemic may continue to impact our business, results of operations, and financial condition and liquidity, but cannot accurately predict at this time the full extent of the future potential impact on our business, results of operations, financial condition and liquidity.

Despite the growing availability of vaccinations against COVID-19, government authorities in certain jurisdictions around the world continue to impose or re-impose, as the case may be, “shelter-in-place” orders, quarantines, executive orders or similar government orders and restrictions for their residents to control the spread of COVID-19, including variants. Such orders or restrictions, and the perception that such orders or restrictions could continue or be reinstated, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions, labor shortages 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, limit our access to customers and limit customer use of our products to comply with government orders to address the public healthcare needs arising from the COVID-19 pandemic. The disruptions to our activities and operations have negatively impacted and may continue to negatively impact our business, operating results and financial condition. There is a risk that government actions will not be effective at containing further COVID-19 outbreaks, including from variants, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a 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, including due to emerging variant strains of the virus. The widespread pandemic has resulted, and may continue to result, in significant disruption of global financial markets, which could 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.

Continued restrictions on the ability to travel in certain jurisdictions, social distancing policies, orders and other restrictions, 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 for how long they will remain relaxed or lifted, or whether such jurisdictions will remain open, including as COVID-19 variants continue to spread in certain jurisdictions. There can be no assurances that patients or providers will continue restarting procedures that use our devices following 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 periodically deferred and may continue to defer their purchases of our products due to the 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. New variants or outbreaks of the virus, including the Omicron variant outbreak, have caused health systems and other healthcare providers in our markets to restrict or limit procedures using our devices or have experienced reductions in or cancellations of planned procedures by patients, which have harmed and may continue to harm our sales and growth. Further, quarantines or government reaction or shutdowns for COVID-19 could disrupt our supply chain. Renewed travel and import restrictions may also disrupt our ability to manufacture or distribute our devices and may materially increase the cost of raw materials and finished goods. 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 obtain raw materials, 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 that we have previously instituted, could reduce the efficiency of our operations or prove insufficient.

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. For example, enrollment for our Orbera365 CE post approval study has been and likely will continue to be 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. The presentation of the results of clinical trials may be delayed due to the cancellation or postponement of scientific meetings. In 2020, we had to prioritize key growth and operational projects over the others due to capital resource constraints resulting from our reduced sales levels and may in the future need to make similar choices, which may negatively impact our growth and operational projects.

Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers. While hospitals and healthcare providers have generally relaxed access restrictions, prior restrictions have harmed our sales and marketing efforts, and renewed restrictions, including due to variant strains of the virus, would have a negative impact on our sales and results of operations. An increase of COVID-19-related hospital admissions, including due to variant strains of the virus, 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.

The global outbreak of COVID-19, including the Delta and Omicron waves, 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, and the duration, continued spread and severity of the pandemic continues to be uncertain, including due to the spread of new variants or mutant strains of the virus as well as future spikes of COVID-19 infections. In addition, actions to contain the disease or treat its impact, the development, availability, and widespread acceptance of effective vaccines and treatments, further restrictions on travel, and the duration, timing and severity of the impact on customer spending, including any recession resulting from the pandemic, continue to be uncertain. However, these effects have harmed our business, financial condition and results of operations since the beginning of the pandemic 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, 2021 and 2020, we had net losses of \$24.7 million and \$22.6 million, respectively. As of December 31, 2021, we had an accumulated deficit of \$297.5 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 regulatory 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. Many of our products are designed to work in cooperation with third party equipment such as flexible endoscopes whose design, specifications and continued availability is outside of our control. Changes to the design or specifications, withdrawals from the market, limited availability or other changes that limit the use and acceptance of such third party equipment may limit the market for our products or make our existing products obsolete. 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 insurance 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 currently 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, geopolitical events (such as increasing tensions between Ukraine and Russia), higher consumer debt levels, lower availability of consumer credit, higher interest rates, inflation, 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 may depend 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;
- lack of adequate coverage and reimbursement for procedures performed with our products;
- 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 or competitive products, including pharmacological treatments or dietary software applications, 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 or competitive products that are perceived to be more effective or less expensive.

***Our future growth depends on developing clinical data that demonstrates the safety and efficacy of our products and the procedures that use our products.***

If clinical or pre-clinical trials with our products and the procedures that use our products do not result in positive outcomes for patients, fail to show meaningful patient benefit or fail or to achieve certain end points, the development of these procedures would be adversely impacted which could negatively impact the sales of our products, operations and financial condition. In March of 2021, the FDA granted a Breakthrough Device Designation for the Orbera Intra-gastric Balloon specifically for use in treating patients with BMI between 30-40 kg/m<sup>2</sup> with noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis. Orbera is currently approved by the FDA as a weight loss aid for adults suffering from obesity, with a body mass index (BMI)  $\geq 30$  and  $\leq 40$  kg/m<sup>2</sup>, who have tried other weight loss programs, such as following supervised diet, exercise, and behavior modification programs, but who were unable to lose weight and/or keep it off. Expanding the approval for Orbera will require the development of additional clinical data to support regulatory submissions to the FDA or foreign regulatory authorities. We cannot guarantee that we will be able to develop a study model that is acceptable to the FDA or that we can contract with an investigator who can timely initiate, enroll and complete such a study at a reasonable cost and who will complete such a study in a reasonable period of time.

Further, with any clinical or pre-clinical study relating to our products, we cannot guarantee that the results of any such study will be timely finalized and made public or that the results of any study will be viewed as favorable by regulatory authorities, physicians, patients or payors. For example, 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 Endoscopic Sleeve Gastroplasty ("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 kg/m<sup>2</sup>. ESG is an endoscopic procedure that involves the creation of plications in the stomach, through a series of stacked suture-based plications, to reduce stomach volume; the plications form a sleeve, which reduces stomach capacity and slows gastric emptying to induce weight loss. Adverse events that may occur during or following an ESG procedure include the following: pharyngitis/sore throat, nausea, vomiting, abdominal pain and/or bloating, hemorrhage, hematoma, conversion to laparoscopic or open procedure, stricture, infection, sepsis, pharyngeal and/or esophageal perforation, esophageal and/or pharyngeal laceration, intra-abdominal (hollow or solid) visceral injury, aspiration, acute inflammatory tissue reaction and death. Additional clinical risks may be identified as more clinical data on ESG is developed and analyzed. In June 2021, one of the principal investigators of the MERIT trial reported that, based on a preliminary analysis, the MERIT trial had achieved its primary end points for safety and efficacy, and outcomes data were published in the fourth quarter of 2021. These data have been submitted to the FDA through a De Novo request to create new devices specifically for ESG and bariatric revision procedures. However, we cannot assure you that such data will be timely reported or that the results will be viewed as favorable by physicians, patients, or regulatory agencies, including the FDA. A delay in making these outcomes results public or a failure to achieve favorable clinical outcomes would negatively impact our business.

***Our future growth depends on obtaining and maintaining adequate coverage and reimbursement for procedures performed with our products.***

If hospitals, surgeons, and other healthcare providers are unable to obtain and maintain coverage and reimbursement from third-party payors for procedures performed using our products, adoption of our products may be delayed, and the expansion of our business would be limited. Maintaining and growing sales of our products depends significantly on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, surgeons, and other healthcare providers that purchase or use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices.

Adequate coverage and reimbursement for procedures performed with our products is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if reimbursement levels are insufficient to support use of our products or compensate physicians for their time spent diagnosing patients and performing procedures using our products.

Market acceptance of our products in foreign markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. We may not obtain additional international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

***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 a 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.***

From time to time, we have experienced supply constraints and may experience them in the future. 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 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 industry 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 addressing potentially non-conforming product before it enters distribution, issuing formal field safety notices when pertinent new information becomes available, and when necessary, 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, in March 2021, we implemented a planned CEO change. The failure to successfully execute this leadership transition and retain key employees could have negatively impacted our business and results of operations.

In order to manage the impact of COVID-19, we implemented cost reduction programs including furloughs, salary reductions and work hour reductions that impacted all employees during 2020 and we have maintained some of these cost efficiencies. The introduction of these cost efficiency measures could increase the likelihood employees may voluntarily terminate employment. 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 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.

***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, as the U.K. diverges 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.

One of the new regulatory requirements associated with Brexit is that a local U.K. Responsible Person ("UKRP") must be appointed as responsible for regulatory affairs and that products must be registered by May 1, 2021. Apollo appointed a UKRP in March 2021 and is in the process of registering in the U.K. Failure to secure these registrations or to comply with new requirements could adversely effect our ability to do business in the U.K. Currently, Apollo is selling product under its existing CE Mark, which is allowed through June 2023.

**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 could result in pricing pressure which could have an adverse effect on our business.***

All third-party payors, whether governmental or commercial, whether inside the U.S. or outside, are developing increasingly sophisticated methods of controlling healthcare costs. These cost-control methods include prospective payment systems, bundled payment models, capitated arrangements, group purchasing, benefit redesign, pre-authorization processes and requirements for second opinions prior to major surgery. These cost-control methods also potentially limit the amount that healthcare providers may be willing to pay for our products. Therefore, coverage or reimbursement for medical devices may decrease in the future. In addition, consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.

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. The resulting pricing pressure from our hospital and ambulatory surgical center ("ASC") customers due to cost sensitivities resulting from healthcare cost containment pressures and reimbursement changes could decrease demand for our products, the prices that customers are willing to pay and the frequency of use of our products, which could have an adverse effect on 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.

***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 United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their healthcare 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. Adequate reimbursement coding, coverage, and payment may be required to support the future growth of some of our products. Inadequate coverage and negative reimbursement policies for our products could affect their adoption and our future revenue. 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 and/or procedures in which our products are used, the commercial success of our products may be limited, and our financial condition and results of operations may be materially and adversely affected.

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

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

Modifications to our products may require new regulatory approvals or clearances, including 510(k) or De Novo clearances or premarket approvals, additional approvals before foreign regulatory authorities, 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 or a notified body, 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 or regulatory approvals from foreign regulatory authorities.***

Expanding the indications for our products may 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 or foreign regulatory authorities may require a separate filing such as a 510(k) or De Novo submission or may deem the desired indication for use to be of high enough risk to require a PMA or similar 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. We have submitted a De Novo classification request to the FDA seeking 510(k) classification and clearance for the Apollo ESG™ and Apollo REVISE™ devices, which consist of the OverStitch® Endoscopic Suturing System and related components (e.g., tissue helix, sutures, cinches). Apollo ESG™ is intended for use in the endoscopic sleeve gastropasty procedure for weight loss and any futures cases and Apollo REVISE™ is intended for use in revision of bariatric surgery procedures. Obtaining clearances and approvals for such expanded uses can be a time consuming and costly process, and we may be unsuccessful in obtaining desired clearances and approvals, either of which 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 hyperinflation 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 directly and solely 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 emphasized certain clinical risks of the Orbera balloon. 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 or geopolitical events;
- 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. For example, audits are routinely performed by our Notified Body to ensure we are meeting the Quality System requirements for Europe, which are organized in many other countries outside of Europe as well, notably Canada, Brazil, Australia and Japan. 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 post-market surveillance once they are available;
- establish explicit provisions on defining the responsibilities of EU economic actors (e.g., manufacturer, importer(s) and distributor(s)) 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 certain requirements of MDR 2017 by May 2021. However, only two 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 implemented at this time. There remains uncertainty on how some new provisions are to be addressed.

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 completed all submissions of our MDR 2017 documentation to our Notified Body review by the end of January 2022. However, there are no assurances that we will not experience delays or 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. Our Notified Body could require changes to product labeling as part of the transition to MDR 2017. If that happens, it would likely result in additional filings globally to have those labeling changes approved in the various countries where we market and sell those products.

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, analyze, and report 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 December 2021, we borrowed \$35.0 million principal amount of debt under a term loan facility (“Term Loans”) with Innovatus Capital Partners, LLC (“Innovatus”). We used \$35.0 million of the proceeds to repay the existing senior secured credit facility. Our outstanding debt is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates without Innovatus’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 Innovatus Term Loans our interest rate is tied to the Wall Street Journal Prime Rate. We do not hedge this variable rate exposure to the Wall Street Journal Prime Rate and in the event of an increase in the Wall Street Journal Prime 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.

We are eligible to draw up to an additional aggregate \$40.0 million under the Term Loans between July 1, 2023 and December 31, 2024, upon the achievement of certain minimum revenue thresholds. We are also eligible to draw an additional \$25.0 million to finance certain approved acquisitions between June 30, 2022 and June 30, 2024. If we are unable to meet the required thresholds, then we may not be able to access these additional borrowings.

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.

*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 high proportion of shares and convertible or exchangeable securities held by affiliates;
- exercises or conversions of our outstanding warrants or convertible notes, respectively;
- 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 have sold and may in the future 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, 2021, a substantial number 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. Investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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 which could harm our business and which may not be effectively mitigated by our insurance programs.

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 11,025 square foot facility in Austin, Texas. The term of the lease for our Austin facility extends through September 30, 2022. Our principal office in Austin houses research and development, sales, marketing, finance and administrative activities. We operate an approximate 22,000 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, 2022, there were approximately 99 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. RESERVED

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

*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. This discussion includes both historical information and forward-looking statements based upon current expectations that involve risk, uncertainties and assumptions. Our actual results may differ materially from management's expectations and those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, the continuing impact of the COVID-19 pandemic and societal and governmental responses as well as those discussed in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. We have omitted discussion of 2019 results where it would be redundant to the discussion previously included in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020. "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 development of next-generation, less invasive medical devices to advance gastrointestinal therapeutic endoscopy. Our Endoscopy product portfolio consists of the OverStitch® Endoscopic Suturing System, the OverStitch Sx® Endoscopic Suturing System, X-Tack® Endoscopic HeliX Tacking System (collectively "ESS") and ORBERA® IntraGastric Balloon ("IGB"). Our products are used by gastroenterologists and bariatric surgeons in a variety of settings to treat multiple gastrointestinal 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); treatment of swallowing disorders (peroral endoscopic myotomy); and esophageal stent fixation and obesity. 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.

Since its market introduction in 2008, over 75,000 OverStitch units have been sold for procedures worldwide. We estimate that approximately 60% of OverStitch uses in the United States were for advanced gastrointestinal therapies. The other uses were for endoscopic sleeve gastropasty, or ESG, approximately 25%, and bariatric revision, approximately 15%. Outside the United States, we estimate that the majority of OverStitch uses, approximately 65%, were for ESG. The other uses outside the United States were for bariatric revision, approximately 20%, and for advanced gastrointestinal therapies, approximately 15%.

Recent research suggests that there may be a significant untapped market for applying the OverStitch Sx® Endoscopic Suturing System, or OverStitch, to obesity treatments, including endoscopic revisions of bariatric surgeries. In the aggregate, over 200 published investigator-initiated clinical trials, involving over 6,500 ESG procedures and conducted by a variety of physicians around the world, have consistently demonstrated clinically significant excess body weight loss (in excess of 50%) and low complication rates (0.8%). In another recently conducted randomized controlled trial, participants were assigned to either an ESG procedure or an ESG procedure plus taking the weight loss drug semaglutide. Patients in the ESG-only arm demonstrated an 18.7% total body weight loss at 12 months and patients undergoing ESG and taking semaglutide had an average of 25.2% total body weight loss. We believe these results demonstrate the potential for a meaningfully expanded market opportunity for obesity treatment given the currently limited use in the United States of OverStitch for ESG and bariatric revision, as well as the ability for ESG to be performed in individuals with lower body mass indices, or BMI, thereby making the option available to more people.

To address this opportunity, in September 2021, we submitted a De Novo classification request to the FDA seeking FDA 510(k) classification and clearance for the Apollo ESG and Apollo REVISE systems, which consist of the OverStitch Endoscopic Suturing System and related components (such as tissue helix, sutures, cinches). Apollo ESG is intended for use in the ESG procedure for weight loss and Apollo REVISE is intended for use in revision of bariatric surgery procedures. Pending FDA approval of the Apollo ESG and Apollo REVISE devices, we expect to begin education and marketing programs to expand visibility of the ESG procedures and thereby increase the use of OverStitch.

#### **Recent Financing Transactions**

In October 2021, we completed a public offering of our common stock for aggregate gross proceeds of \$74.9 million.

In December 2021, we entered into a term loan facility agreement with Innovatus Capital Partners, LLC (“Innovatus”) to borrow up to \$100.0 million (the “Term Loans”). We made an initial draw of \$35.0 million, which we used to repay our previous senior secured credit agreement in full, including interest. We are eligible to draw an additional \$40.0 million between July 1, 2023 and December 31, 2024, upon the achievement of certain minimum revenue thresholds. We are also eligible to draw an additional \$25.0 million to finance certain approved acquisitions between June 30, 2022 and June 30, 2024. The Term Loans mature on December 21, 2027, with principal payments beginning February 1, 2027, and bear interest at the greater of Wall Street Journal Prime Rate (3.25% at December 31, 2021) plus 4.0%.

#### **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. Our sales results in the months of March and April 2020 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. Demand for our products and our business has continued to recover since that time though there can be no assurance that this recovery will continue or that current demand levels will be sustained. In particular, new variants or outbreaks of the virus, including the Omicron variant, have caused health systems and other healthcare providers in our markets to restrict or limit procedures using our devices or have caused reductions in or cancellations of planned procedures, which have harmed and may continue to harm our sales and growth. Despite growing availability of COVID-19 vaccines, the COVID-19 pandemic, including emerging variant strains of the virus, remains active and continues to represent uncertainty concerning our sales outlook and risk to our business operations, including supply chain disruptions. 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 current recovery will be indicative of future results or that we will not experience future sales or business disruptions due to COVID-19, including emerging variants or new outbreaks, 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](#).

## **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 and institutions. 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, buying patterns of distributors, 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.

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

### **Cost of Sales**

Cost of sales for purchased products consist of the actual purchase price from 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.

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 salaries, benefits and other related costs, including 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, 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, stock-based compensation, 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.

### ***Inventory Valuation***

Inventory is stated at the lower of cost or net realizable value. Inventory costs include raw materials, inbound freight charges, warehousing costs, labor, and overhead expenses related to the Company's manufacturing and processing facilities. The allocation of overhead costs requires significant estimates including the capitalization of related overhead costs and the utilization and efficiency of such cost inputs. 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.

## Results of Operations

### Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31, 2021		Year Ended December 31, 2020	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	\$ 62,989	100.0 %	\$ 42,048	100.0 %
Cost of sales	28,030	44.5 %	19,806	47.1 %
Gross margin	34,959	55.5 %	22,242	52.9 %
Operating expenses:				
Sales and marketing	24,311	38.6 %	17,355	41.3 %
General and administrative	18,448	29.3 %	11,062	26.3 %
Research and development	9,524	15.1 %	7,670	18.2 %
Amortization of intangible assets	1,875	3.0 %	1,949	4.6 %
Total operating expenses	54,158	86.0 %	38,036	90.4 %
Loss from operations	(19,199)	(30.5)%	(15,794)	(37.6)%
Other (income) expenses:				
Interest expense, net	8,318	13.2 %	5,251	12.5 %
Gain on forgiveness of PPP loan	(2,852)	(4.5)%	—	— %
Other (income) expense, net	(139)	(0.2)%	1,424	3.4 %
Net loss before income taxes	(24,526)	(39.0)%	(22,469)	(53.5)%
Income tax expense	156	0.2 %	142	0.3 %
Net loss	\$ (24,682)	(39.2)%	\$ (22,611)	(53.8)%

### Revenues

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

	Year Ended December 31, 2021			Year Ended December 31, 2020			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	\$ 25,917	\$ 14,048	\$ 39,965	\$ 15,774	\$ 9,955	\$ 25,729	64.3 %	41.1 %	55.3 %
IGB	7,193	14,904	22,097	5,045	9,739	14,784	42.6 %	53.0 %	49.5 %
Other	894	33	927	1,453	82	1,535	(38.5) %	(59.8) %	(39.6) %
Total revenues	\$ 34,004	\$ 28,985	\$ 62,989	\$ 22,272	\$ 19,776	\$ 42,048	52.7 %	46.6 %	49.8 %
% Total revenues	54.0 %	46.0 %		53.0 %	47.0 %				

Total revenues in 2021 were \$63.0 million, compared to \$42.0 million in 2020, an increase of 49.8% due to improved demand for all of our products, as the impact of the initial outbreak of the COVID-19 pandemic began to dissipate, and the launch of our X-Tack product in the U.S. in 2021. Total U.S. sales increased \$11.7 million, or 52.7%, in 2021 and total OUS sales increased \$9.2 million, or 46.6%, in 2021 due to continued improvement in demand for our ESS products, recovery in elective procedures for our IGB products, and increased demand in our international distributor markets.

Direct market product sales accounted for approximately 79.6% of total product sales in 2021 compared to 83.4% in 2020.

### Non-GAAP Product Sales Percentage Change in Constant Currency

To supplement our financial results, we provide a non-GAAP financial measure, 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 product sales. 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.

Non-GAAP product sales percentage changes in constant currency for the year ended December 31, 2021 were as follows:

	% Increase/Decrease in Constant Currency	
	OUS	Total Revenues
ESS	37.9 %	54.1 %
IGB	48.9 %	46.7 %
Total revenues	42.9 %	48.1 %

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.

#### Cost of Sales

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

	Year Ended December 31, 2021			Year Ended December 31, 2020		
	Dollars	% Total Revenues		Dollars	% Total Revenues	
Materials, labor and purchased goods	19,628	31.2 %		\$ 13,366	31.8 %	
Overhead	5,167	8.2 %		4,562	10.8 %	
Other indirect costs	3,235	5.1 %		1,878	4.5 %	
Total cost of sales	\$ 28,030	44.5 %		\$ 19,806	47.1 %	

#### Gross Margin

Gross margin was 55.5% for 2021 compared to 52.9% for 2020. The increase in gross margin as a percentage of revenue was primarily due to higher product sales and improved overhead absorption in 2021 compared to 2020, which included unabsorbed overhead costs charged to cost of sales in 2020 when we reduced our manufacturing activities in response to the COVID-19 pandemic.

#### Operating Expenses

**Sales and Marketing Expense.** Sales and marketing expense increased \$7.0 million in 2021 as compared to 2020 primarily due to higher compensation and marketing spend in 2021 compared to 2020 when cost efficiency programs were implemented as a response to the COVID-19 pandemic. We expect our sales and marketing expenses to increase in future periods as we continue to invest in our sales channel and marketing programs to invest in sales growth.

**General and Administrative Expense.** General and administrative expense increased \$7.4 million in 2021 as compared to 2020 primarily due to an increase in non-cash stock-based compensation expense of \$4.1 million resulting from leadership changes during 2021 as well as higher compensation and professional service fees compared to 2020 when cost efficiency programs were implemented in response to the pandemic. We expect our general and administrative expenses to increase in future periods as we invest in our business infrastructure.

**Research and Development Expense.** Research and development expense increased \$1.9 million in 2021 as compared to 2020 primarily due to higher compensation in 2021 compared to 2020 when cost efficiency programs were implemented in response to the pandemic. We expect research and development expenses to increase in future periods as we continue to hire additional engineering and development talent and invest in our product pipeline and clinical initiatives.

**Amortization of Intangible Assets.** Amortization of intangible assets remained unchanged in 2021 as compared to 2020.

#### Loss from Operations.

Loss from operations in 2021 was \$19.2 million compared to \$15.8 million in 2020, attributed to a \$16.1 million increase in operating expenses, offset in part by a \$12.7 million increase in gross margin.

#### Other Expenses

*Interest Expense, net.* Net interest expense increased \$3.1 million in 2021 primarily due to the extinguishment of our term loan with Solar in December 2021, including prepayment and final fees, as well as the write off of related deferred financing costs.

*Gain on Forgiveness of PPP Loan.* The PPP loan, including interest, was forgiven in June 2021.

*Other (Income) Expense.* Other (income) expense primarily consists of realized and unrealized foreign exchange gains or losses on short-term intercompany loans denominated in the U.S. dollars payable by our foreign subsidiaries. Fluctuations in currency exchange rates resulted in an unrealized gain of \$0.4 million in 2021 compared to the unrealized loss of \$1.2 million in 2020.

*Income Tax Expense.* Income tax expense related to foreign income taxes on income generated in our OUS tax jurisdictions was \$0.2 million in 2021 compared to \$0.1 million in 2020.

#### Liquidity and Capital Resources

We have experienced operating losses since inception and have an accumulated deficit of \$297.5 million as of December 31, 2021. To date, we have funded our operating losses and acquisitions through equity offerings and the issuance of debt instruments. Our ability to fund future operations and meet debt covenant requirements will depend upon our level of future revenue and operating cash flow and our ability to access future draws on our existing credit facility, or additional funding through either equity offerings, issuances of debt instruments or both.

In October 2021, we issued shares of our common stock in an underwritten public offering for aggregate gross proceeds of \$74.9 million, which increased our cash by \$69.8 million after factoring in share issuance costs of \$5.1 million.

In December 2021, we entered into a term loan facility agreement with Innovatus Capital Partners, LLC (“Innovatus”) to borrow up to \$100.0 million (the “Term Loans”) and drew the Term A Loan of \$35.0 million. We are eligible to draw the Term B Loan of \$15.0 million between July 1, 2023 and December 31, 2023 and the Term C Loan of \$25.0 million between July 1, 2024 and December 31, 2024, in each case upon the achievement of certain minimum revenue thresholds. We are eligible to draw the Term D Loan of \$25.0 million to finance certain approved acquisitions between June 30, 2022 and June 30, 2024. The Term Loans mature on December 21, 2027, with principal payments beginning February 1, 2027, and bear interest at the greater of the Wall Street Journal Prime Rate or 3.25%, plus 4.0%. Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 4.0% of the outstanding amount will be due at the end of the loan term. Prior to December 21, 2025, Innovatus will have the right to make a one-time election to convert up to 10.0% of the outstanding aggregate principal amount of the term loans into shares of common stock of the Company at a price per share equal to \$11.50. The Term Loans include customary affirmative covenants and negative covenants. Additionally, it contains a minimum liquidity covenant, tested on a maintenance basis, and a minimum revenue covenant tested quarterly commencing the earlier of December 31, 2023 or the funding date of the Term B loan. We used \$35.0 million of the proceeds of the Term A Loan to repay our previous senior secured credit agreement in full, including interest, prepayment and final fees.

Management believes our existing cash and cash equivalents, cash from operations, additional term loans available upon certain thresholds under the Term Loans and access to financing sources will be sufficient to meet covenant, liquidity and capital requirements for the next twelve months and beyond. Management periodically evaluates our liquidity requirements, alternative uses of capital, capital needs and available resources. 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 of sales, marketing, and manufacturing activities. We may be required to seek additional equity or debt financing. 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. If we are unable to raise additional capital when desired, our business, operating results and financial condition could be adversely affected.

#### 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 under the Small Business Administration’s (“SBA”) Paycheck Protection Program (“PPP”) established under the CARES Act. In June 2021, we received forgiveness for the full amount of the \$2.9 million loan, inclusive of interest, from the SBA.

## Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2021 and 2020:

	2021	2020
Net cash used in operating activities	\$ (14,454)	\$ (20,812)
Net cash provided by investing activities	1,561	1,370
Net cash provided by financing activities	67,582	25,613
Effect of exchange rate changes on cash	(77)	108
Net change in cash, cash equivalents and restricted cash	<u>\$ 54,612</u>	<u>\$ 6,279</u>

### Operating Activities

Cash used in operating activities of \$14.5 million for 2021 was primarily the result of a net loss of \$24.7 million plus non-cash items of \$9.5 million primarily related to gain on forgiveness of PPP loan, depreciation, amortization, non-cash interest, and stock-based compensation. Additionally, cash used by operating assets and liabilities of \$0.7 million primarily related to accounts receivable due to the increase in revenues, increase in inventory purchases, and the increase in certain prepaid expenses which was partially offset by changes in accounts payable and accrued expenses.

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. Additionally, cash used by operating assets and liabilities was mainly for accounts payable and accrued expenses of \$7.1 million primarily related to clinical study payments and raw material purchases.

### Investing Activities

Cash provided by investing activities in both 2021 and 2020 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 \$67.6 million for 2021 primarily related to net proceeds received from the issuance of common stock in October 2021 of \$69.8 million, proceeds from option exercises of \$2.5 million, partially offset by the prepayment and final fees of \$3.2 million and the payment of deferred financing costs of \$1.5 million for the Term Loan executed in December 2021.

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.

### Contractual and Other Obligations

**Innovatus Term Loans.** As of December 31, 2021, we had \$35.0 million outstanding principal amount drawn under Term Loan A. See [Note 9 to our Consolidated Financial Statements](#) included elsewhere in this Annual Report on Form 10-K for further information.

**Solar Capital Exit Fee.** We remain obligated to pay \$1.9 million upon the earlier to occur of (i) certain exit or change in control events, or (ii) our achievement of trailing twelve-month revenue of \$100.0 million.

**Operating Leases.** Our operating lease commitments related primarily to our office space. As of December 31, 2021, we had fixed lease payment obligations of \$2.6 million, with \$0.9 million expected to be paid within 12 months and the remainder thereafter. See [Note 6 to our Consolidated Financial Statements](#) included elsewhere in this Annual Report on Form 10-K for further information.

### 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

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## Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of  
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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years 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, 2021 and 2020, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### **Basis for Opinion**

These 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 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 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 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.

### **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.

#### **Inventory Valuation**

As described in notes 2 and 4 to the consolidated financial statements, the Company's consolidated inventory balance was \$12.0 million as of December 31, 2021. 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. Valuation of inventory involves significant estimates relating to the capitalization of labor and overhead costs to the work in process and finished goods inventories as well as lower of cost or net realizable value considerations.

Given the importance of inventory to the Company's operations and significance of the inventory value, the valuation of inventories requires management to perform complex manual calculations using significant assumptions, including estimates related to the capitalization of labor and overhead costs as well as the utilization and efficiency of such cost inputs. 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 inventory, including:
  - Sampling of transactions, in order to test actual costs incurred and the transfer of costs throughout the production process by obtaining evidence supporting the cost of raw materials, labor and overhead. We traced the accumulation of costs to bills of materials and tested management's average cost calculations based upon the underlying cost data;
  - Evaluating the reasonableness of the significant assumptions used by management including those related to overhead cost allocation;
- We performed an analysis of historic overhead costs to determine the reasonableness of the adjustments to overhead for significant changes to actual costs incurred; and
- We developed independent expectations of inventory valuation at the product level based on historic and standard costs as well as current year cost increases and compared our expectations to management's valuation for reasonableness.

/s/ Moss Adams LLP

Dallas, Texas  
February 22, 2022

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

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Consolidated Balance Sheets**  
**December 31, 2021 and 2020**  
(In thousands, except for share data)

	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 90,691	\$ 36,235
Accounts receivable, net of allowance for doubtful accounts of \$330 and \$634, respectively	10,078	8,218
Inventory	11,966	10,306
Prepaid expenses and other current assets	1,965	3,771
<b>Total current assets</b>	<b>114,700</b>	<b>58,530</b>
Restricted cash	1,121	965
Property, equipment and right-of-use assets, net	5,593	6,221
Goodwill	5,290	5,290
Intangible assets, net of accumulated amortization of \$14,814 and \$13,231, respectively	4,400	6,017
Other assets	424	414
<b>Total assets</b>	<b>\$ 131,528</b>	<b>\$ 77,437</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 4,584	\$ 3,675
Accrued expenses	9,902	7,357
Current portion of long-term debt	—	636
<b>Total current liabilities</b>	<b>14,486</b>	<b>11,668</b>
Long-term debt	33,473	37,192
Convertible debt	19,513	19,387
Long-term liabilities	2,819	2,439
<b>Total liabilities</b>	<b>70,291</b>	<b>70,686</b>
Commitments and contingencies		
Stockholders' equity:		
Common stock; \$0.001 par value; 100,000,000 shares authorized; 39,546,323 and 25,819,329 shares issued and outstanding at December 31, 2021 and 2020, respectively	40	26
Additional paid-in capital	356,516	276,569
Accumulated other comprehensive income	2,136	2,929
Accumulated deficit	(297,455)	(272,773)
<b>Total stockholders' equity</b>	<b>61,237</b>	<b>6,751</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 131,528</b>	<b>\$ 77,437</b>

See accompanying notes to the consolidated financial statements.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**Years Ended December 31, 2021 and 2020**  
(In thousands, except for share data)

	2021	2020
Revenues	\$ 62,989	\$ 42,048
Cost of sales	28,030	19,806
Gross margin	<u>34,959</u>	<u>22,242</u>
Operating expenses:		
Sales and marketing	24,311	17,355
General and administrative	18,448	11,062
Research and development	9,524	7,670
Amortization of intangible assets	1,875	1,949
Total operating expenses	<u>54,158</u>	<u>38,036</u>
Loss from operations	(19,199)	(15,794)
Other (income) expenses:		
Interest expense, net	8,318	5,251
Gain on forgiveness of PPP loan	(2,852)	—
Other (income) expense, net	(139)	1,424
Net loss before income taxes	<u>(24,526)</u>	<u>(22,469)</u>
Income tax expense	156	142
Net loss	<u>\$ (24,682)</u>	<u>\$ (22,611)</u>
Other comprehensive (loss)/income:		
Foreign currency translation	(793)	1,299
Comprehensive loss	<u>\$ (25,475)</u>	<u>\$ (21,312)</u>
Net loss per share, basic and diluted	<u>\$ (0.82)</u>	<u>\$ (0.99)</u>
Shares used in computing net loss per share, basic and diluted	30,243,264	22,756,167

See accompanying notes to the consolidated financial statements.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Changes in Stockholders' Equity**  
**Years Ended December 31, 2021 and 2020**  
(In thousands, except for share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit
	Shares	Amount			
December 31, 2019	20,951,963	\$ 21	\$ 250,634	\$ 1,630	\$ (250,162)
Exercise of common stock options	5,982	—	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	—	—
Issuance of common stock, net of issuance costs of \$1,721	2,480,000	3	23,259	—	—
Conversion of convertible debt	25,528	—	83	—	—
Stock-based compensation	—	—	2,114	—	—
Foreign currency translation	—	—	—	1,299	—
Net loss	—	—	—	—	(22,611)
December 31, 2020	25,819,329	\$ 26	\$ 276,569	\$ 2,929	\$ (272,773)
Exercise of common stock options	698,070	1	2,487	—	—
Exercise of common stock warrants	2,668,247	3	(1)	—	—
Issuance of restricted stock and performance stock units	433,172	—	—	—	—
Issuance of common stock for convertible debt interest	244,861	—	1,229	—	—
Issuance of common stock, net of issuance costs of \$5,083	9,660,000	10	69,772	—	—
Conversion of convertible debt	22,644	—	74	—	—
Stock-based compensation	—	—	6,386	—	—
Foreign currency translation	—	—	—	(793)	—
Net loss	—	—	—	—	(24,682)
December 31, 2021	39,546,323	\$ 40	\$ 356,516	\$ 2,136	\$ (297,455)

See accompanying notes to the consolidated financial statements.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**  
**Years Ended December 31, 2021 and 2020**  
(In thousands)

	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (24,682)	\$ (22,611)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	3,232	3,730
Gain on forgiveness of PPP loan	(2,852)	—
Amortization of deferred financing costs	1,419	656
Non-cash interest	1,575	1,501
Provision for doubtful accounts receivable	152	52
Inventory impairment	50	50
Stock-based compensation	6,386	2,114
Unrealized foreign exchange on intercompany payables	(444)	1,208
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(2,332)	1,079
Inventory	(1,740)	(1,559)
Prepaid expenses and other assets	(1,251)	56
Accounts payable and accrued expenses	6,033	(7,088)
Net cash used in operating activities	<u>(14,454)</u>	<u>(20,812)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,195)	(486)
Purchases of intangibles and other assets	(261)	(144)
Proceeds from sale of equipment	17	—
Divestiture of Surgical product line	3,000	2,000
Net cash provided by investing activities	<u>1,561</u>	<u>1,370</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	2,488	14
Proceeds from exercise of warrants	2	—
Proceeds from issuance of common stock	69,782	23,262
Proceeds from senior secured term loans	35,000	—
Proceeds from long-term debt	—	2,824
Payments of deferred financing costs	(1,540)	(487)
Repayments of senior secured notes	(38,150)	—
Net cash provided by financing activities	<u>67,582</u>	<u>25,613</u>
Effect of exchange rate changes on cash	(77)	108
Net increase in cash, cash equivalents and restricted cash	54,612	6,279
Cash, cash equivalents and restricted cash at beginning of year	37,200	30,921
Cash, cash equivalents and restricted cash at end of year	<u>\$ 91,812</u>	<u>\$ 37,200</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 6,550	\$ 3,182
Cash paid for income taxes	272	192
Right-of-use assets recognized in exchange for lease obligations (non-cash)	(556)	1,146
Gain on forgiveness of PPP loan (non-cash)	2,852	—
Issuance of common stock for convertible debt interest (non-cash)	1,229	467
Issuance of common stock for conversion of convertible debt (non-cash)	74	83

See accompanying notes to the consolidated financial statements.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**  
**Years Ended December 31, 2021 and 2020**  
**(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 development of next-generation, less invasive medical devices to advance gastrointestinal therapeutic endoscopy. The Company develops and distributes devices that are used by surgeons and gastroenterologists for a variety of procedures related to gastrointestinal conditions including closure of gastrointestinal defects, managing gastrointestinal complications and the treatment of obesity.

The Company’s core products include the OverStitch® Endoscopic Suturing System, X-Tack® Endoscopic HeliX Tacking System (collectively “ESS”) and the Orbera® IntraGastric Balloon System (“IGB”). All devices are regulated by the U.S. Food and Drug Administration (the “FDA”) or an equivalent regulatory body outside the U.S.

**(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 four banks to secure obligations under lease agreements and performance based obligations. These letters of credit are secured by cash balances totaling \$1,121 and \$965 which are recorded in restricted cash on the consolidated balance sheet as of December 31, 2021 and 2020, 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 \$454 and \$115 were written off during the years ended December 31, 2021 and 2020, respectively.

**(f) Inventory**

Inventory is stated at the lower of cost or net realizable value. Inventory costs include raw materials, inbound freight charges, warehousing costs, labor, and overhead expenses related to the Company’s manufacturing and processing facilities. 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 \$35,000 and \$41,100 at December 31, 2021 and 2020, respectively. The Company's convertible debt is estimated by management to approximate \$20,500 for both December 31, 2021 and 2020. 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, 2021 and 2020 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, 2021 and 2020 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.

**(m) Research and Development**

Research and development costs are expensed as incurred.

**(n) Stock-based Compensation Plans**

The Company recognizes compensation costs for all stock-based awards based upon each award's estimated fair value as determined on the date of grant. The Company utilizes the Black-Scholes option-pricing model to determine the fair value of stock option awards. The assumptions used in estimating the fair value of stock-based compensation awards represent management's estimate and involve inherent uncertainties and the application of management's judgement. 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 \$244 and \$227 in advertising costs during the years ended December 31, 2021 and 2020, 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 August 2020, Accounting Standards Update (“ASU”) No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity* was issued, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. This ASU will become effective for the Company on January 1, 2024 and is not expected to have a material impact on the consolidated financial statements.

In May 2021, ASU No. 2021-04, *Issuer’s Accounting for Certain Modifications of Exchanges of Freestanding Equity-Classified Written Call Options* was issued to clarify the accounting for modifications or exchanges of freestanding equity-classified written call options, such as warrants, that remain equity classified after modification or exchange. This ASU became effective for the Company on January 1, 2022 and is not expected to have a material impact on the consolidated financial statements.

**(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, 2021, the Company’s cash and cash equivalents and restricted cash are held in deposit accounts at four different banks totaling \$91,812. 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, 2021 or 2020. The Company had no single customer that comprised more than 10% of the Company’s total revenues for the years ended December 31, 2021 and 2020.

**(4) Inventory**

Inventory consists of the following as of December 31:

	2021	2020
Raw materials	\$ 3,442	\$ 2,344
Work in progress	965	558
Finished goods	7,559	7,404
Total inventory	<u>\$ 11,966</u>	<u>\$ 10,306</u>

The Company recorded an inventory impairment charge of \$50 for each of the years ended December 31, 2021 and 2020. Finished goods included \$120 of inventory on consignment at customer locations at December 31, 2021.

**(5) Prepaid Expenses and Other Assets**

The final installment of \$3,000 from the sale of the surgical product line was received in December 2021. Imputed interest income on this receivable was \$240 and \$416 for the years ended December 31, 2021 and 2020, respectively, and is included within interest expense, net.

**(6) Property, Equipment and Right-of-Use Assets**

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

	Depreciable Lives	2021	2020
Equipment	5 years	\$ 7,472	\$ 7,452
Right-of-use assets	1 - 8 years	3,459	4,031
Furniture, fixtures and tooling	4 - 8 years	1,855	2,156
Computer hardware	3 - 5 years	1,444	1,244
Leasehold improvements	3 - 7 years	2,059	1,744
Construction in process		483	466
		16,772	17,093
Less accumulated depreciation		(11,179)	(10,872)
Property, equipment and right-of-use assets		\$ 5,593	\$ 6,221

The Company recorded depreciation expense of \$1,355 and \$1,779 for the years ended December 31, 2021 and 2020, respectively. There were no impairment charges for the years ended December 31, 2021 or 2020. The Company disposed of \$942 of fully depreciated property and equipment no longer being utilized during the year ended December 31, 2021.

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

As of December 31, 2021, the maturities of the Company's operating lease liabilities are as follows:

2022	\$ 934
2023	555
2024	451
2025	404
2026	416
Thereafter	756
Total lease payments	3,516
Less imputed interest	(926)
Total operating lease liabilities	\$ 2,590

Operating lease liabilities of \$587 and \$2,003 are included in accrued expenses and long-term liabilities, respectively, as of December 31, 2021. Operating lease expense and cash paid within operating cash flows for operating leases was \$1,109 and \$1,156 during 2021 and 2020, respectively. The weighted average remaining lease term was 4.9 years and the weighted average discount rate used to estimate the value of the operating lease liabilities was 8.7%. In June 2021, the Company extended the office lease in Texas for one year.

**(7) Intangible Assets**

Intangible assets consist of the following as of December 31:

	Useful Life	2021	2020
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	2,852	2,597
Capitalized software	1 - 5 years	1,438	2,050
		18,891	19,248
Less accumulated amortization		(14,491)	(13,231)
Intangible assets, net		\$ 4,400	\$ 6,017

The Company recorded amortization expense of \$1,877 and \$1,951 during 2021 and 2020, respectively. Additionally, \$256 and \$144 related to the extension and renewal of patents and trademarks was capitalized during 2021 and 2020, respectively.

Amortization for the next five years is as follows:

2022	\$ 1,727
2023	959
2024	677
2025	615
2026	223
Thereafter	199
Total	\$ 4,400

**(8) Accrued Expenses**

Accrued expenses consists of the following as of December 31:

	2021	2020
Accrued employee compensation and expenses	\$ 6,569	\$ 3,946
Accrued professional service fees	656	358
Accrued interest	613	616
Lease liability	587	675
Accrued taxes	437	442
Accrued returns and rebates	106	129
Other	934	1,191
Total accrued expenses	\$ 9,902	\$ 7,357

**(9) Long-Term Debt**

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

	2021	2020
Term loan facility	\$ 35,000	\$ 35,000
PPP loan	—	2,824
Deferred interest	6	1,217
Deferred financing costs	(1,533)	(1,213)
Less current portion	—	(636)
Long-term debt	<u>\$ 33,473</u>	<u>\$ 37,192</u>

**Term Loan Facility**

In December 2021, the Company entered into a term loan facility agreement with Innovatus Capital Partners, LLC (“Innovatus”) to borrow up to \$100,000 (the “Term Loans”) and drew the Term A Loan of \$35,000. The Company is eligible to draw the Term B Loan of \$15,000 between July 1, 2023 and December 31, 2023 and the Term C Loan of \$25,000 between July 1, 2024 and December 31, 2024, in each case upon the achievement of certain minimum revenue thresholds. The Company is eligible to draw the Term D Loan of \$25,000 to finance certain approved acquisitions between June 30, 2022 and June 30, 2024. The Term Loans mature on December 21, 2027, with principal payments beginning February 1, 2027, and bear interest at the greater of the Wall Street Journal Prime Rate or 3.25%, plus 4.0%. Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 4.0% of the outstanding amount will be due at the end of the loan term. Prior to December 21, 2025, Innovatus will have the right to make a one-time election to convert up to 10.0% of the outstanding aggregate principal amount of the term loans into shares of common stock of the Company at a price per share equal to \$11.50. The Term Loans include customary affirmative covenants and negative covenants. Additionally, it contains a minimum liquidity covenant, tested on a maintenance basis, and a minimum revenue covenant tested quarterly commencing the earlier of December 31, 2023 or the funding date of the Term B loan. The Company used \$35,000 of the proceeds of the Term A Loan to repay the previous senior secured credit agreement in full, including interest. Final and prepayment fees of \$3,150 were also paid in December 2021 and unamortized deferred financing costs of \$938 were written off in December 2021 in connection with the repayment.

Interest expense on the Company’s long-term debt was \$7,137, including \$2,044 of additional interest related to the prepayment and final fees repaid to the previous lender, and \$4,212 for the years ended December 31, 2021 and 2020, respectively.

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

2022 - 2026	\$ —
Thereafter	35,000
Total	<u>\$ 35,000</u>

**PPP Loan**

In March 2020, the CARES Act was signed into law providing certain economic aid packages for qualified entities. In April 2020, the Company was granted a loan of \$2,824 under the PPP established under the CARES Act. In June 2021, the Company received forgiveness for the full amount of the \$2,852 loan, inclusive of interest, from the SBA.

**(10) Convertible debt**

Convertible debt consists of the following as of December 31:

	2021	2020
Convertible debt principal	\$ 20,446	\$ 20,519
Deferred financing costs	(933)	(1,132)
Convertible debt	<u>\$ 19,513</u>	<u>\$ 19,387</u>

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 the Company's 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.

The Company issued 161,184 shares and 12,068 shares of the Company's common stock to holders of the Convertible Debt in January 2021 and May 2021, respectively, in fulfillment of \$616 of accrued interest as of December 31, 2020. In July 2021, the Company issued 71,609 additional shares of common stock for accrued interest as of June 30, 2021.

In January 2022, the Company issued 75,780 shares of the Company's common stock to holders of the Convertible Debt in fulfillment of \$613 of accrued interest as of December 31, 2021.

The Convertible Debt converts, at the option of the holders, into shares of the Company's common stock at an initial conversion price of \$3.25 per share, subject to adjustment. If the VWAP of the Company's common stock has been at least \$9.75 (subject to adjustment) for at least 20 trading days during any 30 consecutive trading day period, the Company 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 February 2021, \$74 of the Convertible Debt, including interest, was converted into 22,644 shares of common stock.

Interest expense on the Convertible Debt was \$1,427 and \$1,531 for the years ended December 31, 2021 and 2020, respectively.

**(11) Long-Term Liabilities**

Included in other long-term liabilities as of December 31, 2021 was \$816 for the estimated non-current portion of the exit fee obligation to Solar Capital Ltd, which has been reclassified from long-term debt in December 2021. The Company remains obligated to pay \$1,925 upon the earlier to occur of (i) certain exit events specified in the Solar Term Loan Facility, or (ii) the Company's achievement of trailing twelve-month revenue of \$100,000.

**(12) 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, 2021:

Warrant Expiration Date	Number of shares	Exercise price per share
February 27, 2022	163,915	\$21.29
Pre-funded - no expiration	13,744,504	\$0.001
Total number of warrants outstanding	<u>13,908,419</u>	
Weighted average exercise price of warrants outstanding		\$0.25

During the year ended December 31, 2021, 2,668,247 of pre-funded warrants were exercised into shares of common stock and 40,456 warrants expired.

(13) 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, 2021, the Company has 799,630 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, 2021 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2020	2,921,946	\$3.86	7.6 years	\$1,664
Options granted	1,507,872	\$6.36		
Options exercised	(698,070)	\$3.57		
Options forfeited	(248,865)	\$3.27		
Options outstanding, vested and expected to vest, December 31, 2021	<u>3,482,883</u>	\$5.04	8.0 years	\$12,307
Options exercisable	<u>1,484,884</u>	\$4.60	6.7 years	\$6,148

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:

	2021	2020
Risk free interest rate	1.0%	0.4%
Expected dividend yield	—%	—%
Estimated volatility	81.1%	73.8%
Expected life	6.1 years	5.8 years

Additional information regarding options is as follows:

	2021	2020
Stock-based compensation cost	\$6,386	\$2,114
Weighted-average grant date fair value of options granted during the period	\$4.40	\$1.31
Aggregate intrinsic value of options exercised during the period	\$3,494	\$8

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, 2021 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, 2021 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.

In March 2021, the Company awarded 848,733 stock options to the Company's chief executive officer in connection with the commencement of his employment. In August 2021, the Company awarded 150,000 stock options to the Company's chief financial officer in connection with the commencement of his employment. The option grant will vest over a period of four years, with one-quarter of the shares underlying the option vesting on the first anniversary of the grant date and the remainder vesting in equal monthly installments thereafter.

In connection with the departure of two executive officers, the terms for the stock option vesting period and exercise period were modified which resulted in additional stock-based compensation of \$222 for the year ended December 31, 2021.

Unrecognized compensation expense related to unvested options was approximately \$6,034 at December 31, 2021, with a weighted-average remaining amortization period of less than 2.9 years.

A summary of the restricted stock unit activity, including performance-based stock units, under the Company's Equity Plans as of December 31, 2021 is presented below:

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding, December 31, 2020	664,666	\$2.55	\$2,260
Restricted stock units granted	1,111,437	\$6.53	
Restricted stock units released	(433,172)	\$3.97	
Restricted stock units forfeited	(148,499)	\$3.08	
Restricted stock units outstanding, December 31, 2021	<u>1,194,432</u>	\$5.67	\$10,069

In March 2021, the Company awarded 707,278 performance-based restricted stock units to the Company's chief executive officer in connection with the commencement of his employment. The performance-based restricted stock units vest in four equal tranches upon the achievement of revenue for the trailing four quarters equal to \$50,000, \$65,000, \$80,000, and \$95,000. The revenue milestone for the first tranche was achieved as of June 30, 2021.

In August 2021, the Company awarded 80,000 time-based restricted stock units and 120,000 performance-based restricted stock units to the Company's chief financial officer in connection with the commencement of his employment. The time-based restricted stock units vest in four equal tranches upon completion of each year of employment. The performance-based

restricted stock units vest in three equal tranches upon the achievement of revenue for the trailing four quarters equal to \$70,000, \$90,000, and \$110,000.

In connection with the departure of an executive officer, the vesting terms for restricted stock units outstanding were modified which resulted in additional stock-based compensation of \$76 for the year ended December 31, 2021.

Unrecognized compensation expense related to unvested restricted stock units and performance-based stock units was approximately \$1,988 and \$2,284, respectively, at December 31, 2021, with a remaining weighted-average amortization period of 1.6 years.

**(14) 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.

**(15) 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 \$729 and \$581 for the years ended December 31, 2021 and 2020 respectively.

**(16) Income Taxes**

Income tax expense of \$156 and \$142 for the years ended December 31, 2021 and 2020, 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:

	2021	2020
Deferred tax assets:		
Capitalized transaction costs	\$ 250	\$ 279
Intangible assets	1,205	1,100
Inventory valuation	43	28
Research and development credit	4,005	4,123
Interest expense carryforward	4,980	3,121
Foreign timing differences	624	578
Depreciable assets	53	—
Other	1,871	1,095
Net operating loss carryforwards	57,739	53,666
	<u>70,770</u>	<u>63,990</u>
Deferred tax liabilities:		
Unremitted foreign earnings	(448)	(463)
Depreciable assets	—	(93)
	<u>(448)</u>	<u>(556)</u>
Total net deferred tax assets	70,322	63,434
Less valuation allowance	(70,055)	(63,243)
Net deferred tax assets (included in other assets)	<u>\$ 267</u>	<u>\$ 191</u>

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 \$6,812 during the year ended December 31, 2021, primarily as a result of changes in net operating loss.

As of December 31, 2021, 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:

	2021	2020
Tax at U.S. statutory rate	\$ (5,150)	\$ (4,719)
State taxes, net of deferred benefit	(783)	(536)
Foreign tax rate differential	(260)	(327)
Foreign taxes	(169)	(13)
Permanent differences	(231)	702
Research and development tax credit	—	(313)
Other	(124)	365
Deferred tax adjustment	(43)	756
Unremitted foreign earnings	27	33
Valuation allowance - current year	6,889	4,194
Income tax expense	<u>\$ 156</u>	<u>\$ 142</u>

Income tax expense consists of the following:

	2021	2020
<b>Current taxes:</b>		
U.S. state	\$ 2	\$ 11
International	239	279
Total current income tax expense	<u>241</u>	<u>290</u>
<b>Deferred taxes:</b>		
International	(85)	(148)
Total deferred income tax expense	<u>(85)</u>	<u>(148)</u>
<b>Income tax expense</b>	<u>\$ 156</u>	<u>\$ 142</u>

As of December 31, 2021, the Company had U.S. federal net operating loss carryforwards of approximately \$239,847, of which \$96,010 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, 2021 were \$139,022. 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, 2021.

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 \$119,712 which will begin to expire in varying amounts beginning in 2022, if not utilized. The Company had foreign net operating losses of approximately \$2,403 which do not expire.

#### (17) 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, including performance-based 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	
	2021	2020
Warrants for common stock	13,908,419	8,068,615
Convertible debt	6,310,235	6,310,621
Common stock options	3,094,197	2,520,029
Restricted stock units	920,066	487,636
	<u>24,232,917</u>	<u>17,386,901</u>

#### (18) Segment and Geographic Information

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company globally manages the business within one reportable segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

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, 2021				Year Ended December 31, 2020			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	\$ 25,917	\$ 14,048	\$ 39,965	63.4 %	\$ 15,774	\$ 9,955	\$ 25,729	61.2 %
IGB	7,193	14,904	22,097	35.1 %	5,045	9,739	14,784	35.2 %
Other	894	33	927	1.5 %	1,453	82	1,535	3.6 %
Total revenues	\$ 34,004	\$ 28,985	\$ 62,989	100.0 %	\$ 22,272	\$ 19,776	\$ 42,048	100.0 %
% Total revenues	54.0 %	46.0 %			53.0 %	47.0 %		

Total distributor sales were 44.3% and 35.2% of total OUS revenues for the years ended December 31, 2021 and 2020, respectively. Sales in the next largest individual country outside the U.S. were 6.3% and 7.6% for the years ended December 31, 2021 and 2020, respectively.

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

	2021	2020
U.S.	\$ 1,855	\$ 2,149
Costa Rica	3,436	3,641
Other	302	431
Total property, equipment and right-of-use assets, net	<u>\$ 5,593</u>	<u>\$ 6,221</u>

**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, 2021 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, 2021 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, 2021.

**Attestation Report of the Independent 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, 2021 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**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**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 2021 fiscal year pursuant to Regulation 14A for our 2022 Annual Meeting of Stockholders, (the "2022 Proxy Statement") and the information to be included in the 2022 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 2022 Proxy Statement and is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item will be included in our 2022 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 2022 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 2022 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 2022 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, 2021:

<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">56</a>
<a href="#">Consolidated Balance Sheets</a>	<a href="#">58</a>
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	<a href="#">59</a>
<a href="#">Consolidated Statements of Changes in Stockholders' Equity</a>	<a href="#">60</a>
<a href="#">Consolidated Statements of Cash Flows</a>	<a href="#">61</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">62</a>

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

Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		Filing Date
			File Number	Exhibit	
2.1**	<a href="#">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.</a>	8-K	001-35706	2.1	September 8, 2016
2.2**	<a href="#">Asset Purchase Agreement, dated December 17, 2018, by and between Apollo Endosurgery, Inc. and ReShape Lifesciences Inc.</a>	8-K	001-35706	2.1	December 19, 2018
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-35706	3.1	June 13, 2017
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-35706	3.2	June 13, 2017
4.1	<a href="#">Form of Common Stock Certificate of the registrant</a>	10-Q	001-35706	4.1	May 4, 2017
4.2	<a href="#">Form of Warrant Issued to Investors in the September 2014 Offering</a>	8-K	001-35706	4.1	September 22, 2014
4.3	<a href="#">Form of Warrant issued to Torreya Capital</a>	S-4	333-214059	4.7	October 11, 2016
4.4	<a href="#">Apollo Common Stock Purchase Warrant issued to Athyrium Opportunities II Acquisition LP dated February 27, 2015</a>	S-4	333-214059	4.8	October 11, 2016
4.5	<a href="#">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</a>	S-4	333-214059	4.9	October 11, 2016
4.6	<a href="#">Form of 6.0% Convertible Debenture due 2024</a>	8-K	001-35706	4.1	August 16, 2019
4.7*	<a href="#">Description of Securities</a>				



Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		Filing Date
			File Number	Exhibit	
10.1	<a href="#">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.</a>	Form 8-K	001-35706	10.2	December 7, 2020
10.2	<a href="#">Addendum No. 2 to Office Lease Agreement dated August 7, 2014 between Apollo Endosurgery Costa Rica and BCR Fondo de Inversion Inmobiliario</a>	10-Q	001-35706	10.1	November 5, 2020
10.3++	<a href="#">Securities Purchase Agreement, dated as of July 17, 2020, by and among Apollo Endosurgery, Inc. and the purchasers named therein.</a>	Form 8-K	001-35706	10.1	July 22, 2020
10.4	<a href="#">Registration Rights Agreement, dated as of July 17, 2020, by and among Apollo Endosurgery, Inc. and the purchasers named therein.</a>	Form 8-K	001-35706	10.2	July 22, 2020
10.5	<a href="#">Form of Pre-Funded Warrant, dated as of July 21, 2020, issued by Apollo Endosurgery, Inc.</a>	Form 8-K	001-35706	10.3	July 22, 2020
10.6#	<a href="#">2021 Bonus Plan</a>	8-K	001-35706	10.1	March 25, 2021
10.7#	<a href="#">Separation Agreement, dated May 3, 2021, by and between Apollo Endosurgery, Inc. and Bret Schwartzhoff</a>	8-K/A	001-35706	10.1	May 7, 2021
10.8#	<a href="#">Gostout offer letter, dated December 9, 2016</a>	10-K	001-35706	10.11	March 1, 2018
10.9#	<a href="#">John Molesphini Offer Letter</a>	10-Q	001-35706	10.2	May 3, 2018
10.10#	<a href="#">Form of Change in Control Agreement</a>	8-K	001-35706	10.1	May 30, 2018
10.11#	<a href="#">Separation and Release Agreement, dated February 28, 2021, by and between Apollo Endosurgery, Inc. and Todd Newton</a>	8-K/A	001-35706	10.1	March 3, 2021
10.12#	<a href="#">Transition Services Agreement, dated February 28, 2021, by and between Apollo Endosurgery, Inc. and Todd Newton</a>	8-K/A	001-35706	10.2	March 3, 2021
10.13#	<a href="#">Employment Letter, dated July 19, 2021, by and between Apollo Endosurgery, Inc. and Stefanie Cavanaugh</a>	10-Q	001-35706	10.1	November 1, 2021
10.14#	<a href="#">Employment Agreement Effective March 1, 2021, by and between the Company and Charles McKhann</a>	10-K	001-35706	10.13	February 25, 2021
10.15#	<a href="#">Employment Agreement, dated July 12, 2021, by and between Apollo Endosurgery, Inc. and Jeffrey Black</a>	10-Q	001-35706	10.2	November 1, 2021
10.16#	<a href="#">Non-Employee Director Compensation Policy May 2018 amendment</a>	10-Q	001-35706	10.5	August 8, 2018
10.17#	<a href="#">Form of Indemnification Agreement</a>	10-Q	001-35706	10.6	August 8, 2018
10.18	<a href="#">First Amendment to Office Lease Agreement dated June 11, 2018, by and between the Company and DPF Cityview LP</a>	10-Q	001-35706	10.4	August 8, 2018

Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		Filing Date
			File Number	Exhibit	
10.19	<a href="#">Second Amendment to Office Lease Agreement, dated June 18, 2021, by and between Apollo Endosurgery, Inc. and BC Exchange Master Tenant, LLC</a>	10-Q	001-35706	10.2	August 3, 2021
10.20	<a href="#">Lease Agreement, dated August 7, 2014, between Apollo Endosurgery Costa Rica Sociedad de Responsabilidad Limitada and Zona Franca Coyoil, S.A.</a>	S-4	331-214059	10.20	October 11, 2016
10.21	<a href="#">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.</a>	S-4	331-214059	10.21	November 14, 2016
10.22#	<a href="#">Apollo Endosurgery, Inc. 2017 Equity Incentive Plan</a>	8-K	001-35706	10.1	June 13, 2017
10.23#	<a href="#">Forms of grant notice, stock option agreement and notice of exercise under the Apollo Endosurgery, Inc. 2017 Equity Incentive Plan</a>	8-K	001-35706	10.2	June 13, 2017
10.24#	<a href="#">Form of restricted stock unit grant notice and award agreement under the Apollo Endosurgery, Inc. 2017 Equity Incentive Plan</a>	8-K	001-35706	10.3	June 13, 2017
10.25#	<a href="#">Apollo Endosurgery, Inc. 2016 Equity Incentive Plan and forms of agreements relating thereto</a>	S-4	333-214059	10.2	October 11, 2016
10.26#	<a href="#">Apollo Endosurgery, Inc. 2006 Stock Option Plan and forms of agreements relating thereto</a>	S-4	333-214059	10.1	October 11, 2016
10.27++	<a href="#">Securities Purchase Agreement, dated as of August 7, 2019, by and among Apollo Endosurgery, Inc. and the purchasers named therein.</a>	8-K	001-35706	10.1	August 16, 2019
10.28	<a href="#">Registration Rights Agreement, dated as of August 7, 2019, by and among Apollo Endosurgery, Inc. and the purchasers named therein.</a>	8-K	001-35706	10.2	August 16, 2019
10.29	<a href="#">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.</a>	8-K	001-35706	10.3	August 16, 2019
10.30	<a href="#">Pre-funded Warrant, dated as of August 12, 2019, issued by Apollo Endosurgery, Inc.</a>	8-K	001-35706	10.4	August 16, 2019
10.31^*	<a href="#">Loan and Security Agreement, dated as of December 21, 2021, by and among Apollo Endosurgery, Inc., certain of its subsidiaries, as co-borrowers, Innovatus Life Sciences Lending Fund I, LP, and the other lenders party thereto.</a>				

Exhibit Number	Description of Document	Schedule / Form	Incorporated by Reference		Filing Date
			File Number	Exhibit	
21.1	<a href="#">List of Subsidiaries</a>	S-4	333-214059	21.1	October 11, 2016
23.1 *	<a href="#">Consent of Moss Adams LLP, Independent Public Accounting Firm to Apollo Endosurgery, Inc.</a>				
31.1 *	<a href="#">Certification of Chief Executive Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934</a>				
31.2 *	<a href="#">Certification of Chief Financial Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934</a>				
32.1 * †	<a href="#">Certification of Chief Executive Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934</a>				
32.2 * †	<a href="#">Certification of Chief Financial Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934</a>				
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				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained within Exhibit 101)				

# 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.

^ Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

#### 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 22, 2022 by the undersigned thereto.  
APOLLO ENDOSURGERY, INC.

/s/ Charles McKhann  
Charles McKhann  
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Charles McKhann and Jeffrey Black, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him 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 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 22, 2022.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Charles McKhann</u> Charles McKhann	Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2022
<u>/s/ Jeffrey Black</u> Jeffrey Black	Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer)	February 22, 2022
<u>/s/ Chrissy Citzler-Carr</u> Chrissy Citzler-Carr	Controller (Principal Accounting Officer)	February 22, 2022
<u>/s/ John Barr</u> John Barr	Chairman of the Board	February 22, 2022
<u>/s/ Rick Anderson</u> Rick Anderson	Director	February 22, 2022
<u>/s/ Julie Shimer</u> Julie Shimer	Director	February 22, 2022
<u>/s/ William D. McClellan, Jr.</u> William D. McClellan, Jr.	Director	February 22, 2022
<u>/s/ R. Kent McGaughy, Jr.</u> R. Kent McGaughy, Jr.	Director	February 22, 2022
<u>/s/ David C. Pacitti</u> David C. Pacitti	Director	February 22, 2022

**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, 2022, there were 39,623,333 shares of common stock issued and outstanding, which shares were held by 99 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<sup>2</sup>/<sub>3</sub>% 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."

**LOAN AND SECURITY AGREEMENT**

**THIS LOAN AND SECURITY AGREEMENT** (as the same may be amended, restated, modified, or supplemented from time to time, this “**Agreement**”) dated as of December 21, 2021 (the “**Effective Date**”) among INNOVATUS LIFE SCIENCES LENDING FUND I, LP, a Delaware limited partnership, 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 hereof or otherwise a party hereto from time to time including INNOVATUS LIFE SCIENCES LENDING FUND I, LP in its capacity as a Lender, and 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, Apollo International and Lpath, individually and collectively, jointly and severally, “**Borrower**”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

**1. DEFINITIONS, ACCOUNTING AND OTHER TERMS**

**1.1** Capitalized terms used herein shall have the meanings set forth in Section 13 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term “financial statements” shall include the accompanying notes and schedules. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified. Notwithstanding anything to the contrary contained herein, all financial statements delivered hereunder shall be prepared, and all financial covenants contained herein shall be calculated, without giving effect to any election under the Statement of Financial Accounting Standards No. 159 (or any similar accounting principle) permitting a Person to value its financial liabilities or Indebtedness at the fair value thereof. For all purposes of this Agreement, if GAAP requires any Person subsequent to the Effective Date to cause operating leases to be treated as capitalized leases or otherwise to be reflected on such Person’s balance sheet, then such change shall not be given effect hereunder, and those types of leases which were treated as operating leases as of the Effective Date shall continue to be treated as operating leases that would not otherwise be required to be reflected on such Person’s balance sheet. For the avoidance of doubt, and without limitation of the foregoing, Permitted Convertible Debt shall at all times be valued at the full stated principle amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof.

**2. LOANS AND TERMS OF PAYMENT**

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loan advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

**2.2 Term Loans. (a)**

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower on the Effective Date in an aggregate principal amount of Thirty Five Million Dollars (\$35,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (the “**Term A Loan**”). After repayment, the Term A Loan may not be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower during the Term B Draw Period in an aggregate principal amount of Fifteen Million Dollars (\$15,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (the “**Term B Loan**”). After repayment, the Term B Loan may not be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower during the Term C Draw Period in an aggregate principal

amount of Twenty Five Million Dollars (\$25,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (the "**Term C Loan**"). After repayment, the Term C Loan may not be re-borrowed.

(iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower during the Term D Draw Period in an aggregate principal amount of up to Twenty Five Million Dollars (\$25,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (the "**Term D Loan**"; each Term A Loan, Term B Loan, Term C Loan and Term D Loan is referred to singly as a "**Term Loan**" and the Term A Loan, Term B Loan, Term C Loan and Term D Loan are referred to collectively as the "**Term Loans**") solely for Borrower to finance an Approved Acquisition. After repayment, the Term D Loan may not be re-borrowed.

(b) **Repayment.** Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of any Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to twelve (12) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) **Mandatory Prepayments.** If an event described in Section 7.2(c)(ii) occurs or the Term Loans are accelerated following the occurrence and during the continuance of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Fee, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Fee had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to each Lender in accordance with its respective Pro Rata Share, the Final Fee in respect of the Term Loans.

(d) **Permitted Prepayment of Term Loan.** After the date that is the first anniversary of the Funding Date of the Term A Loan (provided that a prepayment of the Term Loan A shall be permitted at any time in connection with a Change Of Control), the Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loan at least five (5) Business Days prior to such prepayment, which notice may be conditional based on the happening of a specified future event, and (ii) pays to Collateral Agent for the benefit of each Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Fee, plus (D) all other outstanding Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

### 2.3 Payment of Interest on the Term Loan.

(a) **Interest Rate.** Subject to Section 2.3(b), the principal amount outstanding under the Term Loan shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan and monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e); provided that at the election of Borrower (which shall be considered elected on the Funding Date of the applicable Term Loan) with no less than five (5) Business Days' written notice to Collateral Agent prior to the Effective Date, the PIK Rate of the Basic Rate may be payable in-kind by adding an amount equal to such PIK Rate of the outstanding principal amount to the then outstanding principal balance on a monthly basis until the third anniversary of the Effective Date so as to increase the outstanding

principal balance of the outstanding Term Loans on each Payment Date and which amount shall be payable when the principal amount of the applicable Term Loans is payable in accordance with Sections 2.2(b) and 2.3(e) and on which principal amount interest shall be owed pursuant to Section 2.3(a).

Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) **Default Rate.** Upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) **365 Day Year.** Interest shall be computed on the basis of a three hundred sixty-five (365) day year and the actual number of days elapsed.

(d) **Debit of Accounts.** Collateral Agent and each Lender may debit (or ACH) any deposit accounts maintained by Borrower or any other Loan Party for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set off.

(e) **Payments.** Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

(f) **Changes in Prime Rate.** In the event the Prime Rate is changed from time to time hereafter and because of any such change the Basic Rate changes, the Basic Rate shall be increased or decreased, effective as of the day of such change in the Prime Rate.

#### 2.4 Fees. Borrower shall pay to Collateral Agent:

(a) **Facility Fee.** The Term Loan Facility Fee, which shall be due on the Funding Date of each Term Loan with respect to such Term Loan, to be shared among the Lenders in accordance with their respective Pro Rata Shares;

(b) **Final Fee.** The Final Fee, when due hereunder, to be shared among the Lenders in accordance with their respective Pro Rata Shares;

(c) **Prepayment Fee.** The Prepayment Fee, when due hereunder, to be shared among the Lenders in accordance with their respective Pro Rata Shares;

(d) **Term B Loan Non-Utilization Fee.** If the Term B Draw Period commences and Borrower

(i) fails to draw the full amount of the Term B Loan and (ii) fails to notify Collateral Agent, at any time before the commencement of the Term B Draw Period or at any time before the date that is thirty (30) days after the commencement of the Term B Draw Period, of Borrower's intent to terminate the Term Loan Commitment applicable to the Term B Loan, a non-utilization fee of Four Hundred Fifty Thousand Dollars (\$450,000.00) with respect to the Term B Loan shall become due and payable on the earliest of (i) the termination of the Term B Draw

Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, or (iv) the prepayment of the Term Loans pursuant to Section 2.2(c) or (d);

(e) Term C Loan Non-Utilization Fee. If the Term C Draw Period commences and Borrower

(i) fails to draw the full amount of the Term C Loan and (ii) fails to notify Collateral Agent, at any time before the commencement of the Term C Draw Period or at any time before the date that is two (2) weeks after the commencement of the Term C Draw Period, of Borrower's intent to terminate the Term Loan Commitment applicable to the Term C Loan, a non-utilization fee of Seven Hundred Fifty Thousand Dollars (\$750,000.00) with respect to the Term C Loan shall become due and payable on the earliest of (i) the termination of the Term C Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, or (iv) the prepayment of the Term Loans pursuant to Section 2.2(c) or (d); and

(f) Lenders' Expenses. All Lenders' Expenses (including reasonable and documented out-of-pocket attorneys' fees and expenses for due diligence, investigation, documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due; provided that all such Lenders' Expenses incurred up to and including the Effective Date shall not exceed One Hundred Fifty Thousand Dollars (\$150,000.00) in the aggregate for the account of Borrower.

**2.5 Withholding.** Payments received by the Collateral Agent or the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.5 shall survive the termination of this Agreement.

**2.6 Secured Promissory Notes.** Each Term Loan shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "Secured Promissory Note"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

**2.7 Conversion To Equity.** Prior to the fourth anniversary of the Effective Date, Lenders shall have the right at their election, but not the obligation, to convert up to ten percent (10.00%) of the outstanding aggregate principal amount of the Term Loans into shares of common stock of Parent. Such right may only be exercised one time, regardless of the amount that the Lenders elect to convert. Such shares shall be issued at a price per share equal to \$11.50 (which price shall be subject to appropriate adjustment for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof) (the "Conversion Price"). Such shares shall be referred to herein as "Parent Equity."

To exercise their rights under this Section 2.7, the applicable Lender(s) shall notify Parent in writing of the amount of the Term Loans that is to be converted into Parent Equity and deliver to the Parent a properly completed notice of conversion, the form of which is attached hereto as Exhibit E (each a "Notice of Conversion"). Parent shall no later than seven (7) days after the receipt of such Notice of Conversion issue Parent Equity to the applicable Lender(s). Upon issuance of Parent Equity in accordance with the provisions of this Section 2.7, the principal amount of Term Loans so converted shall be deemed to have been prepaid for the purposes of this Agreement, provided, however, no Prepayment Fee or Final Fee shall be due with respect to such deemed prepayment. Furthermore, contemporaneously with the issuance of Parent Equity, Parent shall deliver to the applicable Lender(s) stock certificates or book-entry positions evidencing Parent Equity.

No fractional shares or scrip representing fractional shares shall be issued upon any conversion of outstanding Term Loans under this Section 2.7. As to any fraction of a share which the Lender(s) would otherwise be entitled to receive upon such conversion, the Parent shall at its election either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

The parties acknowledge and understand that any Parent Equity will be issued in a private transaction within the meaning of Section 3(a)(9) or Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and that the Parent Equity will not be registered under the Securities Act or any other applicable securities law at the time of its issuance. The Lenders acknowledge and understand that the Parent Equity may not be resold, transferred, pledged or otherwise disposed of by any Lender absent an effective registration statement under the Securities Act with respect to the Parent Equity or pursuant to an applicable exemption from the registration requirements of the Securities Act, and that any certificates or book-entry positions representing the Parent Equity shall contain a legend in substantially the following form, unless otherwise determined by the Parent: THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION, AND MAY NOT BE OFFERED, SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM.

Parent hereby undertakes to register the Parent Equity for resale within 90 calendar days of its issuance (the "Filing Period") pursuant to an effective registration statement under the Securities Act (each a "Registration Statement") if, at the time of its issuance, the Parent Equity is not, and will not be within the Filing Period, eligible for resale pursuant to Rule 144 promulgated under the Securities Act ("Rule 144"). Each Lender agrees to furnish the Company with information regarding such Lender that the Company reasonably believes is required to be disclosed in the Registration Statement; *provided*, that the Company will provide such Lender a reasonable opportunity to review such disclosure regarding such Lender that the Company proposes to include in the Registration Statement. The Company will use its reasonable best efforts to keep any Registration Statement continuously effective under the Securities Act until the date that all Parent Equity covered by such Registration Statement (i) have been sold or transferred thereunder, or (ii) may be sold or transferred pursuant to Rule 144. The registration rights provided to the Lenders under this Section 2.7 will terminate in their entirety upon the earliest to occur of: (i) the date on which no principal amounts of Term Loans are outstanding; (ii) at such time all Parent Equity has been sold or transferred or may be sold or transferred pursuant to Rule 144; or (iii) the termination of this Agreement.

The Company will notify the Lenders holding Parent Equity registered on any Registration Statement (which notice shall, pursuant to clauses (iii) through (vi) hereof, be accompanied by an instruction to suspend the use of the prospectus included in such Registration Statement until the requisite changes have been made) as promptly as reasonably possible (i) when a prospectus or any prospectus supplement or post-effective amendment to a Registration Statement is proposed to be filed, (ii) of any request by the Securities and Exchange Commission or any other federal or state governmental authority for amendments or supplements to a Registration Statement or prospectus or for additional information, (iii) of the issuance by the Securities and Exchange Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Parent Equity or the initiation of any proceedings for that purpose, (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of Parent Equity for sale in any jurisdiction, or the initiation or threatening of any proceeding for such purpose, (v) of the occurrence of any event or passage of time that makes the financial statements included in a

Registration Statement ineligible for inclusion therein or any statement made in a Registration Statement or prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to a Registration Statement, prospectus or other documents so that, in the case of a Registration Statement or the prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and (vi) of the occurrence or existence of any pending development with respect to the Company that the Company believes may be material and that, in the determination of the Company, makes it not in the best interest of the Company to allow continued availability of a Registration Statement or prospectus; *provided, however*, that in no event shall any such notice contain any information which would constitute material, non-public information regarding the Company without the applicable Lenders' prior written consent. Each Lender agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in subclauses (iii) through (vi), such Lender will forthwith discontinue disposition of such Parent Equity under a Registration Statement until it is advised in writing by the Company that the use of the applicable prospectus (as it may have been supplemented or amended) may be resumed. The Company will use its best efforts to ensure that the use of the prospectus may be resumed as promptly as is practicable. In addition, the Lenders (i) acknowledge and agree that they be provided with material, non-public information regarding the Company from time to time pursuant to the terms of this Agreement and (ii) will not make any sale or other transfer of Parent Equity at any time in which they reasonably believe that they may be in possession of material, non-public information regarding the Company.

The Lenders understand and agree that if the Parent Equity is subject to transfer restrictions, including pursuant to Rule 144 promulgated under the Securities Act, the Lenders may not be able to readily resell the Parent Equity and may be required to bear the financial risk of an investment in the Parent Equity for until the Parent Equity becomes eligible for resale.

To the extent that the provisions of any securities laws or regulations conflict with the Parent's obligations to issue and deliver Parent Equity under this Section 2.7, the Parent will comply with the applicable securities laws and regulations and will not be deemed to have breached its obligations to issue and deliver Parent Equity upon notice of conversion delivered pursuant to this Section 2.7; provided, however, Parent will, if requested by the Lenders, issue and deliver the Parent Equity as soon as it is able to in compliance with the applicable provisions any securities laws or regulations.

### 3. CONDITIONS OF LOANS

**3.1 Conditions Precedent to Initial Term Loan.** Each Lender's obligation to make the Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- applicable;
- (a) original Loan Documents, each duly executed by Borrower and other Loan Party, as
  - (b) a completed Perfection Certificate for Borrower and each other Loan Party;
  - (c) the Operating Documents and good standing certificates of Borrower and each other Loan Party certified by the Secretary of State (or equivalent agency) of Borrower's and such Loan Party's jurisdiction of organization or formation and each jurisdiction in which Borrower and each Loan Party is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;
  - (d) a copy of resolutions of the governing body for Borrower evidencing approval of the Term Loan and other transactions evidenced by the Loan Documents;

(e) duly executed original officer's certificates for Borrower and each other Loan Party that is a party to the Loan Documents certifying as to (i) the incumbency of each Responsible Officer executing each Loan Document and (ii) the documents delivered pursuant to Section 3.1(d) and 3.1(e), in a form acceptable to Collateral Agent and the Lenders;

(f) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(g) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(h) a copy of any applicable Investors Rights Agreement and any amendments thereto;

hereof; (i) payment of the Facility Fee and Lenders' Expenses then due as specified in Section 2.4

(j) a payoff letter from Solar Capital Ltd. in respect of the Existing Indebtedness;

(k) evidence that (i) the Liens securing the Existing Indebtedness will be terminated and (ii) the documents and/or filings evidencing the perfection of such Liens, including without limitation any financing statements and/or control agreements, have or will, concurrently with the initial Credit Extension, be terminated.

**3.2 Conditions Precedent to all Term Loans.** The obligation of each Lender to extend each Term Loan, including the initial Term Loan, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of (i) an executed Loan Payment Request Form in the form of EXHIBIT B-1 attached hereto and (ii) an executed Disbursement Letter in the form of EXHIBIT B-2 attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of each Loan Payment Request Form and the date of each Disbursement Letter and the Funding Date of each Term Loan; 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; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) there has not been any Material Adverse Change;

(d) no Event of Default or an event that with the passage of time could result in an Event of Default, shall exist;

(e) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Term Loan made by such Lender after the Effective Date;

Loan; (f) if the Term Loan is the Term B Loan, Borrower must have achieved the Term B Milestone as measured on the last day of the month immediately preceding the Funding Date of the Term B

Loan; (g) if the Term Loan is the Term C Loan, Borrower must have achieved the Term C Milestone as measured on the last day of the month immediately preceding the Funding Date of the Term C

(h) if the Term Loan is the Term D Loan, Borrower must be drawing the Term D Loan solely to finance any Approved Acquisition; and



- (i) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Term Loan. Borrower expressly agrees that the Term Loan made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of the Term Loan set forth in this Agreement, to obtain the Term Loan (other than the Term Loan funded on the Effective Date), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon New York City time seven (7) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Disbursement Letter and Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee.

**3.5 Post-Closing Covenants.** Borrower shall:

(a) Within 45 days after the Effective Date (or such longer time agreed to by the Collateral Agent) deliver a landlord's consent executed in favor of Collateral Agent in respect of Borrower's headquarters location and other leased locations in the United States where Borrower maintains Collateral having a book value in excess of Seven Hundred Fifty Thousand Dollars (\$750,000.00);

(b) Within 45 days after the Effective Date (or such longer time agreed to by the Collateral Agent) deliver a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Loan Party maintains Collateral in the United States having a book value in excess of Seven Hundred Fifty Thousand Dollars (\$750,000.00);

(c) Within 30 days after the Effective Date (or such longer time agreed to by the Collateral Agent) deliver evidence reasonably satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;

(d) Within 15 days after the Effective Date (or such longer time agreed to by the Collateral Agent) deliver duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any other Loan Party;

(e) Within 90 days after the Effective Date or such longer time agreed to by the Collateral Agent) deliver duly executed original pledge agreement under the law of England and Wales with respect to the shares of Apollo Endosurgery UK Ltd that are owned by Borrower;

(f) Within 90 days after the Effective Date or such longer time agreed to by the Collateral Agent) deliver duly executed original pledge agreement under the law of Costa Rica with respect to the shares of Apollo Endosurgery Costa Rica S.R.L. that are owned by Borrower; and

(g) Within 90 days after the Effective Date or such longer time agreed to by the Collateral Agent) original share certificates together with assignment separates for certificated equity interests owned by Borrower in its direct Subsidiaries.

#### **4. CREATION OF SECURITY INTEREST**

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now

owned or hereafter acquired or arising, and all proceeds and products thereof. If Borrower shall acquire a commercial tort claim (as defined in the Code) with a potential value in excess of \$200,000, Borrower shall grant to Collateral Agent, for the ratable benefit of the Lenders, a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to extend the Term Loans has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

**4.2 Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents.

## 5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate and any updates or supplements thereto on or before the Effective Date (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that all the information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries is accurate and complete in all material respects.

The execution, delivery and performance by Borrower and each Loan Party of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Loan Party's organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Loan Party, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Loan Parties, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

### 5.2 Collateral.

(a) Borrower and each other Loan Party have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any other Loan Party have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which Borrower or such Loan Party has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein as required under this Agreement. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens.

(c) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral in excess of Seven Hundred Fifty Thousand Dollars (\$750,000.00).

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificate (which, upon the consummation of a transaction not prohibited by this Agreement, may be updated to reflect such transaction), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license.

**5.3 Litigation.** Except as disclosed on the Perfection Certificate or with respect to which Borrower has provided notice as required hereunder, there are no actions, suits, investigations, or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than One Million Dollars (\$1,000,000.00).

**5.4 No Material Adverse Change; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. Since the date of the most recent financial statements submitted to any Lender, there has not been a Material Adverse Change.

**5.5 Solvency.** Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's Knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the Knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti Terrorism Law.

5.7 **Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 **Tax Returns and Payments; Pension Contributions.** Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and material local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries in an amount greater than One Hundred Thousand Dollars (\$100,000.00), in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the next sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted. Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries' prior tax years which could result in additional taxes (in an amount greater than One Hundred Thousand Dollars (\$100,000.00)) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 **Use of Proceeds.** Borrower shall use the proceeds of the Term Loan solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes. A portion of the proceeds of the Term A Loans shall be used by Borrower to repay the Existing Indebtedness in full on the Effective Date. Notwithstanding the foregoing, proceeds of the Term D Loan shall be used only for an Approved Acquisition.

5.10 **Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement, when taken as a whole, given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not materially misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

## 6. **AFFIRMATIVE COVENANTS**

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

### 6.1 **Government Compliance.**

(a) (a) Other than specifically permitted hereunder, maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral.

### 6.2 **Financial Statements, Reports, Certificates; Notices.**

(a) Deliver to Collateral Agent and each Lender:

(i) no later than forty five (45) days after the last day of each of the first three fiscal quarters of each fiscal year, a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) no later than one hundred twenty (120) days after the last day of Parent's fiscal year or within five (5) days of filing with the Securities and Exchange Commission, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on such financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion; provided that Parent's auditor as of the Effective Date and other nationally recognized auditors shall be deemed acceptable to Collateral Agent;

(iii) as soon as available after approval thereof by Parent's board of directors, but no later than the earlier of ten (10) days after such approval and forty-five (45) days after the last day of Parent's fiscal year, Parent's annual (A) financial projections and (B) budget, in each case, for the entire current fiscal year as approved by Parent's board of directors; provided that, any revisions to such projections and/or budget approved by Parent's board of directors shall be delivered to Collateral Agent and the Lenders no later than ten (10) Business Days after such approval;

(iv) within five (5) days of delivery, copies of all non-ministerial statements, reports and notices made available to Parent's board of directors, security holders or holders of Subordinated Debt (other than materials provided to members of Parent's board of directors solely in their capacities as security holder or holders of Subordinated Debt);

(v) within five (5) days of filing, all reports on Form 10 K, 10 Q and 8 K filed with the Securities and Exchange Commission;

(vi) concurrently with delivery of the financial statements required by Section 6.2(a)(i) for the last month of each quarter, notice of any changes the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) as soon as available, but no later than forty five (45) days after the last day of each quarter, copies of the most recent month end account statements for each Collateral Account with a balance in excess of \$250,000 maintained by Borrower or any Loan Party, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), provided that if an Event of Default has occurred and is continuing as of the end of any such fiscal quarter, Borrower shall provide the most recent month end account statements for all Collateral Accounts of Borrower or any Loan Party;

(viii) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change;

(ix) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the Borrower's Intellectual Property and (B) could reasonably be expected to result in a Material Adverse Change;

(x) written notice (10) days' prior to Borrower's creation of a New Subsidiary in accordance with the terms of Section 6.10;

(xi) written notice at least ten (10) days' prior to Borrower's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Seven Hundred Fifty Thousand Dollars (\$750,000.00) in assets or property of Borrower or any of its Subsidiaries),

(B) changing its jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its legal name, or (E) changing any organizational number (if any) assigned by its jurisdiction of organization;

(xii) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within five (5) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default;

(xiii) immediate notice if Borrower or such Subsidiary has Knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xiv) notice of any commercial tort claim reasonably expected to have a value in excess of \$200,000 and of the general details thereof;

(xv) if Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, written notice of such occurrence and information regarding such Person's organizational identification number within seven (7) Business Days of receiving such organizational identification number;

(xvi) concurrently with delivery of (A) the financial statements specified in Section 6.2(a)(i) for the second fiscal quarter of each fiscal year and (B) the financial statements specified in Section 6.2(a)(ii), an updated Perfection Certificate to reflect any amendments, modifications and updates to certain information in the Perfection Certificate after the Effective Date to the extent such amendments, modifications and updates are permitted by one or more specific provisions in this Agreement; in each case, subject to the review and approval of Collateral Agent and each Lender, provided that such updates shall only be required twice per fiscal year; and

(xvii) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the Securities and Exchange Commission) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i), deliver to Collateral Agent and each Lender:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

its Subsidiaries;

(ii) copies of any material Governmental Approvals obtained by Borrower or any of

(iii) written notice of the commencement of, and any material development in, the proceedings contemplated by Section 5.8 hereof;

(iv) written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of more than Five Hundred Thousand Dollars (\$500,000.00);

(v) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Five Hundred Thousand Dollars (\$500,000.00) individually or in the aggregate in any calendar year; and

(vi) an updated list of Borrower's registered Intellectual Property.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing. Notwithstanding the foregoing, upon request of any Lender, Borrower agrees to permit such Lender to communicate with Borrower's accounting firm with respect to the consolidated financial statements delivered pursuant to this Section 6.2.

**6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date.

**6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and material local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof, and shall deliver to Collateral Agent and each Lender, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

**6.5 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request, including, but not limited to, D&O insurance reasonably satisfactory to Collateral Agent. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days' prior written notice before any such policy or policies shall be canceled (other than cancellation for non-payment of premiums, for which ten (10) days' prior written notice shall be required). At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy within 90 days of receipt thereof up to One Hundred Thousand Dollars (\$100,000.00) with respect to any loss, but not exceeding One Hundred Thousand Dollars (\$100,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

**6.6 Operating Accounts.**

(a) Borrower shall provide Collateral Agent ten (10) days' prior written notice before Borrower or any other Loan Party establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any other Loan Party at any time maintains, Borrower or such Loan Party shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.

(b) Neither Borrower nor any other Loan Party shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Section 6.6.

**6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall:

(a) protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of a challenge to the validity, or material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to its business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent. If Borrower or any of its Subsidiaries (i) obtains any patent, registered trademark or servicemark, registered copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any patent or the registration of any trademark or servicemark, then Borrower or such Subsidiary shall provide written notice thereof to Collateral Agent and each Lender in accordance with Section 6.2(b)(vi) and shall execute such intellectual property security agreements and other documents and take such other actions as Collateral Agent shall reasonably request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in such property. If Borrower or any of its Subsidiaries decides to register any copyrights or mask works in the United States Copyright Office, Borrower or such Subsidiary shall provide notice thereof promptly and execute an intellectual property security agreement and such other documents and take such other actions as Collateral Agent may reasonably request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in the copyrights or mask works intended to be registered with the United States Copyright Office. Borrower or such Subsidiary shall promptly provide to Collateral Agent and each Lender with evidence of the recording of the intellectual property security agreement necessary for Collateral Agent to perfect and maintain a first priority perfected security interest in such property.

**6.8 Litigation Cooperation.** Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

**6.9 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any other Loan Party, after the Effective Date, intends to add any new offices or business locations in the United States, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower shall notify Collateral Agent prior to the addition of such location and in the event that the Collateral at any new location in the United States is valued in excess of Seven Hundred Fifty Thousand Dollars (\$750,000.00) in the aggregate, at Collateral Agent's election, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent within thirty (30) days after the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

**6.10 Creation/Acquisition of Subsidiaries.** In the event any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary after the Effective Date (including pursuant to the Approved Acquisition), Borrower or such Subsidiary shall promptly notify Collateral Agent of such creation or acquisition, and Borrower or such Subsidiary shall, within 30 days, take all actions reasonably requested by Collateral Agent to



achieve any of the following with respect to such "New Subsidiary" (defined as a Subsidiary formed after the date hereof during the term of this Agreement): (i) to cause such New Subsidiary to become either a co-Borrower hereunder, if such New Subsidiary is organized under the laws of the United States, or a secured guarantor with respect to the Obligations; and (ii) to grant and pledge to Collateral Agent a perfected security interest in the shares of such New Subsidiary; provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary in an acquisition permitted by Section 7.7 hereof or otherwise approved by the Required Lenders, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to Collateral Agent, for the ratable benefit of Lenders, a perfected security interest in more than sixty-five percent (65%) of the stock, units or other evidence of ownership of such Foreign Subsidiary, if Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary providing such guarantee or pledge and security interest or Borrower providing a perfected security interest in more than sixty-five percent (65%) of the stock, units or other evidence of ownership would create a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code.

**6.11 Further Assurances.** Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

**6.12 Financial Covenant.** Commencing on the earlier of (i) December 31, 2023 or (ii) the Funding Date of the Term B Loan, as tested on the last day of each quarter, Parent, on a consolidated basis, shall achieve actual TTM Revenue for the 12-month period then ended in an amount not less than fifty percent (50.00%) of the projected amounts for such 12-month period as set forth in the Management Plan.

Notwithstanding anything herein to the contrary, Parent shall not be obligated to comply with the provisions of this Section 6.12 for any quarter if either (i) Parent, on a consolidated basis, achieves a TTM Revenue of at least [\*\*\*] as tested on the last day of the immediately preceding quarter or (ii) Parent, on a consolidated basis, has Cash Flow of greater than \$0 for its two most recently completed fiscal quarters.

**6.13 Liquidity Covenant.** Parent and its Subsidiaries, on a consolidated basis, shall at all times maintain a cash and cash equivalent balance of not less than seven and fifty-hundredths percent (7.50%) of the aggregate principal amount of Term Loans funded pursuant to this Agreement.

**6.14 [Reserved].**

**6.15 Material Agreements.** Borrower shall provide Collateral Agent no less than fourteen (14) days' notice after the termination of any Material Agreement. Notwithstanding the foregoing, the notice required to be delivered pursuant to this Section 6.15 (to the extent any such notice included in materials otherwise filed with the Securities and Exchange Commission) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

## **7. NEGATIVE COVENANTS**

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, dispose of (collectively, "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property (including Intellectual Property), except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses, (d) of cash or Cash Equivalents in the ordinary course of business in accordance with the then applicable Board approved annual budget, subject to the restrictions and limitations set forth in the Loan Documents; (e) Transfers to any Loan Party or any of its Subsidiaries that are Loan Parties from any Loan Party; (f) other Transfers in the aggregate not to exceed Five

Hundred Thousand Dollars (\$500,000.00) per fiscal year; (g) sales or discounting of doubtful or delinquent accounts in the ordinary course of business in an amount not to exceed One Million Dollars (\$1,000,000) per year, (h) Permitted IP Assets, (i) the entry into any Permitted Equity Derivative Transaction by the Borrower in connection with the issuance of any Permitted Convertible Debt, or (j) the settlement, unwinding or termination of any Permitted Equity Derivative Transaction.

**7.2 Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent and each Lender within ten (10) days of such cessation, or (ii) enter into any transaction or series of related transactions in which (A) the stockholders of Parent who were not stockholders immediately prior to the first such transaction own more than 49% of the voting stock of Parent immediately after giving effect to such transaction or related series of such transactions or (B) except as permitted by Section 7.3, Borrower ceases to own 100% of the ownership interests of a Subsidiary of Borrower (a "Change of Control"). Borrower shall not, without at least ten (10) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than One Million Dollars (\$1,000,000.00) in assets or property of Borrower or any of its Subsidiaries); (B) change its jurisdiction of organization, (C) except as permitted by Section 7.3, change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

**7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person, other than Approved Acquisitions and Permitted Acquisitions. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder in accordance with Section 6.10) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

**7.4 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.5 Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens".

**7.6 Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

**7.7 Restricted Payments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (a "Restricted Payment") other than (i) the declaration or payment of dividends to any Loan Party, (ii) so long as no Event of Default or event that with the passage of time would result in an Event of Default exists or would result therefrom, the declaration or payment of any dividends solely in the form of equity securities, (iii) purchases or repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, (iv) purchases for value of any rights distributed in connection with any stockholder rights plan; (v) purchases of capital stock pledged as collateral for loans to employees; purchases of capital stock in connection with the exercise of stock options or stock appreciation rights by way of cashless exercise or in connection with the satisfaction of withholding tax obligations; (vi) purchases of fractional shares of capital stock arising out of stock dividends, splits or combinations or business combinations or in connection with exercises or conversions of options, warrants and other convertible securities;

(vii) conversions or exchanges of convertible securities into or for other securities (plus cash in lieu of any fractional shares) pursuant to the terms of such convertible securities or otherwise in exchange thereof; (viii) dividends and distributions by any Subsidiary to any Loan Party, (ix) other Restricted Payments and (x) any payment (including payment of any premium) or delivery with respect to, or early unwind or settlement or termination of, any Permitted Equity Derivative Transaction; provided that, the aggregate amount of all Restricted Payments in the foregoing clauses (i)-(ix) above shall not exceed Two Million Five Hundred Thousand Dollars (\$2,500,000.00) in the aggregate while any Obligations hereunder are outstanding and no more than One Million Dollars (\$1,000,000.00) in the aggregate in any given calendar year, (b) other than the Obligations in accordance with the terms hereof, purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any Indebtedness prior to its scheduled maturity unless being replaced with Indebtedness of at least the same principal amount and such new Indebtedness is Permitted Indebtedness, or (c) be a party to or bound by an agreement that restricts a Subsidiary from paying dividends or otherwise distributing property to any Loan Party. Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit (i) the conversion by holders of (including any cash in lieu of fractional shares) or the forced conversion of any Existing Convertible Debt or Permitted Convertible Debt in to equity securities of Borrower, in each case, in accordance with the terms of the agreements governing such Existing Convertible Debt or Permitted Convertible Debt.

**7.8 Investments.** Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

**7.9 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non affiliated Person, (b) Subordinated Debt or equity investments by Parent's investors in Parent or its Subsidiaries, (c) intercompany transactions expressly permitted by Section 7.1, 7.3, 7.4, 7.7 or 7.8, (d) normal and reasonable compensation and reimbursement of expenses of officers and directors in the ordinary course of business approved by Borrower's or such Subsidiary's board of directors, (e) employment arrangements with executive officers approved by Borrower's Board of Directors and entered into in the ordinary course of business that are consistent with Borrower's past practices and the applicable industry standards, and (f) equity financings of the Borrower that are not prohibited by the terms of this Agreement.

**7.10 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders; provided, that, this Section 7.10 shall not apply to any conversion of Indebtedness into equity interests.

**7.11 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the failure to comply or violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**7.12 Compliance with Anti Terrorism Laws.** Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including,

without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti Terrorism Law.

## **8. EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof);

### **8.2 Covenant Default.**

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 2.7 (Conversion To Equity), 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries), 6.12 (Financial Covenant), 6.13 (Liquidity Covenant) or 6.14 (Equity Raise) or Borrower violates any provision in Section 7; provided, however, in the event that the Borrower fails to comply with the requirements of the financial covenant set forth in Section 6.12, Borrower may cure such breach by means of submitting a new financial plan approved by the board of directors of the Borrower to Collateral Agent, along with a plan of how to finance such new board approved financial plan, no later than thirty (30) days after the occurrence of the breach of the financial covenant; provided, that upon such cure the parties shall amend the covenant in Section 6.12 in accordance with the new financial plan which amendment must be acceptable to Collateral Agent and shall, among other things, require Borrower to achieve the full net revenue projections set forth in the new financial plan; provided that, if for any given fiscal year, there is going concern qualification in Parent's independent certified public accounting firm's opinion on Parent's financial statements in violation of Section 6.2(a)(ii), Parent, in its discretion, may cure such going concern qualification and such default under this Section 8.2(a) by receiving unrestricted net cash proceeds from the issuance and sale of equity securities, convertible unsecured Subordinated Debt or Permitted Convertible Debt, during the period beginning on the date of such opinion and ending on the 1-month anniversary of the date of such opinion, in an amount equal to the difference between (i) Parent's projected 12-month Cash Burn for the 12-month period commencing on the first day of the month in which Parent receives such opinion minus (ii) the Parent's consolidated aggregate unrestricted cash balance on the date of such opinion; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within fifteen (15) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the fifteen (15) day period or cannot after diligent attempts by Borrower be cured within such fifteen (15) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loan shall be made during such cure period);

**8.3 Material Adverse Change.** A Material Adverse Change has occurred;

**8.4 Attachment; Levy; Restraint on Business.**

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any

institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment (other than a Permitted Lien) is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within twenty (20) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

**8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty five (45) days (but no Term Loan shall be extended while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

**8.6 Other Agreements.** There is (a) a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purpose of this Agreement upon Lender receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (i) Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto, (ii) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document, and (iii) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Lender be materially less advantageous to Borrower; provided further, that this Section 8.6 shall not apply to (x) any early payment requirement or unwinding or termination with respect to any Permitted Equity Derivative Transaction, or satisfaction of any condition giving rise to or permitting the foregoing, in accordance with the terms thereof, so long as, in any such case, the Borrower and its Subsidiaries are not the "defaulting party" or otherwise in breach under the terms of such Permitted Equity Derivative Transaction, or (y) any event that permits or causes repurchase, payment, prepayment, redemption, conversion, settlement or exchange of Existing Convertible Debt or Permitted Convertible Debt that is not the result of a breach or default by the Borrower or a Subsidiary of the terms of an agreement governing such Existing Convertible Debt or Permitted Convertible Debt or an event or condition that constitutes an Event of Default hereunder.

**8.7 Judgments.** (a) One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third party insurance) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of twenty (20) days after the entry thereof or (b) any judgments, orders or decrees rendered against Borrower that could reasonably be expected to result in a Material Adverse Change;

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;

**8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

**8.10 Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Section 8 occurs with respect to any Guarantor; or (d) a Material Adverse Change with respect to any Guarantor;

**8.11 Governmental Approvals; FDA Action.** (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA, DOJ, or other Governmental Authority initiates a Regulatory Action or any other enforcement action against Borrower or any of its Subsidiaries or any supplier of Borrower or any of its Subsidiaries that causes Borrower or any of its Subsidiaries to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products, even if such action is based on previously disclosed conduct, which could reasonably be expected to result in a Material Adverse Change; (ii) the FDA issues a warning letter or Regulatory Action to Borrower or any of its Subsidiaries with respect to any of its activities or products which could reasonably be expected to result in a Material Adverse Change; (iii) Borrower or any of its Subsidiaries conducts a mandatory or voluntary recall which could reasonably be expected to result in a Material Adverse Change; (iv) Borrower or any of its Subsidiaries enters into a settlement agreement with the FDA, DOJ, or other Governmental Authority which could reasonably be expected to result in a Material Adverse Change, or that could reasonably be expected to result in a Material Adverse Change even if such settlement agreement is based on previously disclosed conduct; (v) Borrower or any of its Subsidiaries fails to remediate observations identified in an FDA Form 483 notice of inspection observation to Collateral Agent's reasonable satisfaction within six months of receipt or such longer period as specified in such notice; or (vi) the FDA revokes any authorization or permission granted under any Registration, or Borrower or any of its Subsidiaries withdraws any Registration, that could reasonably be expected to result in a Material Adverse Change.

**8.12 Lien Priority; Intellectual Property.** Except as the result of the failure of Collateral Agent to file an applicable UCC financing statement or a continuation thereof or amendment thereto, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens arising as a matter of applicable law. Any Intellectual Property material to Borrower's business shall cease to be validly owned or licensed by Borrower free and clear of any Liens other than Permitted Liens.

## 9. RIGHTS AND REMEDIES

### 9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non exclusive, royalty free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance.

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney in fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or

any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney in fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to extend the Term Loan hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide the Term Loan terminates.

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

**9.4 Application of Payments and Proceeds.** Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other Obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.



**9.5 Liability for Collateral.** So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6 No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

**10. NOTICES**

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: APOLLO ENDOSURGERY, INC.  
1120 S. Capital of Texas Highway Building 1, Suite #300  
Austin, Texas 78746 Attn: General Counsel  
EMAIL: brian.szymczak@apolloendo.com

with a copy (which shall not constitute notice) to: COOLEY LLP  
1299 Pennsylvania Avenue, NW, Suite 700  
Washington, DC 20004-2400 Attn: Michael Tollini  
Email: mtollini@cooley.com

If to Collateral Agent: INNOVATUS LIFE SCIENCES  
LENDING FUND I, LP  
777 Third Avenue, 25th Floor New York, NY 10017  
Attn: Claes Ekstrom  
Email: cekstrom@innovatuscp.com

with a copy (which shall not constitute notice) to: Greenberg Traurig, LLP  
One International Place Boston, MA 02110 Attn: Abdullah Malik Fax: (617) 897-0983  
Email: malikab@gtlaw.com

**11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER**

**11.1 Waiver of Jury Trial.** EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

**11.2 Governing Law and Jurisdiction.**

(a) THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER 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, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

(b) Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

(c) Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law,

including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(d) Non-exclusive Jurisdiction. Nothing contained in this Section 11.2 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

## 12. GENERAL PROVISIONS

**12.1 Successors and Assigns.** This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without the Loan Parties' consent, to any Person which is an Affiliate or Subsidiary of any Loan Party, a then-current direct competitor of any Loan Party, as reasonably determined by Collateral Agent at the time of such assignment.

**12.2 Indemnification.** Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against:  
(a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

**12.3 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**12.4 Correction of Loan Documents.** Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

**12.5 Amendments in Writing; Integration.** (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent

to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.5. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement 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 Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.6 Counterparts.** This Agreement 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 Agreement.

**12.7 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

**12.8 Confidentiality.** In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders'

and Collateral Agent's Subsidiaries or Affiliates; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loan (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent at no fault of the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

**12.9 Right of Set Off.** Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

**12.10 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.8, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

**12.11 Public Announcement.** Borrower hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames and logos.

**12.12 Collateral Agent and Lender Agreement.** Collateral Agent and each Lender hereby agree to the terms and conditions set forth on Annex I attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Annex I attached hereto.

### 13. DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

“**Account**” is any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

“**Account Debtor**” is any “account debtor” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“**Affiliate**” of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person’s senior executive officers, directors, partners if such Person is a partnership and, for any Person that is a limited liability company, that Person’s managers and members.

“**Amortization Date**” is February 1, 2027.

“**Anti Terrorism Laws**” are any laws relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Approved Acquisition**” is the acquisition by Borrower or one of its Subsidiaries of, all or substantially all of the capital stock, shares, assets or property of another Person, which acquisition is approved by Collateral Agent in its discretion.

“**Basic Rate**” is with respect to each Term Loan, the floating per annum rate of interest (based on a year of three hundred sixty five (365) days) equal to the sum of (a) the greater of (i) Prime Rate, subject to Section 2.3(f), or (ii) Three and twenty-five hundredths percent (3.25%), plus (b) Four percent (4.00%).

“**Blocked Person**” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed. “**Cash Burn**” is the cash used by Borrower in its operations and capital expenditures.

“**Cash Flow**” is cash flow from operations minus capital expenditures, determined in accordance with GAAP.

“**Cash Equivalents**” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent and (d) any money market or similar funds that exclusively hold any of the foregoing.

“**Change of Control**” has the meaning set forth in Section 7.2.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “**Code**” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Collateral Account**” is, except for Excluded Accounts, any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Loan Party at any time.

“**Commitment Percentage**” is set forth in Schedule 1.1, as amended from time to time.

“**Commodity Account**” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“**Compliance Certificate**” is that certain certificate in substantially the form attached hereto as Exhibit C.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another Person such as an obligation directly or indirectly guaranteed, endorsed, co made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Control Agreement**” is any control agreement entered into among the depository institution at which Borrower or any Loan Party maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any Loan Party maintains a Securities Account or a Commodity Account, Borrower and such Loan Party, and Collateral Agent pursuant to which Collateral Agent, for the benefit of the Lenders, obtains “control” (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Deposit Account**” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“**Disbursement Letter**” is that certain form attached hereto as EXHIBIT B-2.

“**DOJ**” means the U.S. Department of Justice or any successor thereto or any other comparable Governmental Authority.

“**Dollars**,” “dollars” and “\$” each mean lawful money of the United States.

“**Equipment**” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“**ERISA**” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“**Excluded Accounts**” means (i) Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of any Loan Party’s employees; provided that the amount deposited in all such accounts shall not exceed the aggregate amount reasonably expected to be due and payable for the next two (2) succeeding pay periods, (ii) Deposit Accounts holding cash collateral constituting a Permitted Lien and (iii) Borrower’s lockbox account at Bank of America existing on the Effective Date as long as the balance in such account does not exceed \$150,000 at any time and any amounts in such account are swept into a controlled account on a regular basis.

“**Exigent Circumstance**” means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

“**Existing Convertible Debt**” means those certain 6.00% Convertible Senior Debentures due 2024 (collectively, the “**Convertible Debentures**”), issued pursuant to that certain Securities Purchase Agreement, dated as of August 7, 2019, between Parent and the purchasers party thereto, in an aggregate principal amount of up to \$20,000,000, plus any amounts paid-in-kind pursuant to the terms thereof.

“**Existing Indebtedness**” is the indebtedness of Borrower to Solar Capital in the aggregate principal outstanding amount as of the Effective Date of approximately Thirty Five Million Dollars (\$35,000,000) pursuant to that certain Loan and Security Agreement, dated March 15, 2019, entered into by and between Solar Capital LTD., Borrower and certain of Borrower’s Subsidiaries party thereto.

“**Facility Fee**” is a fee payable to each Lender: (i) due on the Funding Date of Term A Loan equal to 1.00% of the total Term Loan Commitment with respect to Term A Loan of such Lender, (ii) due on the Funding Date of Term B Loan equal to 1.00% of the total Term Loan Commitment with respect to Term B Loan of such Lender, (iii) due on the Funding Date of Term C Loan equal to 1.00% of the total Term Loan Commitment with respect to Term C Loan of such Lender and (iv) due on the Funding Date of Term D Loan equal to 1.00% of the total Term Loan Commitment with respect to Term D Loan of such Lender.

“**FDA**” means the U.S. Food and Drug Administration or any successor thereto or any other comparable Governmental Authority.

“**Final Fee**” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest or any other fee payable hereunder) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of the Term Loans pursuant to Section 2.2(c) or (d), in each case equal to Final Fee Percentage *multiplied* by the aggregate amount of the Term Loans funded and not converted to Parent Equity pursuant to Section 2.7, payable to Lenders in accordance with their respective Pro Rata Shares.

“**Final Fee Percentage**” is four percent (4.00%).

“**Foreign Currency**” means lawful money of a country other than the United States.

“**Foreign Subsidiary**” is a Subsidiary that is not an entity organized under the laws of the United States or any state thereof.

“**Funding Date**” is any date on which the Term Loan is made to or on account of Borrower which shall be a



Business Day.

“**GAAP**” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“**General Intangibles**” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“**Governmental Approval**” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“**Governmental Authority**” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body (including, without limitation, the FDA and any state board of pharmacy or state pharmacy licensing authority), court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self regulatory organization.

“**Guarantor**” is any Person providing a Guaranty in favor of Collateral Agent for the benefit of the Lenders.

“**Guaranty**” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“**Hedging Transaction**” shall mean each interest rate swap transaction, basis swap transaction, forward rate transaction, equity transaction, equity index transaction, foreign exchange transaction, cap transaction, floor transaction (including any option with respect to any of these transactions and any combination of any of the foregoing); provided that the following shall not constitute “Hedging Transactions”: (a) any phantom stock or similar plan providing for payments only on account of services provided by current or former directors, officers, employees or consultants of the Borrower and its Subsidiaries, (b) any stock option or warrant agreement for the purchase of equity interests of the Borrower, and (c) Permitted Equity Derivative Transactions.

“**Indebtedness**” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“**Insolvency Proceeding**” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

“**Insolvent**” means not Solvent.

“**Intellectual Property**” means all of Borrower’s or any of its Subsidiaries’ right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know how, operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above;
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and
- (g) all licenses, sublicenses or other contracts under which Borrower or any Subsidiary is granted rights by third parties in any Intellectual Property asset.

“**Inventory**” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“**Investment**” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

“**IP Security Agreement**” is that certain Intellectual Property Security Agreement executed and delivered by Borrower to Collateral Agent and dated as of the Effective Date, as may be amended, restated, or otherwise modified or supplemented from time to time.

“**Key Person**” is each of Borrower’s Chief Executive Officer, who is Charles McKhann as of the Effective Date.

“**Knowledge**” means to the “best of” Borrower’s knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

“**Lender**” is any one of the Lenders.

“**Lenders**” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“**Lenders’ Expenses**” are all reasonable and documented audit fees and expenses, costs, and expenses (including reasonable and documented out-of-pocket attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“**Lien**” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Loan Documents**” are, collectively, this Agreement, the IP Security Agreement, each Secured Promissory Note, the Perfection Certificate(s), each Control Agreement, each Compliance Certificate, each Loan Payment Request Form, each Disbursement Letter, any subordination agreements, any note, or notes or guaranties executed by

Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified or supplemented from time to time.

“**Loan Party**” means each Borrower and each Guarantor.

“**Loan Payment Request Form**” is that certain form attached hereto as **EXHIBIT B-1**.

“**Management Plan**” is, Borrower’s Board approved projected Revenue for all applicable quarterly periods through the last quarter before the Maturity Date, based on which the financial covenant set forth in Section 6.12 will be tested and which will be delivered at least 10 days prior to the commencement of the financial covenant to Collateral Agent and attached hereto as Annex X.

“**Material Adverse Change**” is (a) a material adverse change in the business, operations or financial or other condition of Borrower or any Subsidiary, when taken as a whole; (b) a material impairment of the prospect of repayment of any portion of the Obligations, or (c) a material adverse effect on the Collateral.

“**Material Agreement**” is any license, agreement or other contractual arrangement with a Person or Governmental Authority filed by Parent with the Securities and Exchange Commission pursuant to an 8 K.

“**Maturity Date**” is December 21, 2027.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Fee, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents.

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**OFAC Lists**” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, re-examination certificates, utility models, extensions and continuations-in-part of the same.

“**Payment Date**” is the first (1st) calendar day of each calendar month, commencing on February 1, 2022.

“**Permitted Acquisition**” is any acquisition, directly or indirectly, by Borrower or any of its Subsidiaries, whether by purchase, merger or otherwise, of all or substantially all of the assets of, all or any of the equity securities of, or a business line or unit or a division of, any Person; provided, that,

- (a) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all applicable laws and in conformity with all applicable governmental authorizations;

(b) Borrower shall have delivered to Lenders (i) at least ten (10) Business Days prior to such proposed acquisition (or such shorter period as may be agreed by Lenders), all relevant available financial information with respect to such acquired assets, including the aggregate consideration for such acquisition and (ii) promptly upon request by Lenders, a copy of the purchase agreement related to the proposed acquisition (and any related available documents reasonably requested by Lenders);

(c) any Person or assets or division as acquired in accordance herewith shall be in substantially the same business or lines of business in which the Borrower and its Subsidiaries are engaged or any business or other activities that are reasonably similar, ancillary, complementary or related to, or a reasonable extension, development or expansion of, the businesses in which Borrower its Subsidiaries are engaged;

(d) no Event of Default has occurred and is continuing or would exist after giving effect to the transaction;

(e) in the case of any merger involving a Borrower, such Borrower is a surviving legal entity after completion of the contemplated transaction and such merger does not result in a change of control of Borrower;

(f) the contemplated transaction is consensual and non-hostile;

(g) with respect to any Person whose capital stock is acquired by a Borrower or any Subsidiary that acquires assets in such contemplated transaction, such Borrower shall comply with the applicable terms of Section 6.10; and

(h) the aggregate cash consideration for all such acquisitions shall not exceed Five Million Dollars (\$5,000,000) per year; provided that solely for purposes of this clause (h), the cumulative incremental Cash Burn (calculated by Parent in good faith on a pro forma basis giving effect to all such Permitted Acquisitions) projected to be realized from and after the date of consummation of the first Permitted Acquisition through and including the Maturity Date shall be deemed cash consideration.

**“Permitted Convertible Debt”** means any unsecured notes issued by the Parent that are or will become convertible into or exchangeable for shares of common stock of the Parent (or other securities or property following a merger event or other change of the common stock of the Parent) (and cash in lieu of fraction shares), cash or any combination thereof (with the amount of such shares, cash or such combination determined by reference to the market price of such common stock or such other securities); *provided* that such Indebtedness must satisfy each of the following conditions: (i) both immediately prior to and after giving effect (including pro forma effect) to the issuance thereof, no Default or Event of Default shall exist or result therefrom, (ii) such Indebtedness matures after, and does not require any scheduled amortization or other scheduled or otherwise required payments of principal or interest prior to, or have a scheduled maturity date earlier than, the date that is ninety one (91) calendar days after all Obligations pursuant to the Loan Documents have been fully repaid and prior to that date, does not provide for or require any payments of principal, interest or any other payments, obligations to settle conversions, redemption rights and customary obligations to offer to repurchase the notes upon the occurrence of a “fundamental change”, asset sale or change of control, in each case, after all Obligations pursuant to the Loan Documents have been fully repaid, (iii) the terms, conditions and covenants (other than pricing terms determined through a customary marketing process) of such Indebtedness must be customary for convertible Indebtedness of such type at the time of issuance (as determined by the Board, or a committee thereof, in good faith), (iv) such Indebtedness is not guaranteed by any Subsidiary of the Parent. For the avoidance of doubt, and without limitation of the foregoing, for purposes of this Agreement, Permitted Convertible Debt shall at all times be valued at the full stated principal amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof and (v) such Indebtedness is subject to a subordination agreement with respect to the Indebtedness incurred pursuant to the Loan Documents which agreement must be in such form and substance as are acceptable to Collateral Agent; provided that a subordination agreement shall not be required if such convertible debt is unsecured and is issued in a registered offering or a private offering pursuant to rule 144A.

**“Permitted Equity Derivative Transaction”** shall mean any forward purchase, accelerated share repurchase, call option, warrant or other derivative transaction relating to Parent’s common stock (or other securities or property following a merger event, reclassification or other change of the common stock of Parent) purchased or sold by Parent in connection with the issuance of any Permitted Convertible Debt and settled in common stock of Parent (or such other securities or property), cash or a combination thereof, as the same may be amended, restated,

supplemented or otherwise modified from time to time; provided that (a) the aggregate net purchase price for such Permitted Equity Derivative Transactions does not exceed the net cash proceeds received by Parent from the sale of the Permitted Convertible Debt in connection with which such Permitted Equity Derivative Transactions were entered into, and (b) the other terms, conditions and covenants of each such transaction shall be such as are customary for transactions of such type (as determined by Parent in good faith).

“Permitted Indebtedness” is:

- (a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors and Indebtedness in connection with credit cards and in respect of any agreement providing for treasury, depository, purchasing card or cash management services, bank card products or services provided in connection therewith, including in connection with any automated clearing house transfers of funds or any similar transactions, netting services, overdraft protections and other like services, in each case, incurred in the ordinary course of business;
- (e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such Person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Three Million Dollars (\$3,000,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);
- (f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower’s business;
- (g) Existing Convertible Debt and Permitted Convertible Debt and any refinancings, refundings, renewals or extensions thereof so long as such Indebtedness continues to qualify as Permitted Convertible Debt;
- (h) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business, in an aggregate amount not to exceed One Million Dollars (\$1,000,000.00) at any one time outstanding;
- (i) Indebtedness constituting reimbursement obligations in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any Subsidiary, in an aggregate amount for all such Indebtedness not to exceed Three Million Dollars (\$3,000,000.00) at any one time outstanding; provided that Borrower shall notify Collateral Agent of any incurrence of Indebtedness pursuant to this clause (i) in excess of Two Million Dollars (\$2,000,000.00) at any time outstanding;
- (j) other Indebtedness at any time not to exceed Five Hundred Thousand Dollars (\$500,000) in the aggregate;
- (k) to the extent constituting Indebtedness, any Permitted Equity Derivative Transaction; provided, however, the aggregate amount of such Indebtedness outstanding at any given time does not exceed Five Hundred Thousand Dollars (\$500,000.00);
- (l) Indebtedness under any Hedging Transactions, provided that such transaction is not entered into for speculative purposes; provided, however, the aggregate amount of such Indebtedness outstanding at any given time does not exceed Five Hundred Thousand Dollars (\$500,000.00); and

(m) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (l) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

“Permitted Investments” are:

- (a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;
- (b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by Borrower’s investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;
- (c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;
- (d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected security interest to the extent required by the terms of this Agreement;
- (e) Investments in connection with Transfers permitted by Section 7.1;
- (f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower’s board of directors, not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate for (i) and (ii) in any fiscal year;
- (g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;
- (h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;
- (i) (x) Investments by Borrowers and Subsidiaries in Subsidiaries that are not Borrowers in an aggregate amount not to exceed \$1,000,000 in any given fiscal year, (y) Investments among Loan Parties and (z) Investments among Subsidiaries that are not Loan Parties;
- (j) non-cash Investments in joint ventures, corporate collaborations or strategic alliances in the ordinary course of Borrower’s business consisting of the non exclusive licensing of technology, the development of technology or the providing of technical support;
- (k) other Investments not exceeding Five Hundred Thousand Dollars (\$500,000) in the aggregate outstanding at any time;
- (l) Approved Acquisitions and Permitted Acquisitions; and
- (m) Investments in respect of Hedging Transactions, provided that such transaction is not entered into for speculative purposes; and the aggregate amount of such Investments does not exceed Five Hundred Thousand Dollars (\$500,000.00) in any given year.

“Permitted IP Assets” means that certain list of Intellectual Property identified by Borrower and delivered to Collateral Agent prior to the Effective Date.

**"Permitted Licenses"** are (A) licenses of over-the-counter software that is commercially available to the public, (B) non exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), the license constitutes an arms length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property and (C) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in this clause (C), the license

(i) constitutes an arms length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) is limited in territory with respect to a limited and discrete geographic country or region (i.e. Japan, Germany, northern China) outside of the United States, (iii) Borrower has obtained the consent and acknowledgement of the counterparty to such license for the collateral assignment of such license to the Collateral Agent and (iv) all proceeds of such license are deposited in a Collateral Account that is subject to a Collateral Agreement in favor of Collateral Agent; provided that such proceeds shall not be required to be deposited into a Collateral Account subject to a Control Agreement if there would be adverse tax consequences caused by the repatriation of cash held outside of the United States and Borrower notifies Collateral Agent of such.

**"Permitted Liens"** are:

- (a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;
- (b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;
- (c) liens securing Indebtedness permitted under clause (e) of the definition of "Permitted Indebtedness," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;
- (d) Liens of carriers, landlords, warehousemen, suppliers, mechanics, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;
- (e) Liens to secure payment of workers' compensation, employment insurance, old age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);
- (f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;
- (g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6 hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Permitted Licenses;

(k) security deposits under real property leases that are made in the ordinary course of business; provided, however, the aggregate amount of such deposits outstanding at any given time does not exceed Two Million Dollars (\$2,000,000.00); provided that Borrower shall notify Collateral Agent of any deposits in excess of One Million Dollars (\$1,000,000.00) in the aggregate at any time;

(l) easements, zoning restrictions, rights of way and similar encumbrances on real property imposed by law or arising in the ordinary course of business, and other minor title imperfections with respect to real property that do not secure any monetary obligations and do not materially impair the value of the affected property or interfere with the ordinary conduct of business of Borrower or any Subsidiary;

(m) deposits or pledges of cash to secure bids, tenders, contracts (other than contracts for the payment of money), leases, surety and appeal bonds and paid to professional employer organizations outside the United States and Canada and other obligations of a like nature arising in the ordinary course of business; provided, however, the aggregate amount of such deposits outstanding at any given time does not exceed Two Million Dollars (\$2,000,000.00); provided that Borrower shall notify Collateral Agent of any deposits in excess of One Million Dollars (\$1,000,000.00) in the aggregate at any time; and

(n) other Liens not exceeding Fifty Thousand Dollars (\$50,000) in the aggregate outstanding at any time; provided that such liens be limited to specific assets and not all assets or substantially all assets of any Loan Party.

"Person" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"PIK Rate" is 1.25%.

"Prepayment Fee" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Effective Date and through and including the date which is the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of the Term Loans prepaid; provided, however, a prepayment may only be made on or prior to the first anniversary of the Effective Date pursuant to Section 2.2(c) or as allowed under Section 2.2(d) (it being agreed and understood that no voluntary prepayment may be during such period other than in connection with a Change Of Control);

(ii) for a prepayment made after the date which is the first anniversary of the Effective Date and through and including the date which is the second anniversary of the Effective Date, two percent (2.00%) of the principal amount of the Term Loans prepaid;

(iii) for a prepayment made after the date which is the second anniversary of the Effective Date through and including the date which is the third anniversary of the Effective Date, one percent (1.00%) of the principal amount of the Term Loan prepaid; and



Loan prepaid. (iv) for a prepayment made after the date which is the third anniversary of the Effective Date and prior to the Maturity Date, zero percent (0.00%) of the principal amount of the Term

“**Prime Rate**” is the Prime Rate published in the Money Rates section of the of The Wall Street Journal.

“**Pro Rata Share**” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of the Term Loan held by such Lender by the aggregate outstanding principal amount of the Term Loan.

“**Property**” means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

“**Registered Organization**” is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“**Registration**” means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, abbreviated new drug applications, biologics license applications, investigational new drug applications, over-the-counter drug monograph, device pre-market approval applications, device pre-market notifications, investigational device exemptions, product recertifications, manufacturing approvals, registrations and authorizations, CE Marks, pricing and reimbursement approvals, labeling approvals or their foreign equivalent, controlled substance registrations, and wholesale distributor permits).

“**Regulatory Action**” means an administrative, regulatory, or judicial enforcement action, proceeding, investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, injunction or consent decree, issued by the FDA or a federal or state court.

“**Related Persons**” means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

“**Required Lenders**” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “**Original Lender**”) have not assigned or transferred any of their interests in the Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least fifty one percent (51%) of the aggregate outstanding principal balance of the Term Loan.

“**Requirement of Law**” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“**Responsible Officer**” is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

“**Revenue**” means the consolidated revenue of Borrower, determined in accordance with GAAP. “**Secured Promissory Note**” is defined in Section 2.6.

“**Secured Promissory Note Record**” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“**Securities Account**” is any “securities account” as defined in the Code with such additions to such term as may

hereafter be made under the Code.

“**Solvent**” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

“**Subordinated Debt**” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

“**Subsidiary**” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries. Unless otherwise specified, references herein to a Subsidiary means a Subsidiary of Borrower.

“**Term B Draw Period**” is the period commencing on the later of (i) the first date on which Borrower achieves the Term B Milestone and (ii) July 1, 2023 and ending on the earlier of (i) December 31, 2023 and (ii) the occurrence of an Event of Default (unless such Event of Default is waived by Collateral Agent and Lenders for the purposes of the continuation of the Term B Draw Period).

“**Term B Milestone**” is the achievement by Borrower of TTM Revenue of at least [\*\*\*] after the Effective Date.

“**Term C Draw Period**” is the period commencing on the later of (i) the first date on which Borrower achieves the Term C Milestone and (ii) July 1, 2024 and ending on the earlier of (i) December 31, 2024 and (ii) the occurrence of an Event of Default (unless such Event of Default is waived by Collateral Agent and Lenders for the purposes of the continuation of the Term C Draw Period).

“**Term C Milestone**” is the achievement by Borrower of TTM Revenue of at least [\*\*\*] after the Effective Date.

“**Term D Draw Period**” is the period commencing on June 30, 2022 and ending on the earlier of (i) June 30, 2024 and (ii) the occurrence of an Event of Default (unless such Event of Default is waived by Collateral Agent and Lenders for the purposes of the continuation of the Term D Draw Period).

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make the Term Loans, up to the principal amounts shown on Schedule 1.1. “**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower and each of its Subsidiaries connected with and symbolized by such trademarks.

“**TTM Revenue**” means trailing twelve (12) months Revenue, as of any date of determination.

*[Balance of Page Intentionally Left Blank]*

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**BORROWERS:**

APOLLO ENDOSURGERY, INC.

By                   /s/ Jeffrey Black                    
Name:                   Jeffrey Black                    
Title:                   Chief Financial Officer                  

APOLLO ENDOSURGERY INTERNATIONAL, LLC

By                   /s/ Jeffrey Black                    
Name:                   Jeffrey Black                    
Title:                   Chief Financial Officer                  

APOLLO ENDOSURGERY US, INC.

By                   /s/ Jeffrey Black                    
Name:                   Jeffrey Black                    
Title:                   Chief Financial Officer                  

LPATH THERAPEUTICS INC.

By                   /s/ Jeffrey Black                    
Name:                   Jeffrey Black                    
Title:                   Chief Financial Officer                  

**COLLATERAL AGENT AND LENDER:**

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By:                   Innovatus Life Sciences GP, LP                    
Its:                   General Partner                  

By                   /s/ Andrew Dym                    
Name:                   Andrew Dym                    
Title:                   Authorized Signatory

SCHEDULE 1.1

**Lenders and Commitments**

**Term A Loan**

<b>Lender</b>	<b>Term Loan A Commitment</b>	<b>Commitment Percentage</b>
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$35,000,000	100.00%
<b>TOTAL</b>	<b>\$35,000,000</b>	<b>100.00%</b>

**Term B Loan**

<b>Lender</b>	<b>Term Loan B Commitment</b>	<b>Commitment Percentage</b>
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$15,000,000	100.00%
<b>TOTAL</b>	<b>\$15,000,000</b>	<b>100.00%</b>

**Term C Loan**

<b>Lender</b>	<b>Term Loan C Commitment</b>	<b>Commitment Percentage</b>
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$25,000,000	100.00%
<b>TOTAL</b>	<b>\$25,000,000</b>	<b>100.00%</b>

**Term D Loan**

<b>Lender</b>	<b>Term Loan D Commitment</b>	<b>Commitment Percentage</b>
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$25,000,000	100.00%
<b>TOTAL</b>	<b>\$25,000,000</b>	<b>100.00%</b>

**EXHIBIT A**

**Description of Collateral**

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the "Collateral" does not include any of the following, whether now owned or hereafter acquired: (a) more than 65.00% of the voting equity interests of a foreign Subsidiary; (b) "any intent-to-use" US trademark application for which an amendment to allege use or statement of use has not been filed and accepted by the US Patent and Trademark Office and that would otherwise be deemed invalidated, cancelled or abandoned due to the grant of a security interest thereon (provided that each intent-to-use application shall be considered Collateral immediately and automatically upon such filing and acceptance); (c) interest of Borrower as a lessee or sublessee under a real property lease or an equipment lease if Borrower is prohibited by the terms of such lease from granting a security interest in such lease or under which such an assignment or Lien would cause a default to occur under such lease (but only to the extent that such prohibition is enforceable under all applicable laws including, without limitation, the Code); provided, however, that upon termination of such prohibition, such interest shall immediately become Collateral without any action by Borrower or Lender; and (d) Excluded Accounts

EXHIBIT B-1

Loan Payment Request Form

Fax To: \_\_\_\_\_ Date: \_\_\_\_\_

**LOAN** APOLLO ENDOSURGERY,

From Account # \_\_\_\_\_ To Account # \_\_\_\_\_  
(Deposit Account #) (Loan Account #)

Principal \$ \_\_\_\_\_ and/or Interest \$ \_\_\_\_\_

Authorized Signature: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
Print Name/Title: \_\_\_\_\_

**LOAN ADVANCE:**

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan

From Account # \_\_\_\_\_ To Account # \_\_\_\_\_  
(Loan Account #) (Deposit Account #)

Amount of Advance \$ \_\_\_\_\_

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; 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; and provided, further that those representations and warranties expressly referring to a specific date

Authorized Signature: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
Print Name/Title: \_\_\_\_\_

**OUTGOING WIRE REQUEST:**  
Complete only if all or a portion of funds from the loan advance

Beneficiary Name: \_\_\_\_\_ Amount of Wire: \$ \_\_\_\_\_  
Beneficiary Bank: \_\_\_\_\_ Account Number: \_\_\_\_\_  
City and State: \_\_\_\_\_

Beneficiary Bank Transit (ABA) #: \_\_\_\_\_ Beneficiary Bank Code (Swift, Sort, Chip, etc.): \_\_\_\_\_  
**(For International Wire Only)**

Intermediary Bank: \_\_\_\_\_ Transit (ABA) #: \_\_\_\_\_  
For Further Credit to: \_\_\_\_\_

Special Instruction: \_\_\_\_\_  
*By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which*

Authorized Signature: \_\_\_\_\_ 2<sup>nd</sup> Signature (if required): \_\_\_\_\_  
Print Name/Title: \_\_\_\_\_ Print Name/Title: \_\_\_\_\_  
Telephone #: \_\_\_\_\_ Telephone #: \_\_\_\_\_ ]

EXHIBIT B-2

**Form of Disbursement Letter**

[see attached]

DISBURSEMENT LETTER

December 21, 2021

The undersigned, being the duly elected and acting Chief Financial Officer of 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, Apollo International and Lpath, individually and collectively, jointly and severally, "**Borrower**"), does hereby certify to INNOVATUS LIFE SCIENCES LENDING FUND I, LP ("**Innovatus**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") in connection with that certain Loan and Security Agreement dated as of December [21], 2021, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Term A Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.

*[Balance of Page Intentionally Left Blank]*



7. The proceeds of the Term A Loan shall be disbursed as follows:

<b>Disbursement from Innovatus:</b>	
Loan Amount	\$35,000,000.00
Plus:	
--Deposit Received	\$75,000.00
--Adjustment to Lender Expenses due to Cap	\$11,282.56
Less:	
--Payoff of Existing Indebtedness to SLR Investment Corp.	(\$22,441,677.62)
--Payoff of Existing Indebtedness to SCP Private Credit Income Fund SPV LLC	(\$5,837,042.35)
--Payoff of Existing Indebtedness to SCP Private Credit Income BDC SPV LLC	(\$4,384,506.35)
--Payoff of Existing Indebtedness to SCP Private Corporate Lending Fund SPV LLC	(\$3,475,325.95)
--Payoff of Existing Indebtedness to SCP Cayman Debt Master Fund SPV LLC	(\$2,192,252.63)
--Solar Capital's Legal Fees (Latham & Watkins LLP)	(\$43,500.00)
--Solar Capital's Legal Fees (Facio & Canas)	(\$1,130.00)
--Facility Fee	(\$350,000.00)
--Interim Interest	(\$76,472.60)
--Lender's Legal Fees (Greenberg Traurig, LLP)	(\$47,000.00) *
--Lender's IP Due Diligence Fees (Cooley LLP)	(\$49,149.00)
--Lender's Management Background Check Fees (Exiger)	(\$2,716.43)
--Lender's Expert Calls (Coleman Research Group)	(\$3,300.00)
--Lender's Regulatory/Clinical Trial and Reimbursement Due Diligence (NDA Partners LLC)	(\$31,567.13)
--Lender's Expert Calls (AlphaSights)	(\$4,050.00)
--Lender's Manufacturing Due Diligence Fees (Medpoint, LLC)	(\$23,500.00)
<b>TOTAL TERM A LOAN NET PROCEEDS FROM INNOVATUS:</b>	<b>(\$3,876,907.50)</b>
<b>Net Proceeds from Apollo Endosurgery to Innovatus:</b>	<b>\$3,876,907.50</b>

8. The Term A Loan shall amortize in accordance with the Loan Interest Rate And Payment Of Principal schedule attached as Annex Y (as amended or restated from time to time) to the Loan Agreement.

9. The net proceeds from Apollo Endosurgery to Innovatus shall be deposited as follows:

Account Name: Innovatus Life Sciences Lending Fund I, LP Bank Name: First Republic Bank  
Bank Address: 111 Pine Street  
San Francisco, CA 94111  
Account Number: [\*\*\*]  
ABA Number: [\*\*\*]

*[Balance of Page Intentionally Left Blank]*

\* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

Dated as of the date first set forth above.

**BORROWER:**

APOLLO ENDOSURGERY, INC. APOLLO ENDOSURGERY INTERNATIONAL, LLC

By By  
Name: Name:  
Title: Title:

APOLLO ENDOSURGERY US, INC. LPATH THERAPEUTICS INC.

By By  
Name: Name:  
Title: Title:

**COLLATERAL AGENT AND LENDER:**

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By: Innovatus Life Sciences GP, LP Its: General Partner

By\_\_ Name:\_\_ Title:\_\_\_

**EXHIBIT C**

**Compliance Certificate**

TO: INNOVATUS LIFE SCIENCES LENDING FUND I, LP, as Collateral Agent and Lender FROM: APOLLO ENDOSURGERY, INC., as Borrower

The undersigned authorized officer (“**Officer**”) of 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, Apollo International and Lpath, individually and collectively, jointly and severally, “**Borrower**”), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement dated as of December 21, 2021, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the “**Loan Agreement**,” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

- (a) Borrower is in complete compliance for the period ending\_\_with all required covenants except as noted below;
- (b) There are no Defaults or Events of Default, except as noted below;
- (c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; 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; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.
- (d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;
- (e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

**Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.**

	<b>Reporting Covenant</b>	<b>Requirement</b>	<b>Actual</b>	<b>Complies</b>		
1)	Financial statements	Quarterly within 45 days		Yes	No	N/A
2)	Annual (CPA Audited) statements	Within 120 days after FYE		Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within earlier 10 days of approval or 45 days of FYE), and when revised (no later than 7 days of approval)		Yes	No	N/A

4)	8-K, 10-K and 10-Q Filings	Within 5 days of filing	Yes	No	N/A
5)	Compliance Certificate	Quarterly within 45 days	Yes	No	N/A
6)	IP Report	Quarterly within 45 days	Yes	No	N/A
7)	Quarter end account statements	Quarterly within 45 days	Yes	No	N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A
9)	Loan confirmation submitted to the fund administrator for Innovatus Life Sciences Lending Fund I, LP (see Exhibit C-2 to the Loan Agreement)	Quarterly within 45 days	Yes	No	N/A

**Negative Covenant Compliance**

**Negative Covenant    Complies**

- |     |   |     |    |     |
|-----|---|-----|----|-----|
| 1)  | Dispositions (§ 7.1)  | Yes | No | N/A |
| 2)  | Changes in Business, Management, Ownership, or Business Locations (§ 7.2) | Yes | No | N/A |
| 3)  | Mergers or Acquisitions (§ 7.3)   | Yes | No | N/A |
| 4)  | Indebtedness (§ 7.4)  | Yes | No | N/A |
| 5)  | Encumbrance (§ 7.5)   | Yes | No | N/A |
| 6)  | Maintenance of Collateral Accounts (§ 7.6)                                | Yes | No | N/A |
| 7)  | Restricted Payments (§ 7.7)   | Yes | No | N/A |
| 8)  | Investments (§ 7.8)   | Yes | No | N/A |
| 9)  | Transactions with Affiliates (§ 7.9)                                      | Yes | No | N/A |
| 10) | Subordinated Debt (§ 7.10)  | Yes | No | N/A |
| 11) | Compliance (§ 7.11)   | Yes | No | N/A |
| 12) | Compliance with Anti-Terrorism Laws (§ 7.12)                              | Yes | No | N/A |

Please attach supporting documentation and calculations for the below financial covenants.

	<b>Covenant Requirement</b>	<b>Actual</b>	<b>Complies</b>					
1)	Minimum TTM Revenue	Set forth in Section 6.12	\$__	Yes	No	N/A		
2)	Minimum Cash Balance	Set forth in Section 6.13	\$__	Yes	No	N/A		

**Deposit and Securities Accounts (Please list all accounts; attach separate sheet if additional space needed)**

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

**Other Matters**

1)	Have there been any changes in any Key Person since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Five Hundred Thousand Dollars (\$500,000.00)?	Yes	No
4)	Have there been any amendments of or other changes to the Operating Documents of Borrower or any other Loan Party? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No
6)	Since the last Compliance Certificate, do you anticipate any impending product shortages or supply chain disruptions? If yes, please explain.	Yes	No
7)	Are there major components from suppliers that are single sourced? If yes, please explain.	Yes	No
8)	Does the Business Continuity Plan address potential business interruptions and provide a plan to resume business operations?	Yes	No
9)	Have there been any changes to insurance policies providing coverage for business interruption since the last Compliance Certificate? If yes, please explain.	Yes	No

**Exceptions**

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

**APOLLO ENDOSURGERY, INC. APOLLO ENDOSURGERY INTERNATIONAL, LLC**

By\_\_ By\_\_ Name:\_\_ Name:\_\_ Title:\_\_ Title: \_\_

**APOLLO ENDOSURGERY US, INC. LPATH THERAPEUTICS INC.**

By\_\_ By\_\_ Name:\_\_ Name:\_\_ Title:\_\_ Title: \_\_

**COLLATERAL AGENT USE ONLY**

Received by: \_\_ Date: \_\_

Verified by: \_\_ Date: \_\_

Compliance Status: Yes No



**Exhibit C-2 Loan Confirmation**

In accordance with the loan documents, Innovatus Life Sciences Lending Fund I, LP and Innovatus Life Sciences Offshore Fund I-A, LP (collectively, the "Funds"), managed by Innovatus Capital Partners, LLC, please complete the information below on a quarterly basis and sign and date this confirmation. Please then send directly to the Funds administrator, HedgeServ Corporation., the following information related to the Funds' total investment in APOLLO ENDOSURGERY, INC.:

- 1) Please provide the following information as it relates to the Funds (Include: Date, Loan Description, Principal Outstanding): Please see table below

Date – For the Quarter	Loan Description	Principal Outstanding	Ended
<b>Total</b>			

Please sign, date, and email a copy of your response to HedgeServ at [HS\\_InnovatusNAV@HedgeServ.com](mailto:HS_InnovatusNAV@HedgeServ.com) and copy [Accounting@InnovatusCP.com](mailto:Accounting@InnovatusCP.com) no later than 30 days after quarter end.

**CONFIRMATION:**

Signature: \_\_\_

Print Name: \_\_\_

Title: \_\_\_

Date: \_\_\_

Phone: \_\_\_



EXHIBIT D

Form of Secured Promissory Note

[see attached]

SECURED PROMISSORY NOTE (Term [A][B][C][D] Loan)

\$\_\_ Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, 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, Apollo International and Lpath, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of INNOVATUS LIFE SCIENCES LENDING FUND I, LP ("**Lender**") the principal amount of [ ] MILLION DOLLARS (\$\_\_) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C][D] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C][D] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated December 21, 2021 by and among Borrower, Lender, INNOVATUS LIFE SCIENCES LENDING FUND I, LP, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B][C][D] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C][D] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C][D] Loan, interest on the Term [A][B][C][D] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

*[Balance of Page Intentionally Left Blank]*

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

**APOLLO ENDOSURGERY, INC. APOLLO ENDOSURGERY INTERNATIONAL, LLC**

By\_\_ By\_\_ Name:\_\_ Name:\_\_ Title:\_\_ Title: \_\_

**APOLLO ENDOSURGERY US, INC. LPATH THERAPEUTICS INC.**

By\_\_ By\_\_ Name:\_\_ Name:\_\_ Title:\_\_ Title: \_\_

## EXHIBIT E NOTICE OF CONVERSION

The undersigned hereby elects to convert principal pursuant to Section 2.7 of the Loan and Security Agreement (the "**Agreement**"), dated December 21, 2021, by and among Apollo Endosurgery, Inc., a Delaware corporation (the "**Company**"), Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership, as collateral agent and the lenders listed on Schedule 1.1 of the Agreement, into shares of common stock (the "**Common Stock**") of the Company according to the conditions hereof, as of the date written below. No fee will be charged to the holder for any conversion, except for such transfer taxes, if any.

By its delivery of this notice of conversion, the undersigned acknowledges and agrees as follows:

- The undersigned may be provided with material, non-public information regarding the Company from time to time pursuant to the terms of the Agreement and will not make any sale or other transfer of Common Stock at any time in which they reasonably believe that they may be in possession of material, non-public information regarding the Company.
- The undersigned agrees to comply with the prospectus delivery requirements under applicable securities laws in connection with any transfer of shares of Common Stock pursuant to a Registration Statement (as defined in the Agreement).

### Conversion Calculations:

Date to Effect Conversion and Issue Shares: \_\_\_

Principal Amount to be Converted: \_\_\_

Number of Shares of Common Stock to be Issued Pursuant to Section 2.7: \_\_\_

\_\_\_\_\_Rule 144 Status:

Please respond to the following questions. Based on the responses, the shares may be eligible for registration under the Securities Act of 1933, as amended, pursuant to Section 2.7 of the Agreement.

1. The undersigned acquired and fully paid for the shares, through its ownership of one or more promissory notes representing the principal amount requested to be converted in accordance with Rule 144(d), at least six (6) months prior to the date hereof.

\_\_\_\_\_Yes, for the full amount to be converted.  
\_\_\_ Yes, for only a partial amount to be converted, equal to: \$\_\_\_  
\_\_\_ No

2. The undersigned is not now, and has not been during the preceding three months, an "affiliate" of the Company (as that term is defined in Rule 144(a)(1)).

\_\_\_ Yes  
\_\_\_ No

3. The undersigned and its affiliates are not underwriters with respect to the shares, nor will any future sale of the shares be part of a distribution of securities of the Company.

Correct

Not correct Delivery Information:

If the undersigned wishes to hold its conversion shares through DTC at a prime broker, custodian or nominee, please provide the following information (option only available if shares are eligible for resale under Rule 144 upon issuance):

Full Name of Holder:

DTC Participant Name:

DTC Participant Number:

Account Number at DTC Participant to Credit Shares:

If shares not eligible to be deposited through DTC upon issuance, please fill in the following delivery information. The shares will be held in a newly opened account in the undersigned's name at the Company's transfer agent to be held on the transfer agent's register and will include a securities legend.

Full Name of Holder:

Address of Holder to Receive Account Information:

Holder Tax Identification Number:

Signature:

Name:

Title:

CORPORATE BORROWING CERTIFICATE

**BORROWER:** APOLLO ENDOSURGERY, INC.  
**LENDER:** INNOVATUS LIFE SCIENCES LENDING FUND I, LP, as  
Collateral Agent and Lender

**DATE:** [DATE]

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Articles/Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Articles/Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

*[Balance of Page Intentionally Left Blank]*

RESOLVED, that any one of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

RESOLVED FURTHER, that any one of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

**Borrow Money.** Borrow money from the Lenders.

**Execute Loan Documents.** Execute any loan documents any Lender requires.

**Grant Security.** Grant Collateral Agent a security interest in any of Borrower's assets.

**Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]



5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

**By:**\_\_

**Name:**\_\_

**Title:**\_\_

*\*\*\* If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the\_\_\_of Borrower, hereby certify as to paragraphs 1 through 5 above, as [print title]  
of the date set forth above.

**By:**\_\_

**Name:**\_\_

**Title:**\_\_

*[Signature Page to Corporate Borrowing Certificate]*

EXHIBIT A

Articles/Certificate of Incorporation (including amendments)

[see attached]

**EXHIBIT B**

**Bylaws**

[see attached]

## ANNEX I

### Collateral Agent and Lender Terms

#### 1. Appointment of Collateral Agent.

(a) Each Lender hereby appoints INNOVATUS LIFE SCIENCES LENDING FUND I, LP (together with any successor Collateral Agent pursuant to Section 7 of this Annex I) as Collateral Agent under the Loan Documents and authorizes Collateral Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Collateral Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Without limiting the generality of clause (a) above, Collateral Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Collateral Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Collateral Agent and Lenders with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Lender), (iii) act as collateral agent for Collateral Agent and each Lender for purposes of the perfection of all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to Collateral Agent and the other Lenders with respect to the Borrower and/or the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided, however, that Collateral Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Collateral Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any Deposit Account maintained by Borrower with, and cash and Cash Equivalents held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Collateral Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed. Collateral Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Lender). Any such Person shall benefit from this Annex I to the extent provided by Collateral Agent.

(c) Under the Loan Documents, Collateral Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the defined term "Collateral Agent", the terms "agent", "Collateral Agent" and "collateral agent" and similar terms in any Loan Document to refer to Collateral Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Collateral Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above. Except as expressly set forth in the Loan Documents, Collateral Agent shall not have any duty to disclose, and shall not be liable for failure to disclose, any information relating to Borrower or any of its Subsidiaries that is communicated to or obtained by [LENDER 2] or any of its Affiliates in any capacity.

#### 2. Binding Effect; Use of Discretion; E-Systems.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Collateral Agent or Required Lenders (or, if expressly required in any Loan Document, a greater proportion

of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Collateral Agent in reliance upon the instructions of Required Lenders (or, where so required, such greater proportion) and (iii) the exercise by Collateral Agent or Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of Lenders.

(b) If Collateral Agent shall request instructions from Required Lenders or all affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Collateral Agent shall be entitled to refrain from such act or taking such action unless and until Collateral Agent shall have received instructions from Required Lenders or all affected Lenders, as the case may be, and Collateral Agent shall not incur liability to any Person by reason of so refraining. Collateral Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Collateral Agent, be contrary to any Requirement of Law or any Loan Document, (ii) if such action would, in the opinion of Collateral Agent, expose Collateral Agent to any potential liability under any Requirement of Law or (iii) if Collateral Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under any Loan Document in accordance with the instructions of Required Lenders or all affected Lenders, as applicable.

(c) Collateral Agent is hereby authorized by Borrower and each Lender to establish procedures (and to amend such procedures from time to time) to facilitate administration and servicing of the Term Loan and other matters incidental thereto. Without limiting the generality of the foregoing, Collateral Agent is hereby authorized to establish procedures to make available or deliver, or to accept, notices, documents (including, without limitation, borrowing base certificates) and similar items on, by posting to or submitting and/or completion, on E-Systems. Borrower and each Lender acknowledges and agrees that the use of transmissions via an E-System or electronic mail is not necessarily secure and that there are risks associated with such use, including risks of interception, disclosure and abuse, and Borrower and each Lender assumes and accepts such risks by hereby authorizing the transmission via E-Systems or electronic mail. Each "e-signature" on any such posting shall be deemed sufficient to satisfy any requirement for a "signature", and each such posting shall be deemed sufficient to satisfy any requirement for a "writing", in each case including pursuant to any Loan Document, any applicable provision of any Code, the federal Uniform Electronic Transactions Act, the Electronic Signatures in Global and National Commerce Act and any substantive or procedural Requirement of Law governing such subject matter. All uses of an E-System shall be governed by and subject to, in addition to this Section, the separate terms, conditions and privacy policy posted or referenced in such E-System (or such terms, conditions and privacy policy as may be updated from time to time, including on such E-System) and related contractual obligations executed by Collateral Agent, Borrower and/or Lenders in connection with the use of such E-System. ALL E-SYSTEMS AND ELECTRONIC TRANSMISSIONS SHALL BE PROVIDED "AS IS" AND "AS AVAILABLE". NO REPRESENTATION OR WARRANTY OF ANY KIND IS MADE BY AGENT, ANY LENDER OR ANY OF THEIR RELATED PERSONS IN CONNECTION WITH ANY E-SYSTEMS.

**3. Collateral Agent's Reliance, Etc.** Collateral Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Collateral Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of competent jurisdiction) in connection with the duties of Collateral Agent expressly set forth herein. Without limiting the foregoing, Collateral Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Collateral Agent acted with gross

negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Collateral Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Collateral Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any Event of Default, and shall not be deemed to have notice or Knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such Event of Default that is clearly labeled "notice of default" (in which case Collateral Agent shall promptly give notice of such receipt to all Lenders, provided that Collateral Agent shall not be liable to any Lender for any failure to do so, except to the extent that such failure is attributable to Collateral Agent's gross negligence or willful misconduct as determined by a final non-appealable judgment of a court of competent jurisdiction); and, for each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action it might have against Collateral Agent based thereon.

4. **Collateral Agent Individually.** Collateral Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, Borrower or any Affiliate of Borrower as though it were not acting as Collateral Agent and may receive separate fees and other payments therefor. To the extent Collateral Agent or any of its Affiliates makes the Term Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Required Lender" and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Collateral Agent or such Affiliate, as the case may be, in its individual capacity as Lender, or as one of the Required Lenders.

5. **Lender Credit Decision; Collateral Agent Report.** Each Lender acknowledges that it shall, independently and without reliance upon Collateral Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Collateral Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Collateral Agent to the Lenders, Collateral Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, Property, financial and other condition or creditworthiness of Borrower or any Affiliate of Borrower that may come in to the possession of Collateral Agent or any of its Related Persons. Each Lender agrees that it shall not rely on any field examination, audit or other report provided by Collateral Agent or its Related Persons (a "Collateral Agent Report"). Each Lender further acknowledges that any Collateral Agent Report (a) is provided to the Lenders solely as a courtesy, without consideration, and based upon the understanding that such Lender will not rely on such Collateral Agent Report, (b) was prepared by Collateral Agent or its Related Persons based upon information provided by Borrower solely for Collateral Agent's own internal use, and (c) may not be complete and may not reflect all information and findings obtained by Collateral Agent or its Related Persons regarding the operations and condition of Borrower. Neither Collateral Agent nor any of its Related Persons makes any representations or warranties of any kind with respect to (i) any existing or proposed financing, (ii) the accuracy or completeness of the information contained in any Collateral Agent Report or in any related documentation, (iii) the scope or adequacy of Collateral Agent's and its Related Persons' due diligence, or the presence or absence of any errors or omissions contained in any Collateral Agent Report or in any related documentation, and (iv) any work performed by Collateral Agent or Collateral Agent's Related Persons in connection with or using any Collateral

Agent Report or any related documentation. Neither Collateral Agent nor any of its Related Persons shall have any duties or obligations in connection with or as a result of any Lender receiving a copy of any Collateral Agent Report. Without limiting the generality of the foregoing, neither Collateral Agent nor any of its Related Persons shall have any responsibility for the accuracy or completeness of any Collateral Agent Report, or the appropriateness of any Collateral Agent Report for any Lender's purposes, and shall have no duty or responsibility to correct or update any Collateral Agent Report or disclose to any Lender any other information not embodied in any Collateral Agent Report, including any supplemental information obtained after the date of any Collateral Agent Report. Each Lender releases, and agrees that it will not assert, any claim against Collateral Agent or its Related Persons that in any way relates to any Collateral Agent Report or arises out of any Lender having access to any Collateral Agent Report or any discussion of its contents, and agrees to indemnify and hold harmless Collateral Agent and its Related Persons from all claims, liabilities and expenses relating to a breach by any Lender arising out of such Lender's access to any Collateral Agent Report or any discussion of its contents.

**6. Indemnification.** Each Lender agrees to reimburse Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents) promptly upon demand for its Pro Rata Share of any out-of-pocket costs and expenses (including, without limitation, fees, charges and disbursements of financial, legal and other advisors and any taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Collateral Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Collateral Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Collateral Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Collateral Agent or any of its Related Persons under this Section 6 of this Annex I to the extent such liability has resulted from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction. To the extent required by any applicable Requirement of Law, Collateral Agent may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding tax. If the Internal Revenue Service or any other Governmental Authority asserts a claim that Collateral Agent did not properly withhold tax from amounts paid to or for the account of any Lender for any reason, or if Collateral Agent reasonably determines that it was required to withhold taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Collateral Agent fully for all amounts paid, directly or indirectly, by Collateral Agent as tax or otherwise, including penalties and interest, and together with all expenses incurred by Collateral Agent. Collateral Agent may offset against any payment to any Lender under a Loan Document, any applicable withholding tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Collateral Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 6 of this Annex I.

**7. Successor Collateral Agent.** Collateral Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice or, if no such date is set forth therein, upon the date such notice shall be effective, in accordance with the terms of this Section 7 of this Annex I. If Collateral Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Collateral Agent. If, after 30 days after the date of the retiring Collateral Agent's notice of resignation, no successor Collateral Agent has been appointed by the Required Lenders that has accepted such appointment, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent from among the Lenders. Effective immediately upon its resignation, (a) the retiring Collateral Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of

Collateral Agent until a successor Collateral Agent shall have accepted a valid appointment hereunder, (c) the retiring Collateral Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Collateral Agent was, or because such Collateral Agent had been, validly acting as Collateral Agent under the Loan Documents, and (d) subject to its rights under Section 2(b) of this Annex I, the retiring Collateral Agent shall take such action as may be reasonably necessary to assign to the successor Collateral Agent its rights as Collateral Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Collateral Agent, a successor Collateral Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Collateral Agent under the Loan Documents.

**8. Release of Collateral.** Each Lender hereby consents to the release and hereby directs Collateral Agent to release (or in the case of clause (b)(ii) below, release or subordinate) the following:

(a) any Guarantor or Subsidiary "co-Borrower" if all of the stock of such Subsidiary owned by Borrower is sold or transferred in a transaction permitted under the Loan Documents (including pursuant to a valid waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guaranty any Obligations pursuant to any Loan Document; and

(b) any Lien held by Collateral Agent for the benefit of itself and the Lenders against (i) any Collateral that is sold or otherwise disposed of by Borrower in a transaction permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any Collateral subject to a Lien that is expressly permitted under clause (c) of the definition of the term "Permitted Lien" and (iii) all of the Collateral and Borrower, upon (A) termination of all of the Commitments, (B) payment in full in cash of all of the Obligations that Collateral Agent has theretofore been notified in writing by the holder of such Obligation are then due and payable, and (C) to the extent requested by Collateral Agent, receipt by Collateral Agent and Lenders of liability releases from Borrower in form and substance acceptable to Collateral Agent (the satisfaction of the conditions in this clause (iii), the "Termination Date").

**9. Setoff and Sharing of Payments.** In addition to any rights now or hereafter granted under any applicable requirement of law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 10(d) of this Annex I, each Lender is hereby authorized at any time or from time to time upon the direction of Collateral Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Term Loan made or other Obligations held by other Lenders or holders may exercise all rights of offset, bankers' lien, counterclaim or similar rights with respect to such participation as fully as if such Lender or holder were a direct holder of the Term Loan and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

**10. Advances; Payments; Non-Funding Lenders; Actions in Concert.**

(a) Advances; Payments. If Collateral Agent receives any payment with respect to the Term Loan for the account of Lenders on or prior to 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on such Business Day. If Collateral Agent receives any payment with respect to the Term Loan for the account of Lenders after 2:00 p.m.



(New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on the next Business Day.

(b) Return of Payments.

(i) If Collateral Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Collateral Agent from Borrower and such related payment is not received by Collateral Agent, then Collateral Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Collateral Agent determines at any time that any amount received by Collateral Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Collateral Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Collateral Agent on demand any portion of such amount that Collateral Agent has distributed to such Lender, together with interest at such rate, if any, as Collateral Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind and Collateral Agent will be entitled to set off against future distributions to such Lender any such amounts (with interest) that are not repaid on demand.

(c) Non-Funding Lenders.

(i) Unless Collateral Agent shall have received notice from a Lender prior to the date of any Term Loan that such Lender will not make available to Collateral Agent such Lender's Pro Rata Share of such Term Loan, Collateral Agent may assume that such Lender will make such amount available to it on the date of such Term Loan in accordance with Section 2(b) of this Annex I, and Collateral Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Collateral Agent, such Lender and Borrower severally agree to repay to Collateral Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Collateral Agent, at a rate per annum equal to the interest rate applicable to the Obligation that would have been created when Collateral Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Collateral Agent, the amount so repaid shall constitute such Lender's portion of such Term Loan for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Term Loan or any other payments required to be made by it under the Loan Documents after any such Term Loan is required to be made or such payment is due (a "Non-Funding Lender"), Collateral Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from Borrower. The failure of any Non-Funding Lender to make any Term Loan or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "Other Lender") of its obligations to make such Term Loan, but neither any Other Lender nor Collateral Agent shall be responsible for the failure of any Non-Funding Lender to make such Term Loan or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of "Required Lender" hereunder) for any voting or consent rights under or with respect to any Loan Document. At Borrower's request, Collateral Agent or a Person reasonably acceptable to Collateral Agent shall have the right with Collateral Agent's consent and in Collateral Agent's sole discretion (but Collateral Agent or any such Person shall have no obligation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Collateral Agent's request, sell and assign to Collateral Agent or such Person, all of the Term Loan Commitment (if any), and all of the outstanding Term Loan of that Non-Funding Lender for an amount equal to the aggregate outstanding principal balance of the Term Loan held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement in form and substance reasonably satisfactory to, and acknowledged by, Collateral Agent.

(d) Actions in Concert. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Collateral Agent or Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Collateral Agent or Required Lenders.

ANNEX X

**Management Plan** (INITIAL BOARD APPROVED PLAN APPROVED IN CONNECTION WITH THE COMMENCEMENT OF THE PERFORMANCE COVENANT)

ANNEX Y

**LOAN INTEREST RATE AND PAYMENT OF PRINCIPAL**  
(Term Loan)

*PLEASE SEE ATTACHED*

Month	Beginning Date	Ending Date	Payment Date	Beginning Loan Balance	Greater of Prime Rate or 3.25%	Interest Rate	Interest Earned	PIK Interest	Cash Interest	Principal Amortization	Total Payment	Tranche B/ C/ D Funding	Ending Loan Balance
	12/21/21	12/31/21		\$35,000,000.00		3.25%	7.25%		\$76,472.60				\$35,000,000.00
1	1/1/22	1/31/22	2/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
2	2/1/22	2/28/22	3/1/22	\$35,000,000.00	3.25%	7.25%	\$194,657.53	--	\$194,657.53	--	\$194,657.53	--	\$35,000,000.00
3	3/1/22	3/31/22	4/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
4	4/1/22	4/30/22	5/1/22	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
5	5/1/22	5/31/22	6/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
6	6/1/22	6/30/22	7/1/22	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
7	7/1/22	7/31/22	8/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
8	8/1/22	8/31/22	9/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
9	9/1/22	9/30/22	10/1/22	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
10	10/1/22	10/31/22	11/1/22	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
11	11/1/22	11/30/22	12/1/22	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
12	12/1/22	12/31/22	1/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
13	1/1/23	1/31/23	2/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
14	2/1/23	2/28/23	3/1/23	\$35,000,000.00	3.25%	7.25%	\$194,657.53	--	\$194,657.53	--	\$194,657.53	--	\$35,000,000.00
15	3/1/23	3/31/23	4/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
16	4/1/23	4/30/23	5/1/23	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
17	5/1/23	5/31/23	6/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
18	6/1/23	6/30/23	7/1/23	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
19	7/1/23	7/31/23	8/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
20	8/1/23	8/31/23	9/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
21	9/1/23	9/30/23	10/1/23	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
22	10/1/23	10/31/23	11/1/23	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
23	11/1/23	11/30/23	12/1/23	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
24	12/1/23	12/31/23	1/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
25	1/1/24	1/31/24	2/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
26	2/1/24	2/29/24	3/1/24	\$35,000,000.00	3.25%	7.25%	\$201,609.59	--	\$201,609.59	--	\$201,609.59	--	\$35,000,000.00
27	3/1/24	3/31/24	4/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
28	4/1/24	4/30/24	5/1/24	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
29	5/1/24	5/31/24	6/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
30	6/1/24	6/30/24	7/1/24	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
31	7/1/24	7/31/24	8/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
32	8/1/24	8/31/24	9/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
33	9/1/24	9/30/24	10/1/24	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
34	10/1/24	10/31/24	11/1/24	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
35	11/1/24	11/30/24	12/1/24	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
36	12/1/24	12/31/24	1/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
37	1/1/25	1/31/25	2/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
38	2/1/25	2/28/25	3/1/25	\$35,000,000.00	3.25%	7.25%	\$194,657.53	--	\$194,657.53	--	\$194,657.53	--	\$35,000,000.00
39	3/1/25	3/31/25	4/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
40	4/1/25	4/30/25	5/1/25	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
41	5/1/25	5/31/25	6/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
42	6/1/25	6/30/25	7/1/25	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
43	7/1/25	7/31/25	8/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
44	8/1/25	8/31/25	9/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
45	9/1/25	9/30/25	10/1/25	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
46	10/1/25	10/31/25	11/1/25	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
47	11/1/25	11/30/25	12/1/25	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
48	12/1/25	12/31/25	1/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
49	1/1/26	1/31/26	2/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
50	2/1/26	2/28/26	3/1/26	\$35,000,000.00	3.25%	7.25%	\$194,657.53	--	\$194,657.53	--	\$194,657.53	--	\$35,000,000.00
51	3/1/26	3/31/26	4/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
52	4/1/26	4/30/26	5/1/26	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
53	5/1/26	5/31/26	6/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
54	6/1/26	6/30/26	7/1/26	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
55	7/1/26	7/31/26	8/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
56	8/1/26	8/31/26	9/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
57	9/1/26	9/30/26	10/1/26	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
58	10/1/26	10/31/26	11/1/26	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
59	11/1/26	11/30/26	12/1/26	\$35,000,000.00	3.25%	7.25%	\$208,561.64	--	\$208,561.64	--	\$208,561.64	--	\$35,000,000.00
60	12/1/26	12/31/26	1/1/27	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	--	\$215,513.70	--	\$35,000,000.00
61	1/1/27	1/31/27	2/1/27	\$35,000,000.00	3.25%	7.25%	\$215,513.70	--	\$215,513.70	\$2,916,666.67	\$3,132,180.37	--	\$32,083,333.33
62	2/1/27	2/28/27	3/1/27	\$32,083,333.33	3.25%	7.25%	\$178,436.07	--	\$178,436.07	\$2,916,666.67	\$3,095,102.74	--	\$29,166,666.67
63	3/1/27	3/31/27	4/1/27	\$29,166,666.67	3.25%	7.25%	\$179,594.75	--	\$179,594.75	\$2,916,666.67	\$3,096,261.42	--	\$26,250,000.00
64	4/1/27	4/30/27	5/1/27	\$26,250,000.00	3.25%	7.25%	\$156,421.23	--	\$156,421.23	\$2,916,666.67	\$3,073,087.90	--	\$23,333,333.33
65	5/1/27	5/31/27	6/1/27	\$23,333,333.33	3.25%	7.25%	\$143,675.80	--	\$143,675.80	\$2,916,666.67	\$3,060,342.47	--	\$20,416,666.67
66	6/1/27	6/30/27	7/1/27	\$20,416,666.67	3.25%	7.25%	\$121,660.96	--	\$121,660.96	\$2,916,666.67	\$3,038,327.63	--	\$17,500,000.00
67	7/1/27	7/31/27	8/1/27	\$17,500,000.00	3.25%	7.25%	\$107,756.85	--	\$107,756.85	\$2,916,666.67	\$3,024,423.52	--	\$14,583,333.33
68	8/1/27	8/31/27	9/1/27	\$14,583,333.33	3.25%	7.25%	\$89,797.37	--	\$89,797.37	\$2,916,66			

**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, 333-233439 and 333-255786) and Form S-8 (Nos. 333-215817, 333-218773, 333-223461, 333-231202, 333-237919, 333-253568 and 333-254109) of Apollo Endosurgery, Inc. (the "Company"), of our report dated February 22, 2022, 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, 2021.

/s/ Moss Adams LLP

Dallas, Texas  
February 22, 2022

## 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, Charles McKhann, 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 22, 2022

By: /s/ Charles McKhann  
Charles McKhann  
Chief Executive Officer  
(Principal Executive Officer)

## 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, Jeffrey Black, 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 22, 2022

By: /s/ Jeffrey Black  
Jeffrey Black  
Chief Financial Officer  
(Principal Financial Officer)



**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), Charles McKhann, 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, 2021, 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 22, 2022

By:           /s/ Charles McKhann            
Charles McKhann  
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.

