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Apollo Endosurgery, Inc.

Form: 10-Q

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

FORM 10-Q

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

For the quarterly period ended March 31, 2020

OR

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

For the transition period from to

Commission file number: 001-35706

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

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

Registrant's telephone number, including area code **(512) 279-5100**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	APEN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically 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, or a smaller reporting 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 o	Accelerated filer o
Non-accelerated filer x	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. o

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

As of April 24, 2020, there were 21,128,101 shares of the issuer's $0.001 par value common stock issued and outstanding.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
FOR THE QUARTER ENDED MARCH 31, 2020
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PART I - FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except for share data)

	March 31, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 23,206	$ 29,905
Accounts receivable, net of allowance for doubtful accounts of $ 619 and $658, respectively	7,524	9,232
Inventory, net	10,245	8,865
Prepaid expenses and other current assets	3,117	2,998
Total current assets	44,092	51,000
Restricted cash	833	1,016
Property, equipment and right-of-use assets	6,206	6,612
Goodwill	5,290	5,290
Intangible assets, net of accumulated amortization of $ 12,093 and $11,648, respectively	7,377	7,831
Other assets	2,899	2,833
Total assets	$ 66,697	$ 74,582
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 9,528	$ 9,902
Accrued expenses	8,613	8,438
Current portion of long-term debt	34,481	34,449
Total current liabilities	52,622	52,789
Convertible debt	18,632	18,554
Long-term liabilities	896	1,116
Total liabilities	72,150	72,459
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock; $0.001 par value; 100,000,000 shares authorized; 21,128,101 and 20,951,963 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	21	21
Additional paid-in capital	251,502	250,634
Accumulated other comprehensive income	3,442	1,630
Accumulated deficit	(260,418)	(250,162)
Total stockholders' (deficit) equity	(5,453)	2,123
Total liabilities and stockholders' (deficit) equity	$ 66,697	$ 74,582

See accompanying notes to the condensed consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except for share data)
(unaudited)

	Three Months Ended March 31,	
	2020	2019
Revenues	$ 10,718	$ 13,211
Cost of sales	5,081	5,970
Gross margin	5,637	7,241
Operating expenses:		
Sales and marketing	6,330	7,697
General and administrative	3,339	3,717
Research and development	2,147	3,428
Amortization of intangible assets	496	553
Settlement gain	—	(5,609)
Total operating expenses	12,312	9,786
Loss from operations	(6,675)	(2,545)
Other expenses:		
Interest expense, net	1,244	959
Other expense (income), net	2,294	(751)
Net loss before income taxes	(10,213)	(2,753)
Income tax expense	43	51
Net loss	$ (10,256)	$ (2,804)
Other comprehensive income (loss):		
Foreign currency translation	1,812	(888)
Comprehensive loss	$ (8,444)	$ (3,692)
Net loss per share, basic and diluted	$ (0.49)	$ (0.13)
Shares used in computing net loss per share, basic and diluted	21,117,126	21,907,281

See accompanying notes to the condensed consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' (Deficit) Equity
(In thousands, except for share data)
(unaudited)

	Three Months Ended March 31, 2020 and 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2018	21,899,522	$ 22	$ 249,115	$ 2,501	$ (222,730)	$ 28,908
Exercise of common stock options	1,573	—	3	—	—	3
Issuance of restricted stock units	21,249	—	—	—	—	—
Stock based compensation	—	—	323	—	—	323
Foreign currency translation	—	—	—	(888)	—	(888)
Net loss	—	—	—	—	(2,804)	(2,804)
Balances at March 31, 2019	21,922,344	$ 22	$ 249,441	$ 1,613	$ (225,534)	$ 25,542
Balances at December 31, 2019	20,951,963	$ 21	$ 250,634	$ 1,630	$ (250,162)	$ 2,123
Issuance of restricted stock units	11,341	—	—	—	—	—
Issuance of common stock for Convertible Debt interest	164,797	—	467	—	—	467
Stock based compensation	—	—	401	—	—	401
Foreign currency translation	—	—	—	1,812	—	1,812
Net loss	—	—	—	—	(10,256)	(10,256)
Balances at March 31, 2020	21,128,101	$ 21	$ 251,502	$ 3,442	$ (260,418)	$ (5,453)

See accompanying notes to the condensed consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (10,256)	$ (2,804)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	955	1,104
Amortization of deferred financing costs	154	298
Non-cash interest	356	3
Provision for doubtful accounts receivable	77	(37)
Inventory impairment	—	40
Stock based compensation	401	323
Unrealized foreign exchange on intercompany payables	2,240	(936)
Settlement gain	—	(5,609)
Changes in operating assets and liabilities:		
Accounts receivable	1,430	790
Inventory	(1,522)	(502)
Prepaid expenses and other assets	(113)	(350)
Accounts payable and accrued expenses	15	1,618
Net cash used in operating activities	(6,263)	(6,062)
Cash flows from investing activities:		
Purchases of property and equipment	(272)	(112)
Purchases of intangibles and other assets	(46)	(65)
Net cash used in investing activities	(318)	(177)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	3
Proceeds from long-term debt	—	35,000
Payments of deferred financing costs	(206)	(1,129)
Payment of long-term debt	—	(21,668)
Net cash (used in) provided by financing activities	(206)	12,206
Effect of exchange rate changes on cash	(95)	18
Net change in cash, cash equivalents and restricted cash	(6,882)	5,985
Cash, cash equivalents and restricted cash at beginning of year	30,921	25,007
Cash, cash equivalents and restricted cash at end of period	$ 24,039	$ 30,992
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 814	$ 1,160
Cash paid for income taxes	7	—
Right-of-use assets recognized in exchange for new lease obligations (non-cash)	36	2,789

See accompanying notes to the condensed consolidated financial statements.

(1) Organization and Business Description

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

Apollo is a medical technology company primarily focused on the design, development, and commercialization of innovative medical devices. The Company's products are used by gastroenterologists to address a variety of closure needs in the gastrointestinal tract and used by gastroenterologists and bariatric surgeons to treat obesity.

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

The Company has offices in the United Kingdom and Italy that oversee commercial activities outside the U.S. and a products manufacturing facility in Costa Rica. All other activities are managed and operated from facilities in Austin, Texas.

Going Concern Uncertainty

ASC Topic 205-40, *Presentation of Financial Statements - Going Concern* (“ASC 205-40”), requires management to assess the Company’s ability to continue as a going concern for one year after the date the financial statements are issued. Under ASC 205-40, management has the responsibility to evaluate whether conditions and/or events raise substantial doubt about the Company’s ability to meet future financial obligations as they become due within one year after the date that the financial statements are issued. As required by this standard, management’s evaluation shall initially not take into consideration the potential mitigating effects of management’s plans that have not been fully implemented as of the date the financial statements are issued.

The Company has experienced operating losses since inception and expects its negative cash flows from operating activities to continue. The reduction in sales due to the COVID-19 pandemic and uncertainty over how long the COVID-19 impact on the Company's business will last, along with the existing capital resources of the Company, has raised substantial doubt about the Company’s ability to continue as a going concern within one year of the issuance date of these condensed consolidated financial statements. The Company will likely require additional funding in order to meet its covenant requirements. In this regard, management’s plans include, but are not limited to, sales of the Company's common stock, preferred stock, convertible debt securities or debt financings, reduction of planned expenditures, and other sources.

There are no assurances that such additional funding will be obtained, regarding the degree or duration that the COVID-19 pandemic will negatively have on the Company's business, or that the Company will succeed in its future operations. If the Company cannot successfully raise additional capital and implement its business plan, its liquidity, financial condition and business prospects will be materially and adversely affected.

(2) Significant Accounting Policies

(a) Basis of Presentation

The Company prepared its interim condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP"). They do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying condensed consolidated financial statements include the Company's accounts and the accounts of its wholly-owned subsidiaries. The Company has eliminated all intercompany balances and transactions.

The Company has made estimates and judgments affecting the amounts reported in its condensed consolidated financial statements and the accompanying notes. The actual results that the Company experiences may differ materially from the Company's estimates. The accounting estimates that require the Company's most significant, difficult and subjective judgments include revenue recognition, useful lives of intangible assets and long-lived assets, impairment of long-lived assets and goodwill, valuation of inventory, allowance for doubtful accounts, stock compensation, and deferred tax asset valuation.

(In thousands, except for share data)

(b) Unaudited Interim Results

In management's opinion, the unaudited financial information for the interim periods presented includes all adjustments necessary for a fair presentation of the results of operations, financial position, and cash flows. All adjustments are of a normal recurring nature unless otherwise disclosed. Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. This interim information should be read in conjunction with the audited consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

(c) Recent Accounting Pronouncements

On January 1, 2020, the Company adopted the provision of ASU 2017-04, *Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"). The guidance removes step two of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary.

(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 March 31, 2020, the Company's cash, cash equivalents and restricted cash are held in deposit accounts at five different banks totaling $24,039. 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 one customer representing approximately 15% of the Company's net accounts receivable balance as of December 31, 2019. There were no concentrations greater than 10% of the Company's net accounts receivable as of March 31, 2020. The Company had no single customer that comprised more than 10% of the Company's total revenues for the three months ended March 31, 2020 and 2019.

(4) Inventory

Inventory consists of the following as of:

	March 31, 2020	December 31, 2019
	(unaudited)	
Raw materials	$ 2,594	$ 2,834
Work in progress	639	532
Finished goods	7,012	5,499
Total inventory	$ 10,245	$ 8,865

The Company recorded inventory impairment charges of $0 and $40 for the three months ended March 31, 2020 and 2019, respectively. Finished goods includes $115 of consigned inventory at March 31, 2020.

(In thousands, except for share data)

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

Property, equipment and right-of-use assets consists of the following:

	Depreciable Lives	March 31, 2020	December 31, 2019
		(unaudited)	
Equipment	5 years	$ 7,480	$ 7,491
Right-of-use assets	1-5 years	2,883	2,890
Furniture, fixtures and tooling	4-8 years	2,141	2,233
Computer hardware	3-5 years	1,237	1,261
Leasehold improvements	3-5 years	1,745	1,671
Construction in process		330	198
		15,816	15,744
Less accumulated depreciation		(9,610)	(9,132)
Property, equipment and right-of-use assets		$ 6,206	$ 6,612

The Company recorded depreciation expense of $458 and $503 for the three months ended March 31, 2020 and 2019, respectively. There were no impairment charges for the three months ended March 31, 2020 and 2019, respectively. The Company disposed of $189 of fully depreciated property, equipment and right-of-use assets no longer being utilized during the three months ended March 31, 2020 .

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

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

2020	$ 862
2021	924
2022	179
2023	92
2024	28
Thereafter	—
Total lease payments	2,085
Less imputed interest	(234)
Total operating lease liabilities	$ 1,851

Operating lease liabilities of $955 and $932 are included in accrued expenses and $ 896 and $1,116 are included in long-term liabilities, as of March 31, 2020 and December 31, 2019, respectively. Operating lease expense and cash paid within operating cash flows for operating leases was $294 and $333 for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, the weighted average remaining lease term was 1.95 years and the weighted average discount rate used to estimate the value of the operating lease liabilities was 9.6%.

(6) Other Assets

Included in other assets as of March 31, 2020 and December 31, 2019 is $ 2,573 and $2,511 for the non-current portion of the remaining $ 5,000 receivable due from ReShape, respectively, for the remaining unpaid consideration from the divestiture of the Surgical product line in December 2018. Interest on the receivable accretes 10% annually. Imputed interest income on the ReShape receivable was $ 106 and $172 for the three months ended March 31, 2020 and 2019, respectively, and is included within interest expense, net.

(In thousands, except for share data)

(7) Accrued Expenses

Accrued expenses consists of the following as of:

	March 31, 2020	December 31, 2019
	(unaudited)	
Accrued employee compensation and expenses	$ 2,930	$ 3,183
Settlement liability	1,625	1,625
Lease liability	955	932
Accrued professional service fees	1,290	653
Accrued interest	300	467
Accrued insurance and taxes	318	271
Accrued returns and rebates	57	216
Other	1,138	1,091
Total accrued expenses	$ 8,613	$ 8,438

(8) Long-Term Debt

Long-term debt consists of the following as of:

	March 31, 2020	December 31, 2019
	(unaudited)	
Term loan facility	$ 35,000	$ 35,000
Payment-in-kind interest	679	517
Deferred financing costs	(1,198)	(1,068)
Less current portion	(34,481)	(34,449)
Long-term debt	$ —	$ —

In March 2019, the Company entered into a Term Loan Facility (the "Credit Agreement") with Solar Capital Ltd. ("Solar") to borrow $ 35,000. The Credit Agreement matures on September 1, 2023, with principal payments beginning in March 2021, and bears interest at the greater of LIBOR or 1.35575%, plus 7.5%. Interest only is payable in arrears until March 1, 2021 (or July 1, 2021 if certain revenue milestones are achieved). Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 4.9% of the outstanding amount will be due at end of the loan term and an additional 4.5% fee of the Term Loan funded amount will be due at the earlier of an Exit Event (as defined in the Credit Agreement) or if the Company achieves trailing twelve-month revenue of $100,000 before March 15, 2029. The Credit Agreement provides that the Company may borrow an additional $ 5,000 upon its request, subject to further credit approval. The Credit Agreement includes customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity requirement and minimum product revenues. The Company used $22,372 of the proceeds of the Credit Agreement to repay its previous senior secured credit agreement in full including interest. Unamortized deferred financing costs and discount of $388 were written off in March 2019 in connection with the repayment.

In March 2020, the Company entered into the Fourth Amendment and Limited Waiver to the Credit Agreement which (i) established the trailing six-month Endoscopy revenue requirements for 2020, (ii) will provide an additional $10,000 of funding upon the achievement of these revenue requirements through June 2020, (iii) extended the interest-only period until July 1, 2021, if certain revenue milestones are achieved, (iv) requires the Company to raise additional cash of $15,000 from debt or equity financing by August 2020, (v) established a minimum LIBOR interest rate, and (vi) waived the financial statement covenant default associated with the going concern opinion of the Company's independent registered public accounting firm for the year ended December 31, 2019. Due to the negative impact of COVID-19 on the Company's revenues, the Company will unlikely be eligible to access the $10,000 of additional funding under the Fourth Amendment.

In April 2020, the Company entered into the Fifth Amendment and Limited Waiver to the Credit Agreement. See Note 15 for further details.

As of March 31, 2020, the Company was in compliance with all financial covenants.

(In thousands, except for share data)

Interest expense on the Company's long term debt was $ 1,041 and $ 1,274 for the three months ended March 31, 2020 and 2019, respectively.

The Company has classified its long-term debt obligations with long-term contractual maturities as current liabilities at March 31, 2020 and December 31, 2019 based on the Company's assessment that it may not be able to meet the debt covenant requirements included in the Credit Agreement for at least one year from the issuance of the condensed consolidated financial statements considering factors such as the uncertainties from the COVID-19 pandemic. The contractual terms of the Credit Agreement set out principal payments as follows:

2020	$ —
2021	11,667
2022	14,000
2023	9,333
2024	—
Thereafter	—
	$ 35,000

(9) Convertible Debt

Convertible debt consists of the following as of:

	March 31, 2020 (unaudited)	December 31, 2019
Convertible debt	$ 20,000	$ 20,000
Deferred financing costs	(1,368)	(1,446)
Total convertible debt	$ 18,632	$ 18,554

In August 2019, the Company issued $ 20,000 aggregate principal amount of 6.0% convertible senior debentures due 2024 (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. The Convertible Debt will mature on August 12, 2024 unless earlier converted or repurchased in accordance with its terms.

In January 2020, the Company issued 164,797 shares of the Company's common stock to holders of the Convertible Debt in fulfillment of $ 467 of accrued interest as of December 31, 2019.

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.

Interest expense on the Convertible Debt was $ 378 for the three months ended March 31, 2020.

(10) Stock Based Compensation

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

(In thousands, except for share data)

A summary of the stock option activity under the Company's 2017 Plan and Prior Plans (collectively, the "Equity Plans") as of March 31, 2020 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2019	1,927,194	$5.01	7.5 years	$87
Options forfeited	(30,338)	$5.22		
Options outstanding, vested and expected to vest, March 31, 2020	1,896,856	$5.01	7.2 years	$10
Options exercisable	1,051,196	$5.30	6.1 years	$10

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 options by means of a net exercise will be deducted from the shares available under the 2017 Plan.

No options were granted during the three months ended March 31, 2020 and 2019.

Additional information regarding options is as follows:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Aggregate intrinsic value of options exercised during the period	$ —	$ 2

The aggregate intrinsic value in the tables above represents the total pre-tax value of the options shown, calculated as the difference between the Company's closing stock price on March 31, 2020 and the exercise prices of the options shown, multiplied by the number of in-the money options. This is the aggregate amount that would have been received by the option holders if they had all exercised their options on March 31, 2020 and sold the shares thereby received at the closing price of the Company's common stock on that date. This amount changes based on the closing price of the Company's common stock.

The total compensation cost recognized for stock-based awards was $ 401 and $323 for the three months ended March 31, 2020 and 2019, respectively.

Unrecognized compensation expense related to unvested options was approximately $ 1,986 at March 31, 2020, with a remaining amortization period of 2.2 years.

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

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested units, December 31, 2019	243,695	$4.06	$695
Restricted stock units vested	(11,341)	$6.58	
Unvested units, March 31, 2020	232,354	$3.94	$446

Unrecognized compensation expense related to unvested restricted stock units was approximately $ 689 at March 31, 2020, with a remaining amortization period of 2.6 years.

(11) Income Taxes

The provision for income taxes for the three months ended March 31, 2020 and 2019 primarily consists of foreign income taxes.

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.

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

As of March 31, 2020, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions.

(In thousands, except for share data)

(12) Net Loss Per Share

The basic and diluted net loss per common share presented in the condensed consolidated statements of operations and comprehensive loss is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Potentially dilutive shares, which include warrants for the purchase of common stock, convertible debt, restricted stock units, and options outstanding under the Company's equity incentive plans, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Potentially dilutive securities that are 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):

	Three Months Ended March 31,	
	2020	2019
Warrants for common stock	1,204,371	251,189
Convertible debt	6,293,076	—
Common stock options	1,896,856	1,481,631
Restricted stock units	232,354	73,691
	9,626,657	1,806,511

(13) Fair Value Measurements

The carrying amounts of the Company's financial instruments, which primarily include cash, 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 and Convertible Debt is estimated by management to approximate $38,000 and $20,000, respectively at March 31, 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.

(14) 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.

(In thousands, except for share data)

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:

	Three Months Ended March 31, 2020				Three Months Ended March 31, 2019			
	(unaudited)							
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 3,755	$ 3,077	$ 6,832	63.7 %	$ 3,007	$ 3,491	$ 6,498	49.2 %
IGB	898	2,628	3,526	32.9 %	1,459	2,863	4,322	32.7 %
Total Endoscopy	4,653	5,705	10,358	96.6 %	4,466	6,354	10,820	81.9 %
Surgical	—	—	—	— %	—	1,700	1,700	12.9 %
Other	327	33	360	3.4 %	683	8	691	5.2 %
Total revenues	$ 4,980	$ 5,738	$ 10,718	100.0 %	$ 5,149	$ 8,062	$ 13,211	100.0 %
% Total revenues	46.5 %	53.5 %			39.0 %	61.0 %		

Total distributor sales were 34.0% and 27.9% of total OUS revenues for the three months ended March 31, 2020 and 2019, respectively. Sales in the largest individual country outside the U.S. was 8.1% and 9.2% of total revenues for the three months ended March 31, 2020 and 2019, respectively.

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

	March 31, 2020	December 31, 2019
	(unaudited)	
United States	$ 2,906	$ 2,934
Costa Rica	2,762	3,039
Other	538	639
Total property, equipment and right-of-use assets, net	$ 6,206	$ 6,612

(15) Subsequent Events

On April 15, 2020, the Compensation Committee of the Board of Directors of the Company, approved a comprehensive plan to continue to preserve the Company's liquidity given the ongoing business disruptions resulting from the international efforts to contain the spread of COVID-19. As part of this plan, the Company furloughed 57 U.S. employees and reduced the employment arrangements of an additional 34 employees outside the United States, effective April 20, 2020. In addition, the base salary of all employees was capped at $100,000, including the Company's Chief Executive Officer, Chief Financial Officer and other executive officers, effective April 16, 2020.

On April 30, 2020, the Company entered into the Fifth Amendment and Limited Waiver to the Credit Agreement which (i) permits the Company to enter into a loan under the Small Business Administration's Paycheck Protection Program ("PPP") established under the CARES Act, (ii) waives the trailing six-month Endoscopy revenue requirements for the second and third quarter of 2020 and reduces the revenue requirements for the fourth quarter of 2020, (iii) increases the minimum liquidity requirement to $17,500 until the earlier of August 14, 2020 or when the Company meets the requirement to raise additional capital of $ 15,000, at which time the minimum liquidity requirement increases to $20,000, and decreases the minimum liquidity requirement to $ 12,500 in January 2021 if revenue covenant compliance is maintained for October and November 2020, (iv) provides a limited waiver on the monthly financial statement reporting requirements through June 2020, and (v) increases the final fee due at end of the loan term to 5.0% from 4.9%.

On April 27, 2020, the Company was granted a loan (the "Loan") of $ 2,824 under the PPP established under the CARES Act. The Loan matures on April 27, 2022 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on November 27, 2020.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This quarterly report ("Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks, uncertainties and other important factors. In particular, statements, whether express or implied, concerning future operating results or the ability to generate sales, income or cash flow are forward-looking statements. They involve risks, uncertainties and assumptions that are beyond our ability to control or predict, including those discussed in Part II, Item 1A, of this Quarterly Report, such as the continuing effects of the COVID-19 pandemic on our financial condition and results of operations. 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 Quarterly Report. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

The following discussion should be read in conjunction with the condensed consolidated financial statements and accompanying notes, and our Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 26, 2020 with the Securities and Exchange Commission ("SEC"). "Apollo,", Orbera®, OverStitch™, the Apollo logo and other trademarks, service marks and trade names of Apollo are registered and unregistered marks of Apollo Endosurgery, Inc. in the United States and other jurisdictions.

Overview

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

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

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

Impact of COVID-19 on Our Business

The recent COVID-19 pandemic has adversely impacted our sales levels, business operations and results of operations in March 2020, in particular due to significantly decreased procedures being performed that use our products across our markets and the broader economic contraction resulting from the pandemic. While the ultimate economic impact of the COVID-19 pandemic is highly uncertain, we expect our sales levels, business operations and results from operations will continue to be adversely impacted to varying degrees for as long as the COVID-19 pandemic and related reductions in procedures that use our products persist. See Part II, Item 1A. Risk Factors—Risks Related to Our Business—Our business has been and will continue to be adversely affected by the ongoing COVID-19 outbreak.

COVID-19 Response

On March 10, 2020, the World Health Organization declared that the COVID-19 outbreak had reached pandemic status and a number of countries, particularly countries in Europe that comprise the majority of our OUS sales and the United States, implemented a number 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 to be utilized for elective or deferrable procedures, including those that use our products. Following sales growth in the months of January and February that were consistent with management's pre-COVID-19 expectations, our sales results in the month of March declined commensurate with the global decline in elective procedures. Patient access to treatments has been stymied by shelter in place and social distancing rules resulting in cancellation or postponement of procedures, including those that use our products. Our sales personnel who deliver in-person customer support and generate additional business with new customers and facilities are restricted from accessing our customers for these same reasons.

Due to the continued business disruptions stemming directly from the COVID-19 pandemic and the resulting international efforts to contain the spread of COVID-19, we have taken several actions to preserve the Company's liquidity. As described in Item 9B of our Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 26, 2020, we reduced 2019 cash bonuses and implemented reductions in compensation across our workforce. Effective April 20, 2020, we furloughed 57 U.S. employees and reduced the employment arrangements of an additional 34 employees outside the United States. While our intention is for the furlough of employees to be temporary, the adopted furlough program does not have a specific end date, and we will continue to evaluate business conditions to determine when to recall individual or groups of furloughed employees. In addition, we implemented a $100,000 salary cap, effective April 16, 2020, for all employees. Our intention is for the reductions in salary to be temporary; however, the duration of the salary reductions is indefinite due to the uncertain duration of the current COVID-19 business disruption.

The objective of the above cost reduction actions is to preserve liquidity with the goal of completing the second quarter of 2020 with the same cash on hand that we were expecting prior to the COVID-19 outbreak. In addition, we have maintained an ability to deliver essential customer support and continue to invest in critical growth projects including the ongoing MERIT trial and other reimbursement initiatives, the development of our new lower GI suturing product, and select projects focused on improving parts of our supply chain.

On April 27, 2020, the Company was granted a Loan of $2.8 million under the Small Business Administration's PPP established under the CARES Act. The Loan matures on April 27, 2022 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on November 27, 2020.

Divestiture of the Surgical Product Line

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

ReShape agreed to pay $17.0 million in cash, of which $10.0 million was paid at the closing of the transaction, $2.0 million was paid on the first anniversary of the closing date and $2.0 million and $3.0 million remains payable on each of the second and third anniversaries of the closing date, respectively.

Upon completion of the ReShape transaction, the parties entered into a transition services agreement, supply agreement and distribution agreements. All transition and distribution services were completed as of December 31, 2019. We remain obligated to perform manufacturing services through December 2020.

Financial Operations Overview

Revenues

Our principal source of revenues are sales of our Endoscopy products. The majority of our sales come from direct markets where sales are made to the final end customers, typically healthcare providers. In other markets, we sell our products to distributors who resell our products to end users. Revenues between periods will be impacted by several factors, including the continuing COVID-19 pandemic, physician procedures and therapy preferences, patient procedures and therapy preferences, other market trends, the stability of the average sales price we realize on products and changes in foreign exchange rates used to translate foreign currency denominated sales into U.S. dollars.

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

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

Cost of Sales

Our ESS products, representing the majority of our Endoscopy product sales, have historically been purchased from third-party manufacturers, and our cost of sales for these products has consisted of the actual purchase price from these manufacturers plus an allocation of our internal overhead cost. Cost of sales for products which we manufacture includes 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 excess and obsolete inventory charges, royalties, shipping, inspection and related costs incurred in making our products available for sale or use.

Our gross margin comparability between periods has been impacted by the shift in our revenue mix from Surgical to Endoscopy products. Our divested Surgical products historically have higher gross margins compared to our Endoscopy products. In addition, manufacturing overhead as a percentage of revenue between periods can fluctuate as a result of manufacturing rates and the degree to which manufacturing overhead is allocated to production during the period. Comparability of cost of sales and gross margin between periods could also be affected by changes in inventory valuation allowances related to obsolete or excess inventory. We expect 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 our sales, marketing and medical education departments. In addition, our sales and marketing expense includes costs associated with advertising, physician training, industry events and other promotional activities.

General and Administrative Expense

General and administrative expense primarily consists of salaries, benefits and other related costs, including stock-based compensation, for personnel employed in the corporate management, finance, legal, compliance, information technology and human resource departments. General and administrative expense also includes facilities cost, insurance, audit fees, legal fees, bad debt expense and costs 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, depreciation and other costs associated with development of our products. Research and development expense also includes compensation and stock-based compensation expense for personnel dedicated to these activities. Research and development expense may fluctuate between periods depending on the activity associated with our various product development and clinical obligations.

Amortization of Intangible Assets

Definite-lived intangible assets primarily consist of customer relationships, product technology, trade names, patents and trademarks and capitalized software. Intangible assets are amortized over the asset's estimated useful life.

Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures is in conformity with U.S. generally accepted accounting principles and the Company's discussion and analysis of its financial condition and operating results require the Company's management to make judgments, assumptions and estimates that affect the amounts reported in its condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical evidence and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

Note 2, "Significant Accounting Policies" in Part I, Item 1 of this Form 10-Q and in the Notes to Consolidated Financial Statements in Part II, Item 8 of the Company's Annual Report on Form 10-K for the year ended December 31, 201 9 (the "2019 Form 10-K"), and "Critical Accounting Policies and Estimates" in Part II, Item 7 of the 2019 Form 10-K describe the significant accounting policies and methods used in the preparation of the Company's condensed consolidated financial statements. There have been no material changes to the Company's critical accounting policies and estimates since the 2019 Form 10-K.

Non-GAAP Financial Measures

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

We believe the non-GAAP financial measure included herein is helpful in understanding our current financial performance. We use this supplemental non-GAAP financial measure internally to understand, manage and evaluate our business, and make operating decisions. We believe that making non-GAAP financial information available to investors, in addition to GAAP financial information, may facilitate more consistent comparisons between the company’s performance over time with the performance of other companies in the medical device industry, which may use similar financial measures to supplement their GAAP financial information. However, our non-GAAP financial measure is not meant to be considered in isolation or as a substitute for the comparable GAAP metric.

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019

	Three Months Ended March 31, 2020		Three Months Ended March 31, 2019	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues [1]	$ 10,718	100.0 %	$ 13,211	100.0 %
Cost of sales	5,081	47.4 %	5,970	45.2 %
Gross margin	5,637	52.6 %	7,241	54.8 %
Operating expenses:				
Sales and marketing	6,330	59.1 %	7,697	58.3 %
General and administrative	3,339	31.2 %	3,717	28.1 %
Research and development	2,147	20.0 %	3,428	25.9 %
Amortization of intangible assets	496	4.6 %	553	4.2 %
Settlement gain	—	— %	(5,609)	(42.5)%
Total operating expenses	12,312	114.9 %	9,786	74.0 %
Loss from operations	(6,675)	(62.3)%	(2,545)	(19.2)%
Interest expense, net	1,244	11.6 %	959	7.3 %
Other expense (income), net	2,294	21.4 %	(751)	(5.7)%
Net loss before income taxes	(10,213)	(95.3)%	(2,753)	(20.8)%
Income tax expense	43	0.4 %	51	0.4 %
Net loss	$ (10,256)	(95.7)%	$ (2,804)	(21.2)%

[1] Revenue between periods declined $2.1 million due to the divestiture of the Surgical product line in December 2018. See the product sales table under "Revenues" for additional information for product group and geographic market.

Revenues

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

	Three Months Ended March 31, 2020			Three Months Ended March 31, 2019			% Increase/ (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 3,755	$ 3,077	$ 6,832	$ 3,007	$ 3,491	$ 6,498	24.9 %	(11.9)%	5.1 %
IGB	898	2,628	3,526	1,459	2,863	4,322	(38.5)%	(8.2)%	(18.4)%
Total Endoscopy	4,653	5,705	10,358	4,466	6,354	10,820	4.2 %	(10.2)%	(4.3)%
Surgical	—	—	—	—	1,700	1,700	— %	(100.0)%	(100.0)%
Other [1]	327	33	360	683	8	691	(52.1)%	312.5 %	(47.9)%
Total revenues	$ 4,980	$ 5,738	$ 10,718	$ 5,149	$ 8,062	$ 13,211	(3.3)%	(28.8)%	(18.9)%
% Total revenues	46.5 %	53.5 %		39.0 %	61.0 %				

[1] Other U.S. revenue includes $0.2 million and $0.6 million of transition and manufacturing services provided to ReShape for the three months ended March 31, 2020 and 2019, respectively.

Endoscopy product sales percentage change in constant currency were as follows:

	Three Months Ended March 31, 2020	
	% Increase/Decrease in Constant Currency	
	OUS	Total Revenues
ESS	(7.5) %	7.5 %
IGB	(5.2) %	(16.4) %
Total Endoscopy	(6.5) %	(2.1) %

Total revenues for the three months ended March 31, 2020 were $10.7 million, compared to $13.2 million for the three months ended March 31, 2019, a decrease of 18.9%. Of the decline in total revenues, 83.5% was due to the reduction in Surgical product sales following our divestiture of this product line. The remaining decline in revenues in the three months ended March 31, 2020 was due to the impact of the COVID-19 pandemic.

Following sales growth in the months of January and February that were consistent with management's pre-COVID-19 expectations, our sales results in the month of March declined commensurate with the global decline in elective procedures. Total Endoscopy product sales decreased $0.5 million, or 4.3%, for the three months ended March 31, 2020 from $10.8 million in the same period of 2019. In constant currency, total Endoscopy sales decreased 2.1% for the three months ended March 31, 2020. Direct market Endoscopy product sales accounted for approximately 81.2% of total Endoscopy product sales for the three months ended March 31, 2020, compared to 80.7% for the same period of 2019.

Total ESS product sales increased $0.3 million, or 5.1%, for the three months ended March 31, 2020, when compared to the same period of 2019. In constant currency, total ESS product sales increased 7.5% for the three months ended March 31, 2020. Despite the impact of COVID-19 in March 2020, U.S. ESS product sales increased $0.7 million, or 24.9% for the three months ended March 31, 2020, when compared to the same period in 2019, primarily due to increased sales volume from new user adoption and greater product utilization in our existing customer base.

OUS ESS product sales decreased $0.4 million, or 11.9%, for the three months ended March 31, 2020 when compared to the same period of 2019. In constant currency, OUS ESS product sales decreased 7.5% for the three months ended March 31, 2020 when compared to the same period of 2019. OUS direct market ESS sales, excluding Brazil, increased 11.1% (14.5% in constant currency) compared to the same period in 2019. In early March of 2020, we entered into a distributor agreement with a third party medical device distribution company and ceased our direct sales operations in Brazil. Overall in the three months ended March 31, 2020, ESS product sales to OUS distributor orders originally scheduled to ship in March were deferred due to distributor concerns of how COVID-19 will affect procedure demand in their respective country of operation. As a result, sales to distributors in the three months ended March 31, 2020 were lower than in the same period of 2019.

Total IGB product sales decreased $0.8 million, or 18.4%, for the three months ended March 31, 2020, when compared to the same period of 2019. U.S. IGB product sales decreased $0.6 million, or 38.5%, while OUS IGB product sales decreased $0.2 million, or 8.2%, for the three months ended March 31, 2020, when compared to the same period in 2019. In constant currency, OUS IGB product sales decreased 5.2%, primarily due to the impact of the COVID-19 pandemic in our direct markets and its resulting decrease in consumer demand. OUS distributor IGB sales, excluding Brazil, increased 31.7% compared to the same period in 2019, as most expected IGB distributor orders were fulfilled earlier in the three months ended March 31, 2020 prior to the COVID-19 outbreak.

Included in other revenues for the three months ended March 31, 2020 and 2019 is $0.2 million and $0.6 million of transition and manufacturing services provided to ReShape, respectively. We remain obligated to perform manufacturing services through December 2020.

Cost of Sales

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

	Three Months Ended March 31, 2020		Three Months Ended March 31, 2019	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 3,373	31.5 %	$ 3,653	27.6 %
Overhead	1,139	10.6 %	1,515	11.5 %
Other indirect costs	569	5.3 %	802	6.1 %
Total cost of sales	$ 5,081	47.4 %	$ 5,970	45.2 %

Gross Margin

Gross margin was 52.6% for the three months ended March 31, 2020, compared to 54.8% for the same period of 2019. The decline in gross margin is primarily due to cessation of Surgical product sales. Gross margin for our Endoscopy products was 51.9% for the three months ended March 31, 2020 compared to 50.7% for the same period of 2019, respectively, due to the implementation of a portion of our gross margin improvement projects offset partially by declining IGB sales.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense decreased $1.4 million for the three months ended March 31, 2020 compared to the same period in 2019, primarily due to lower U.S. direct consumer advertising costs, and lower sales compensation and travel due to the impact of the COVID-19 pandemic.

General and Administrative Expense. General and administrative expense decreased $0.4 million for the three months ended March 31, 2020 when compared to the same period of 2019, primarily due to lower audit fees.

Research and Development Expense. Research and development expense decreased $1.3 million for the three months ended March 31, 2020 when compared to the same period for 2019, primarily due to lower clinical trial costs as enrollment milestones were achieved for clinical studies that we are funding.

Amortization of Intangible Assets. Amortization of intangible assets decreased $0.1 million for the three months ended March 31, 2020 compared to the same period in 2019.

Settlement gain. Settlement gain of $5.6 million for the three months ended March 31, 2019 resulted from the resolution of a dispute with Allergan Inc. related to amounts previously charged for inventory purchases and transition services provided through 2016.

Loss from Operations

Loss from operations for the three months ended March 31, 2020 was $6.7 million compared to $2.5 million for the three months ended March 31, 2019. Excluding the settlement gain recorded in the three months ended March 31, 2019 of $5.6 million, our loss from operations decreased by $1.5 million, or 18.1% in the three months ended March 31, 2020 on lower operating expenses offset in part by the reduction in gross margin following the completion of our distribution services obligations following the divestiture of our Surgical product line and the impact of COVID-19 on our Endoscopy product sales.

Other Expenses

Interest Expense, net. Net interest expense increased by $0.3 million for the three months ended March 31, 2020 when compared to the same period in 2019 primarily due to non-cash interest on the Convertible Debt.

Other Expense (Income), net. Other expense (income) primarily consists of realized and unrealized foreign exchange gains or losses. The increase of $3.0 million in comparing the three months ended March 31, 2020 to the same period in 2019 was primarily caused by the movement in exchange rates on short-term intercompany loans denominated in U.S. dollars payable by our foreign subsidiaries. During the three months ended March 31, 2020, unrealized exchange rate losses on these intercompany loans were $2.2 million compared to unrealized gains of $0.9 million for the same period in 2019.

Liquidity and Capital Resources

We have experienced operating losses since inception and occasional debt covenant violations and have an accumulated deficit of $260.4 million as of March 31, 2020. 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 additional funding through either equity offerings, issuances of debt instruments or both.

We expect our negative cash flows from operating activities to continue. The reduction in our sales due to the COVID-19 pandemic and uncertainty over how long the COVID-19 impact on our business will last, along with our existing capital resources, has raised substantial doubt about our ability to continue as a going concern within one year of the issuance date of these condensed consolidated financial statements. We will likely require additional funding in order to meet our covenant requirements. In this regard, management's plans include, but are not limited to, sales of our common stock, preferred stock, convertible debt securities or debt financings, reduction of planned expenditures, and other sources.

There are no assurances that such additional funding will be obtained, the degree or duration that the COVID-19 pandemic will negatively have on our business, or that we will succeed in our future operations. If we cannot successfully raise additional capital and implement our business plan, our liquidity, financial condition and business prospects will be materially and adversely affected. As of March 31, 2020, cash, cash equivalents, and restricted cash was $24.0 million.

Term Loan Facility

In March 2019, we entered into a term loan facility agreement with Solar Capital, Ltd. to borrow $35.0 million (the "Credit Agreement"). The Credit Agreement matures on September 1, 2023, with principal payments beginning in March 2021, and bears interest at the greater of LIBOR or 1.35575%, plus 7.5%. Interest only is payable in arrears until March 1, 2021 (or July 1, 2021 if certain revenue milestones are achieved). Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 4.9% of the outstanding amount will be due at end of the loan term and an additional 4.5% fee of the Term Loan funded amount will be due at the earlier of an Exit Event (as defined in the Credit Agreement) or if we achieve trailing twelve-month revenue of $100.0 million before March 15, 2029. The Credit Agreement provides that we may borrow an additional $5.0 million upon our request, subject to further credit approval. The Credit Agreement includes the customary affirmative covenants, negative covenants and financial covenants, including a minimum liquidity requirement and minimum product revenues. We used $22.4 million of the proceeds of the Credit Agreement to repay our previous senior secured credit agreement in full, including interest.

In March 2020, we entered into the Fourth Amendment and Limited Waiver to the Credit Agreement which (i) established the trailing six-month Endoscopy revenue requirements for 2020, (ii) will provide an additional $10.0 million of funding upon the achievement of these revenue requirements through June 2020, (iii) extended the interest-only period until July 1, 2021, if certain revenue milestones are achieved, (iv) requires that we raise $15.0 million of additional cash from debt or equity financing by August 2020, (v) established a minimum LIBOR interest rate, and (vi) and waived the financial statement covenant default associated with the going concern opinion of our independent registered public accounting firm for the year ended December 31, 2019. Due to the negative impact of COVID-19 on our revenues, we will unlikely be eligible to access the $10,000 of additional funding under the Fourth Amendment.

In April 2020, we entered into the Fifth Amendment and Limited Waiver to the Credit Agreement. See Note 15, "Subsequent Events" in Part I, Item 1 of this Form 10-Q.

The Credit Agreement is classified as a current liability on the balance sheet as of March 31, 2020, based on our assessment that we may not be able to meet our debt covenant requirements for at least one year from the issuance of our condensed consolidated financial statements considering factors such as the uncertainties from the COVID-19 pandemic. Should we fall short of the target, we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver.

Convertible Senior Debt

In August 2019, we issued $20.0 million aggregate principal amount of Convertible Debt. Interest on the Convertible Debt will be payable semi-annually in shares of our common stock on January 1 and July 1 of each year, beginning on January 1, 2020, at a rate of 6.0% per year. The number of shares of common stock required to settle the amount of interest payable will be based on the volume-weighted average price ("VWAP"), of our common stock for the 10 consecutive trading days immediately preceding the applicable interest payment date. The Convertible Debt will mature on August 12, 2024 unless earlier converted or repurchased in accordance with its terms.

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

CARES Act

On March 27, 2020, the CARES Act was signed into law providing certain economic aid packages for small businesses. In April 2020, we were granted a loan of $2.8 million under the PPP established under the CARES Act. The Loan matures on April 27, 2022 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on November 27, 2020.

Cash Flows

The following table provides information regarding our cash flows:

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (6,263)	$ (6,062)
Net cash used in investing activities	(318)	(177)
Net cash (used in) provided by financing activities	(206)	12,206
Effect of exchange rate changes on cash	(95)	18
Net change in cash, cash equivalents and restricted cash	$ (6,882)	$ 5,985

Operating Activities

Cash used in operating activities of $6.3 million for the three months ended March 31, 2020 was primarily the result of a net loss of $10.3 million offset by non-cash items of $4.2 million, primarily related to depreciation, amortization, foreign currency on intercompany loans, non-cash interest, and stock based compensation. Net loss, after adjustment for non-cash items, improved $1.5 million compared to the same period in 2019 due to lower operating expenses which offset reduced gross margin resulting from the divestiture of the Surgical product line.

Cash used in operating activities of $6.1 million for the three months ended March 31, 2019 was primarily the result of a net loss of $2.8 million plus non-cash items of $4.8 million primarily related to the settlement gain of $5.6 million, depreciation, amortization, foreign currency on intercompany loans, and stock based compensation. Additionally, cash provided by operating assets and liabilities of $1.6 million related to working capital changes primarily related to accounts receivable, accounts payable and accrued liabilities.

Investing Activities

Cash used in investing activities of $0.3 million for the three months ended March 31, 2020 and $0.2 million for the three months ended March 31, 2019 were primarily related to equipment purchases associated with our product development and gross margin improvement projects, as well as ongoing investments in our intellectual property portfolio.

Financing Activities

Cash used in financing activities of $0.2 million for the three months ended March 31, 2020 was related to the payment of financing costs associated with the Fourth Amendment to our Credit Agreement.

Cash provided by financing activities of $12.2 million for the three months ended March 31, 2019 was primarily related to the net proceeds received from the Term Loan Facility refinancing.

Future Funding Requirements

As of March 31, 2020, we had cash, cash equivalents and restricted cash balances totaling $24.0 million. We cannot be certain that our existing cash and cash equivalents will continue to be adequate to fund our operations, or that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by issuing equity or convertible securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring new debt obligations, the terms of the debt will likely require significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. As discussed in Note 1 of the notes to the condensed consolidated financial statements, conditions or events have raised substantial doubt about our ability to continue as a going concern.

Off-balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 2(c) to the condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report for a discussion of recently enacted accounting pronouncements.

ITEM 3. 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 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, our management (with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO)) conducted an evaluation pursuant to Rule 13a-15 promulgated under the Exchange Act, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, the CEO and CFO concluded that as of the end of the period covered by this Quarterly Report such disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the last quarter covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation 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 a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by individuals' acts, by collusion of two or more people, or by management overriding the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

ITEM 1. 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 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.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2019.

Risks Related to Our Business

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

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19 has spread to multiple countries, including the United States and all of the primary markets where we conduct business. On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed travel restrictions on travel between the United States and Europe for a 30-day period. Further, on March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Several states and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions, and the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects. We continue to monitor our operations and government mandates and may elect or be required to temporarily close our offices to protect our employees, and limit our access to customers and limit customer use of our products as they are required to prioritize resources to address the public healthcare needs arising from the COVID-19 pandemic. The disruptions to our activities and operations will negatively impact our business, operating results and financial condition. There is a risk that government actions will not be effective at containing COVID-19, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a devastating negative impact on the world economy at large, in which case the risks to our sales, operating results and financial condition described herein would be elevated significantly.

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

Restrictions on the ability to travel, social distancing policies, orders and restriction, including those described above, and recommendations and fears of COVID-19 spreading within medical centers has caused both patients and providers to delay or cancel procedures that use our devices, which has harmed our sales, results of operations and financial condition. We are unable to accurately predict when these policies, orders and restrictions will be relaxed or lifted, and there can be no assurances that patients or providers will restart procedures that use our devices upon termination of these policies, orders and restrictions, particularly if there remains any continued community outbreak of COVID-19. Our distributors have deferred 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 following a slowdown in the pandemic, which would harm the recovery of our sales growth as well. Further, quarantines or government reaction or shutdowns for COVID-19 could disrupt our supply chain. Travel and import restrictions may also disrupt our ability to manufacture or distribute our devices. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products would restrict our ability to manufacture and ship products and harm our business, financial condition and results of operations. Our key personnel and other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce could reduce the efficiency of our operations or prove insufficient. We may delay or reduce certain capital spending and related projects until the travel and logistical impacts of COVID-19 are lifted, which will delay the completion of such projects.

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

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

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole. However, these effects have harmed our business, financial condition and results of operations in the near term and could have a continuing material impact on our 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, 2019 and 2018, we had net losses of $27.4 million and $45.8 million, respectively, and for the three months ended March 31, 2020 we had a net loss of $10.3 million. As of March 31, 2020, we had an accumulated deficit of $260.4 million. To date, we have funded our operations primarily through equity offerings, the issuance of debt instruments, and from sales of our products. We have devoted substantially all of our resources to the acquisition of products, the research and development of products, sales and marketing activities and clinical and regulatory initiatives to obtain approvals for our products. Our ability to generate sufficient revenue from our existing products, and to transition to profitability and generate consistent positive cash flows is uncertain. We may need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all. We expect that our operating expenses may increase as we continue to build our commercial infrastructure, develop, enhance and commercialize our products and incur additional costs associated with being a public company. As a result, we may incur operating losses for the foreseeable future and may never achieve profitability.

Our long-term growth depends on our ability to successfully develop the therapeutic endoscopy market and successfully commercialize our Endoscopy products.

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

- properly identify and anticipate physician and patient needs;
- effectively train physicians on how to use our products and achieve good patient outcomes;
- effectively communicate with physicians, payors and patients and educate them on the benefits of Endoscopy procedures;
- achieve adoption of procedures for the use of our products in a timely manner, including for procedures that may not receive third party insurance coverage or reimbursement;
- develop clinical data that demonstrate the safety and efficacy of the procedures that use our products;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- market new devices or modified products in compliance with the regulations of the FDA and other applicable regulatory authorities;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- train 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.

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

Adverse economic conditions in the U.S. and international markets, including the economic contraction resulting in part from the COVID-19 pandemic, may negatively affect our revenues and operating results. Our Endoscopy products, such as the Intragastric Balloon products, have limited reimbursement, and in most cases are not reimbursable by governmental or other health care plans and instead are partially or wholly paid for directly by patients. Sales of our products may be negatively affected by adverse economic conditions impacting consumer spending, including among others, increased taxation, higher unemployment, lower consumer confidence in the economy, disasters or disease outbreaks, such as the COVID-19 pandemic, higher consumer debt levels, lower availability of consumer credit, higher interest rates and hardships relating to declines in the housing and stock markets which have historically caused consumers to reassess their spending choices and reduce their likelihood to pursue elective surgical procedures. Any reduced consumer demand due to adverse economic or market conditions could have a material adverse effect on our business, cause sales and profitability to suffer, reduce operating cash flow and result in a decline in the price of our common stock. Adverse economic and market conditions could also have a negative impact on others, such as creditors, third-party contractors and suppliers, causing them to fail to meet their obligations to us.

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

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

- existing preferences for competitor products or with alternative medical procedures and a general reluctance to change to or use new products or procedures;
- lack of experience or proficiency with our products;
- time and skill commitment that may be necessary to gain familiarity with a new product or new treatment;
- a perception that our products are unproven, unsafe, ineffective, experimental or too expensive;
- reluctance for a related hospital or healthcare facility to approve the introduction of a new product or procedure;
- a preference for an alternative procedure that may afford a physician or a related hospital or healthcare facility greater remuneration; and,
- the development of new weight loss treatment options, including pharmacological treatments, that are less costly, less invasive, or more effective.

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

The procedures that utilize our products are generally elective in nature and demand for our products is driven significantly by patient awareness and preference for the procedures that use our products. We provide patient education materials about our products and related procedures 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 the level of patient satisfaction achieved from procedures that use our products. If patients who undergo treatment using our product are not satisfied with their results, our reputation and that of our products may suffer. Even if we are able to raise favorable awareness among patients, patients may be hesitant to proceed with a medical treatment for various reasons including:

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

- alternative treatments that are perceived to be more effective or less expensive.

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

Our future financial performance will depend in part on our ability to develop and manufacture new products or to acquire new products in a cost-effective manner, to introduce these products to the market on a timely basis and to achieve market acceptance of these products. Factors which may result in delays of new product introductions include capital constraints, research and development delays, lack of personnel with sufficient experience or competence, delays in acquiring regulatory approvals or clearances, including obtaining regulatory approval for new indications for use or delays in closing acquisition transactions. 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 information provided in training or product labeling, or fail to obtain adequate training, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. 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 materials or training relating to a particular procedure is 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.

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. In addition, as part of our cost reduction program to manage the impact of COVID-19, we have implemented furloughs, salary reductions and work hour reductions to employees, including to sales and marketing employees. As a result, our future success will depend largely on our ability to recall furloughed employees and 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 recall furloughed employees or failure to return employees to prior salary or work hour levels may negatively impact our ability to maintain our employees to support business activities in the future, if and when market activities return to pre-COVID-19 levels. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales. Additionally, new hires require training and take time before they achieve full productivity. If we fail to train new hires adequately, new hires may not become as productive as may be necessary to maintain or increase our sales and we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition. In addition, we may change our sales approach in certain markets from direct sales to healthcare providers to sales to distributors who then resell our products. If we were to change our sales approach in a given market, our product sales price in the affected market would be reduced which would lower our revenue and gross margin and the resulting reduction in our operating expense may not be sufficient to offset this reduction in our gross margin.

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

If the supply of materials from our suppliers or provision of services from our vendors were to be interrupted or if we experience delays or interruptions from our manufacturers, including due to the COVID-19 pandemic, replacement or alternative sources might not be readily obtainable. In particular, the products which together comprise our ESS products are sourced from a variety of suppliers and manufacturers, and these suppliers and manufacturers further depend on many component providers. If our suppliers experience unanticipated quality issues or fail to supply components that meet design specifications, or if our contract sterilizers experience delays or shutdowns, we may experience manufacturing delays or product quality issues that may erode customer confidence in our products and negatively affect our sales. As ESS product sales increase, we have experienced times of temporary supply and vendor disruption for a variety of reasons and this has caused delays in our fulfillment of customer orders. For example, we have experienced production and inventory shortages for OverStitch as a result of supply shortages from component suppliers from time to time. Continued interruptions or shortages in these inputs or services, or future unexpected interruptions and shortages, could harm our business, financial condition and results of operations. If such a condition were to persist, our business could suffer as our reputation with customers could be damaged and eventually could lead to reduced future demand for our products. An inability to continue to source materials or components, or receive services, from any of our suppliers, vendors or manufacturers could be due to reasons outside of our direct control, such as regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier or manufacturer, labor disputes or shortages at the supplier and unexpected demands or quality issues. We may also face disputes with our current or previous suppliers and vendors. In any of these cases, we could face a delay of several months to identify and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier or vendor transition plans. In addition, the failure of our third-party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products.

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

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

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

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

We create internal operational forecasts to determine requirements for components and materials used in the manufacture of our products and to make production plans. Our limited operating history and commercial experience, as well as the ongoing COVID-19 pandemic, may make it difficult for us to accurately predict future production requirements. If we forecast inaccurately, this may cause us to have shortfalls or backorders that may negatively impact our reputation with customers and cause them to seek alternative products, or could lead us to have excessive inventory, scrap or similar operational and financial inefficiency that could harm our business.

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

Our industry is highly competitive, subject to change and significantly affected by new product introductions and activities of other industry participants.

These participants may enjoy several competitive advantages, including:

- greater financial and human capital resources;
- significantly greater name recognition;
- established relationships with physicians, referring physicians, customers and third-party payors;

- additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- established sales, marketing and worldwide distribution networks.

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

We may be unable to successfully integrate or expand operations and processes in connection with acquisitions or we may be unable to efficiently transfer divested assets.

In the future, should we grow or acquire new assets or businesses, we expect to incrementally hire and train new personnel and implement appropriate financial and managerial controls, systems and procedures in order to effectively manage our growth and integrate newly acquired operations and processes. In the future, should we divest assets or portions of our business, we will need to implement financial and managerial controls and procedures to efficiently manage the divestiture of such assets and the transition of such business to an acquirer. Failure to successfully manage the integration of newly acquired assets or business or to efficiently transition divested assets to an acquirer could adversely affect our business.

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

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved or cleared for commercial sale by the FDA and manufactured in facilities regulated by the FDA, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products contribute to, or merely appear to or are alleged to have contributed to, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Further, because we are obligated to continue providing certain transition services, including manufacturing and distribution support, to ReShape for our divested Surgical Product line, we may be subject to product liability claims from sales of Surgical products by ReShape, over which we have limited to no control. Product liability claims may be brought against us by 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 ourself against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

In addition, although we maintain product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

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

We do not have redundant facilities. We perform substantially all of our manufacturing in a single location in Costa Rica 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, potential liabilities under our supply agreement with ReShape for the manufacture of Surgical products or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

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

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

If we experience significant disruptions in our or our third-party service providers' information technology systems, our business may be adversely affected.

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

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

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

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

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

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

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

Certain state laws may also be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the California Consumer Privacy Act (the “CCPA”), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm 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 results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without coverage from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

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

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

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

In order to manage the impact of COVID-19, we have implemented cost reduction programs including furloughs, salary reductions and work hour reductions that have impacted all employees. The introduction of these cost reduction measures increases the likelihood the employees may terminate employment. Our future success will depend largely on our ability maintain our workforce until business conditions improve such that we can recall furloughed employees and return employees to previous salary and work hour levels. However, we cannot assure you we will be able to maintain our workforce or to replace any departing personnel on favorable or commercially reasonable terms, if at all. Failure to recall furloughed employees or failure to return employees to prior salary or work hours levels may negatively impact our ability to maintain our workforce to support business activities in the future if and when market activities return to pre-COVID-19 levels. The cost reduction programs including salary reductions, work hour reductions and furlough of employees in multiple jurisdictions may also expose us to contract or other disputes with impacted employees that may be detrimental to our business.

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

We have entered into a supply agreement with ReShape in connection with the sale of our Surgical product line to ReShape pursuant to which we agreed, among other things, to manufacture the Surgical products for ReShape until December 2020. If we do not satisfactorily perform our obligations under the supply agreement, we may be subject to liabilities to ReShape and our business may be adversely affected.

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

As part of the sale of the Surgical product line to ReShape, we are owed future payments of $2.0 million in December 2020 and $3.0 million in December 2021. Any failure of ReShape to timely pay some or all of the remaining future payments will adversely affect our business and financial position.

COVID-19 is likely to reduce demand for the Surgical products sold by ReShape. Any failure by ReShape to timely pay for products ordered under the Supply Agreement with ReShape will adversely impact our business and results of operations.

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

In connection with the audit of our consolidated financial statements for the year ended December 31, 2018, we identified a material weakness in our internal controls over financial reporting. The reported material weakness did not result in any adjustment to our financial statements or restatement of previously reported financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. 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.

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.

The U.K's withdrawal from the EU is commonly referred to as "Brexit." The U.K. and the EU have agreed to a withdrawal agreement (the "Withdrawal Agreement") which was approved by the U.K. Parliament in January 2020. Under the Withdrawal Agreement, the U.K. will be subject to a transition period until December 31, 2020 (the "Transition Period"), during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue to determine the customs and trading relationship that will exist between the U.K. and the EU following the expiration of the Transition Period. 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. Our efforts to mitigate the risk of this supply disruption to our U.K. customers may not prove sufficient.

If the U.K. and the EU are unable to negotiate acceptable trading and customs terms or if other EU member states pursue withdrawal, barrier-free access between the U.K. and other EU member states or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets after the Transition Period. Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations. There may continue to be economic uncertainty surrounding the consequences of Brexit which could negatively impact our financial condition, results of operations and cash flows.

Risks Related to Regulatory Review and Approval of Our Products

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

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other pre-amendment, 510(k)-exempt, 510(k) cleared products, or PMA-approved products that have subsequently been down-classified. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for a direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. 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. Of our products, Orbera is a class III product and has been approved through the FDA's PMA process and our OverStitch products are class II products and have been cleared through the 510(k) process. In addition, although FDA has granted PMA approval for our class III products, holding those approvals in good standing requires ongoing compliance with FDA reporting requirements and conditions of approval including the completion of lengthy and expensive post market approval studies. 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 penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs and the curtailment of our operations, any of which could adversely impact our reputation and business operations.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid; the FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented, a claim to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, and the federal Health Information Technology for Economic and Clinical Health Act of 2009, each as amended, and their implementing regulations, which impose requirements upon certain entities relating to the privacy, security, and transmission of health information;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the federal Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and
- foreign or U.S. state law equivalents of each of the above federal laws

While we do not submit claims for reimbursement to payors and our customers make the ultimate decision on how to submit claims, from time-to-time, we may be asked for reimbursement guidance by our customers. Failure to comply with any of these laws, or any action against us for alleged violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting agreements with physicians, including some who use our products and may influence the ordering and use of our products. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, should the government take the position that these transactions are prohibited arrangements that must be restructured or discontinued, we could be subject to significant penalties. The medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies could significantly harm our business.

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

In addition, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Affordable Care Act's provision commonly referred to as the federal Physician Payment Sunshine Act, as well as similar state and foreign laws, impose obligations on medical device manufacturers to annually report certain payments and other transfers of value provided, directly or indirectly, to certain physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Failure to comply with any of these state, federal, or foreign transparency and disclosure requirements could subject us to significant fines and penalties. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

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

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

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

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

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

Federal and state governments in the U.S. and outside the U.S. may enact legislation to modify the healthcare system which may result in increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. These reform measures may limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payors are willing to pay. These changes could result in reduced demand for our products and may adversely affect our operating results.

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

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

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

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

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

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

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

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

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

The FDA may issue safety alerts in response to its review of reported Adverse Events that do not require voluntary corrective actions or agency enforcement but that still negatively affect our product marketing efforts. For instance, in February of 2017, the FDA issued an update to alert health care providers of reported adverse events of liquid-filled intragastric balloons including several dozen incidents of balloon over-inflation and, separately, a set of reports of acute pancreatitis. In August of 2017, the FDA issued a second update to alert health care providers of five reports of unanticipated deaths that had been reported since 2016 in patients with liquid-filled intragastric balloons, four of which had received our IGB. In June 2018, the FDA issued a new update to alert health care providers of five additional reports worldwide of unanticipated deaths that had been reported since the August 2017 letter to Health Care Providers and also announced the approval of labeling changes for the Orbera Balloon System. Four of the additional mentioned reported deaths involved patients who had received our IGB product. In each case, the occurrence had been self-reported by us to the FDA as part of our normal product surveillance process. Neither the FDA's August 2017 letter to Health Care Providers nor the June 2018 letter to Health Care Providers indicates that the patient deaths were related to the intragastric balloon product or the insertion procedures. However, both letters to Health Care Providers subjected us to adverse publicity that harmed our business. In April 2020, the FDA issued a new update to Health Care Providers following the completion of the Orbera post approval study, which may further subject us to adverse publicity and harm our business. The FDA has full authority to issue these updates or letters and to choose to include or exclude key context and facts based solely on their regulatory discretion and may from time to time issue new letters or updates in the future.

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 that we may experience internationally;
- competitive disadvantage to competitors who have more established business and customer relationships in a given market;

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

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

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

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

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

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

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

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

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

We may, under our own initiative, recall a product if any material deficiency in a device is found. In addition, the FDA and similar foreign governmental authorities can require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of voluntary recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

In addition, on May 25, 2017, the new EU Medical Devices Regulation ("MDR 2017") was published and will 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. The MDR 2017 changes certain obligations of medical device manufacturers with product in the EU and will subject high risk medical devices to additional scrutiny during the conformity assessment process. MDR 2017 repeals and replaces the EU Medical Devices Directive and intends to eliminate current differences in the regulation of medical devices among EEA Member States. The new regulations will among other things:

- add new rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- require the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database 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

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

In order to continue to sell our products in Europe, we must maintain our CE marks and continue to comply with certain EU directives and, in the future with 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. In many of these circumstances, 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.

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. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to applicable clinical protocols or regulatory requirements or for other reasons, our clinical activities or clinical trials may be extended, delayed, suspended or terminated, and we may be at risk of losing our regulatory approvals, or fail to obtain desired regulatory approvals, which could harm our business.

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

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

The auditor's opinion on our audited financial statements for the fiscal year ended December 31, 2019, included in the annual report on Form 10-K, contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2019 includes an explanatory paragraph stating that our losses and negative cash flows from operations and uncertainty in generating sufficient cash to meet our operations raise substantial doubt about our ability to continue as a going concern. While we are pursuing a variety of funding sources and transactions that could raise capital, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our product development, commercialization and strategic plans. Accordingly, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited consolidated financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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

In March 2019, we borrowed $35.0 million principal amount of debt under a term loan facility ("Solar Debt Facility") with Solar Capital, Ltd. ("Solar"). In March 2020, we entered into an amendment to this agreement that provides an additional $10 million of funding in July 2020 if certain revenue milestones are achieved through June 2020. We may borrow an additional $5.0 million upon our request subject to further credit approval. We cannot assure you that additional funding will be received. In April 2020, we entered into an amendment to this agreement to allow us to enter into a loan under PPP and provide revenue covenant relief for the remainder of 2020 due to the impact of COVID-19. We used $22.4 million of the proceeds to repay the existing senior secured credit facility. Our outstanding debt is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates without Solar's consent. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent of the lender. In addition, we are required to prepare our financial statements and receive audits on our annual financial statements in a timely manner, meet certain financial ratio requirements and pay interest and principal when due. Furthermore, under the Solar Debt Facility our interest rate is tied to LIBOR. We do not hedge this variable rate exposure to LIBOR and in the event of an increase in the LIBOR rate, we will be required to pay greater interest expenses, which may be material and have an adverse effect on our net loss and financial condition.

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

We cannot assure you that we will be able to generate sufficient cash flows or revenue to meet the financial covenants or pay the principal and interest on our debt. Furthermore, we cannot assure you that future working capital, borrowings or equity financing will be available to repay or refinance any such debt.

In April 2020, we were granted a loan of $2.8 million under the PPP of the CARES Act, or the PPP Loan, all or a portion of which may be forgiven dependent on our use of proceeds. The PPP Loan matures on April 27, 2022 and bears interest at a rate of 1.0% per annum. Commencing November 27, 2020, we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 27, 2022 any principal amount outstanding on the PPP Loan as of October 24, 2020. All or a portion of the PPP Loan may be forgiven by the SBA upon application by us beginning 60 days, but not later than 120 days, after loan approval and upon documentation of expenditures in accordance with the SBA’s requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight week period beginning on the date of loan approval. Not more than 25% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven will be reduced if our full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness, that we will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan.

The PPP Loan application required us to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan. In the event that we seek forgiveness of all or a portion of the PPP Loan, we will also be required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate, including under the False Claims Act. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could harm our business, results of operations and financial condition.

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;
- inability to obtain adequate supply of the components for, or receive services for, any of our products, including due to supply or service interruptions, 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, as well as distributors;
- the results of our current and any future clinical trials of our devices, including to support future product modifications;
- unanticipated or serious safety concerns related to the use of any of our products;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by us, our commercial partners or our competitors of new products or product enhancements, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- competition from existing technologies and products or new technologies and products that may emerge;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who may cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the low trading volume and the high proportion of shares and convertible notes held by affiliates;
- changes in the structure of health care payment systems and insurance coverage related to our products and procedures that utilize our products; and
- period-to-period fluctuations in our financial results.

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

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

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

We will continue to incur significant legal, accounting and other expenses including costs associated with public company reporting requirements. We will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and The Nasdaq Stock Market LLC. Our executive officers, service providers and other personnel will need to devote substantial time to these rules and regulations. These rules and regulations are expected to increase our legal and financial compliance costs and to make some other activities more time consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of the Company, which may adversely affect investor confidence and could cause our business or stock price to suffer.

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

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

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

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

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

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

The conversion of some or all of our outstanding convertible notes 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, including pursuant to our registration statement on Form S-3 with respect to shares underlying these convertible notes, could negatively impact prevailing market prices of our common stock. In addition, the anticipated conversion of the convertible notes into shares of our common stock or a combination of cash and shares of our common stock could depress the price of our common stock.

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

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

As of March 31, 2020, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders has the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

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

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

Our amended and restated certificate of incorporation designates 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. 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.

These 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. 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 and our amended and restated bylaws. 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

In April 2020, we entered into the Fifth Amendment and Limited Waiver to the Credit Agreement which (i) permits us to enter into a loan under the PPP established under the CARES Act, (ii) waives the trailing six-month Endoscopy revenue requirements for the second and third quarter of 2020 and reduces the revenue requirements for the fourth quarter of 2020, (iii) increases the minimum liquidity requirement to $17.5 million until the earlier of August 14,2020 or when we meet the requirement to raise additional capital of $15.0 million, at which time the minimum liquidity requirement increases to $20.0 million, and decreases the minimum liquidity requirement to $12.5 million in January 2021 if revenue covenant compliance is maintained for October and November 2020, (iv) provides a limited waiver on the monthly financial statement reporting requirements through June 2020, (v) and increases the final fee due at end of the loan term to 5.0% from 4.9%.

On March 27, 2020, the CARES Act was signed into law providing certain economic aid packages for small businesses. In April 2020, we were granted a loan of $2.8 million, or the Loan, under the PPP established under the CARES Act, issued by Dallas Capital Bank, N.A. The Loan matures on April 27, 2022 and bears interest at a rate of 1.0% per annum with equal interest and principal payments beginning on November 27, 2020.

Commencing November 27, 2020, we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 27, 2022 the principal amount outstanding on the Loan as of October 24, 2020. The Loan is evidenced by a promissory note dated April 27, 2020, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. We may prepay the Loan at any time prior to maturity with no prepayment penalties.

ITEM 6. EXHIBITS

		Incorporated by Reference			
Exhibit No.	Exhibit Description	Schedule / Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	Form 8-K	001-35706	3.1	June 13, 2017
3.2	Amended and Restated Bylaws	Form 8-K	001-35706	3.2	June 13, 2017
10.1 *	Fourth Amendment and Limited Waiver to Loan and Security Agreement, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders				
10.2 *	Fifth Amendment and Limited Waiver to Loan and Security Agreement and Second Amendment to Fee Letter, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders				
10.3 *	Promissory Note, dated April 27, 2020, by and among Apollo Endosurgery, Inc. and Dallas Capital Bank, N.A.				
31.1 *	Certification of Chief Executive Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
31.2 *	Certification of Chief Financial Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
32.1# *	Certification of Chief Executive Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
32.2# *	Certification of Chief Financial Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
101.INS *	Instance Document - the instance document does not appear in the Interactive data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH *	XBRL Taxonomy Extension Schema Document				
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document				

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* Filed 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 Quarterly Report on Form 10-Q 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.

SIGNATURES

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 May 4, 2020.

APOLLO ENDOSURGERY, INC.

/s/ Todd Newton

Todd Newton
Chief Executive Officer
(Principal Executive Officer)

/s/ Stefanie Cavanaugh

Stefanie Cavanaugh
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer)

Exhibit 10.1

Execution Version

FIRST AMENDMENT TO FOURTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO FOURTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of March 20, 2020 (the "**Amendment Effective Date**"), is made by and among Apollo Endosurgery, Inc., a Delaware corporation (" **Parent**"), Apollo Endosurgery US, Inc., a Delaware corporation ("**Apollo Endo**"), Apollo Endosurgery International LLC, a Delaware limited liability company (" **Apollo International**"), Lpath Therapeutics Inc., a Delaware corporation (" **Lpath**"; together with Parent, Apollo Endo and Apollo International, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

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

The Borrower, Collateral Agent and the Lenders agree to certain amendments to the Fourth Amendment.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

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

"**UK Debenture**" means that certain English-law Debenture dated June 4, 2019 between Apollo UK and the Collateral Agent.

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

SECTION 2 Amendments to the Fourth Amendment.

(i) New Definitions. The following definition is hereby added to Section 3(a)(ii) of the Fourth Amendent in its proper alphabetical order:

"**Second Draw Conditions**" are satisfaction of each of the following: (a) no Event of Default has occurred and is continuing and (b) Borrower has maintained complete compliance with the covenants set forth in Section 7.13(a) and Section 7.13(b) at all times through and including June 30, 2020.

(ii) Section 3(a)(viii)(2) of the Fourth Amendment is hereby deleted in its entirety and replaced with the following:

"(2) Subclause (ii) thereof is amended and restated in its entirety as follows:

(ii) Subject to satisfaction of the Second Draw Conditions and the other terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on July 31, 2020 in an aggregate principal amount of Ten Million Dollars ($10,000,000) according to each Lender's Term B Loan Commitment Percentage as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**). After repayment, no Term B Loan may be re-borrowed."

SECTION 3 Miscellaneous.

(a) **UK Security Confirmation**. Apollo UK acknowledges and confirms that the Supplemental Security Documents (as defined in the Fourth Amendment) executed by it will on and from the date hereof continue in full force and effect and continue to secure the Secured Obligations (as defined in the UK Debenture) including, without limitation, under or in connection with the Loan Documents including the Loan and Security Agreement as amended as amended by this Amendment.

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

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

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

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

BORROWER:

APOLLO ENDOSURGERY, INC.

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

APOLLO ENDOSURGERY INTERNATIONAL, LLC

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

APOLLO ENDOSURGERY US, INC.

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

LPATH THERAPEUTICS INC.

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

GUARANTOR:

APOLLO ENDOSURGERY UK LTD

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

GUARANTOR:

APOLLO ENDOSURGERY COSTA RICA S.R.L.

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

STATE OF) Texas
) ss.
COUNTY OF) Travis

On March 20, 2020, before me, the undersigned Notary Public, personally appeared Stefanie Cavanaugh (name of signer), personally known to me or proved to me on the basis of satisfactory evidence of identification, which were _(license), to be the person(s) whose name is signed on the preceding or attached document, and acknowledge to me that he/she/they signed it voluntarily and for its stated purpose.

SEAL

WITNESS my hand and official seal.

/s/ Margaret Rose Keller
_____

Notary Public in and for said State

COLLATERAL AGENT:

SOLAR CAPITAL LTD.

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

LENDER:

SOLAR CAPITAL LTD.

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

SCP PRIVATE CREDIT INCOME FUND SPV LLC

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

SCP PRIVATE CREDIT INCOME BDC SPV LLC

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

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

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

SCP SF DEBT FUND L.P.

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

FOURTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT

THIS **FOURTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of March 16, 2020 (the "**Amendment Effective Date**"), is made by and among Apollo Endosurgery, Inc., a Delaware corporation (" **Parent**"), Apollo Endosurgery US, Inc., a Delaware corporation ("**Apollo Endo**"), Apollo Endosurgery International LLC, a Delaware limited liability company (" **Apollo International**"), Lpath Therapeutics Inc., a Delaware corporation ("**Lpath**"; together with Parent, Apollo Endo and Apollo International, individually and collectively, jointly and severally, " **Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of March 15, 2019 (as amended, by that certain First Amendment to Loan and Security Agreement, dated as of June 20, 2019, Second Amendment to Loan and Security Agreement, dated as of August 7, 2019, Third Amendment to Loan and Security Agreement, Waiver and First Amendment to Fee Letter, dated as of October 25, 2019 and as further amended restated, modified or supplemented from time to time, the "**Loan and Security Agreement**").

The Borrower has informed Collateral Agent that it may be unable, for the fiscal year ended December 31, 2019 (the " **Specified Period**"), to comply with the requirement contained in Section 6.2(a)(iii) (the "**Financial Statement Covenant**") of the Loan and Security Agreement to deliver audited consolidated financial statements that are not subject to any "going concern" or like qualification or exception, which inability to so comply, unless waived by Collateral Agent, would constitute an Event of Default under Section 8.2(a) of the Loan and Security Agreement.

The Borrower has requested that Collateral Agent and the Lenders (i) waive the Borrower's compliance with the Financial Statement Covenant for the Specified Period and (ii) agree to certain amendments to the Loan and Security Agreement. Collateral Agent and the Lenders have agreed to such requests, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation.

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

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

SECTION 2. Limited Waiver.

(a) Subject to the terms of this Amendment, Collateral Agent and the Lenders hereby waive the Borrower's compliance with the Financial Statement Covenant for the Specified Period. Collateral Agent's and the Lenders' waiver of the Borrower's compliance with the Financial Statement Covenant shall apply only to the Specified Period.

(b) Collateral Agent's and the Lenders' agreement to waive the Borrower's compliance with the Financial Statement Covenant (i) in no way shall be deemed an agreement by Collateral Agent or the Lenders to waive the Loan Parties' compliance with the Financial Statement Covenant as of all other dates, (ii) shall not limit or impair Collateral Agent's or the Lenders' rights to demand strict performance of all other covenants as of all other dates and (iii) shall not limit or impair Collateral Agent's or the Lenders' right to demand strict performance of all other covenants as of any date.

(c) The waiver set forth in this Section 2 is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (i) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document or (ii) otherwise prejudice any right or remedy which Collateral Agent or the Lenders may now have or may have in the future under or in connection with any Loan Document.

SECTION 3. Amendments to the Loan and Security Agreement.

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

(i) Definitions Chart. The chart of definitions in Section 1.4 is amended as follows:

(1) "Term Loan" is defined in Section 2.2(a)(iii).

(2) A new line for "Term C Loan" is added, which is defined in Section 2.2(a)(iii).

(ii) New Definitions. The following definitions are hereby added to Section 1.4 in their proper alphabetical order:

"**Fourth Amendment Effective Date** " means March 16, 2020.

"**Second Draw Conditions**" are satisfaction of each of the following: (a) no Event of Default has occurred and is continuing and (b) Borrower has maintained complete compliance with the covenants set forth in Section 7.13(a) and Section 7.13(b) at all times through and including June 30, 2020.

(iii) The definition of "Amortization Date" is hereby amended and restated in its entirety as follows:

"Amortization Date" is July 1, 2021; provided that if the Interest Only Extension Conditions are not satisfied as of December 31, 2020, then the Amortization Date is March 1, 2021.

(iv) The definition of "Applicable Margin" is hereby amended and restated in its entirety as follows:

""Applicable Rate" means (a) 7.50% plus (b) the greater of (A) the London Interbank Offered Rate per annum published by the Intercontinental Exchange Benchmark Administration Ltd. (the "Service") (or on any successor or substitute page of such Service, or any successor to or substitute for such Service, as determined by Collateral Agent) for a term of one month, which determination by Collateral Agent shall be conclusive in the absence of manifest error; provided that if, at any time, Lenders notify Collateral Agent that Lenders have determined that (x) Lenders are unable to determine or ascertain such rate, (y) the applicable regulator has made public statements to the effect that the rate published by the Service is no longer used for determining interest rates for loans or (z) by reason of circumstances affecting the foreign exchange and interbank markets generally, deposits in eurodollars in the applicable amounts or for the relative maturities are not being offered for such period, then the Applicable Rate shall be equal to an alternate benchmark rate and spread agreed between Collateral Agent and Borrower (which may include SOFR, to the extent publicly available quotes of SOFR exist at the relevant time), giving due consideration to (i) market convention or (ii) selection, endorsement or recommendation by a Relevant Governmental Body, which alternative benchmark rate and spread shall be binding unless the Required Lenders object within five (5) days following notification of such amendment, and (B) 1.35575%."

(v) The definition of "Interest Only Extension Conditions" is hereby amended and restated in its entirety as follows:

"Interest Only Extension Conditions" are satisfaction of each of the following: (a) no default or Event of Default shall have occurred and is continuing and (b) on or before December 31, 2020, Borrower shall have provided evidence to Collateral Agent satisfactory to Collateral Agent in its reasonable discretion that Borrower has achieved Specified Product Revenues for the fiscal quarter ending December 31, 2020 of greater than or equal to Twenty-Six Million Nine Hundred Thousand Dollars ($26,900,000) on a trailing six-month basis.

(vi) The definition of "Qualified Cash Amount" is hereby amended and restated in its entirety as follows:

"Qualified Cash Amount" means Twelve Million Five Hundred Thousand Dollars ($12,500,000).

(vii) The definition of "Second Draw Period" is hereby deleted in its entirety.

(viii) Section 2.2(a) is hereby amended as follows:

(1) Subclause (i) thereof is amended by amending and restating the last sentence thereof in its entirety as follows:

"After repayment, no Term A Loan may be re-borrowed."

(2) Subclause (ii) thereof is amended and restated in its entirety as follows:

"(ii) Subject to satisfaction of the Second Draw Conditions and other terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on July 31, 2020 in an aggregate principal amount of Ten Million Dollars ($10,000,000) according to each Lender's Term B Loan Commitment Percentage as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**). After repayment, no Term B Loan may be re-borrowed."

(3) A new subclause (iii) is added immediately after subclause (ii) thereof, which new subclause (iii) shall read in its entirety as follows:

"(iii) Subject to the terms and conditions of this Agreement and conditioned on approval by each Lender's credit committee in its sole discretion, the Lenders agree, severally and not jointly, to make term loans to Borrower from and after the Fourth Amendment Effective Date in an aggregate principal amount of Five Million Dollars ($5,000,000) according to each Lender's Term C Commitment Percentage as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a " **Term C Loan**", and collectively as the "**Term C Loans**" "; each Term A Loan, Term B Loan and Term C Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans, the Term B Loans and the Term C Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term C Loan may be re-borrowed."

(ix) Section 2.2(c) is hereby amended by adding the following text immediately after the first sentence thereof:

"In the event that Specified Product Revenues for the trailing six month period ending December 31, 2020, is less than Twenty-Six Million Nine Hundred Thousand Dollars ($26,900,000), Borrower shall, on or before April 1, 2021, prepay the outstanding principal of the Term Loans to each Lender in accordance with its Pro Rata Share in an amount equal to (i) Ten Million Dollars ($10,000,000) of outstanding principal of the Term Loans, plus accrued and unpaid interest thereon through such prepayment date, (ii) any fees payable under the Fee Letter by reason of such

prepayment, (iii) the Prepayment Premium, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts."

(x) Article 6 of the Loan and Security Agreement is hereby amended by adding the following new Section 6.13 immediately after Section 6.12 thereof, which Section 6.13 shall read in its entirety as follows:

"**6.13. Equity Event.** Borrower shall receive, after the Fourth Amendment Effective Date and on or before August 15, 2020, unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) net cash proceeds of not less than Fifteen Million Dollars ($15,000,000) from one or more bona fide equity financings and/or Subordinated Debt, in each case subject to reasonable verification by Collateral Agent (including supporting documentation reasonably requested by Collateral Agent)."

(xi) Section 7.13(b) is hereby amended by amending and restating Section 7.13(b) in its entirety as follows:

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

Month-End	Specified Product Revenue
January 2020	$19,628,818
February 2020	$20,006,809
March 2020	$22,100,000
April 2020	$20,036,421
May 2020	$19,319,545
June 2020	$22,500,000
July 2020	$22,654,434
August 2020	$22,625,123
September 2020	$23,000,000
October 2020	$22,719,042
November 2020	$22,843,597
December 2020	$23,500,000
January 2021 and thereafter	80% of projected Specified Product Revenue in accordance with an annual plan submitted by Borrower to Lenders pursuant to Section 6.2(a)(iv), such plan to be approved by Borrower's board of directors and by Agent and Lenders in writing

(xii) Section 8.2(a) of the Loan and Security Agreement is hereby amended and restated in its entirety as follows:

"(a) Any Loan Party or any of its Subsidiaries fails or neglects to perform any obligation in Sections 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), 6.13 (Equity Event) or such Loan Party or any such Subsidiary violates any provision in Section 7; or".

(b) **Amendment to Schedule 1.1 to the Loan and Security Agreement**. Schedule 1.1 to the Loan and Security Agreement is hereby amended and restated in its entirety and replaced with Schedule 1.1 hereto.

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

SECTION 4. Conditions of Effectiveness. The effectiveness of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Borrower shall have paid (i) an amendment fee of Seventy-Five Thousand Dollars ($75,000), which shall be deemed fully earned and non-refundable upon payment, (ii) all invoiced costs and expenses then due in accordance with Section 6(e), and (iii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by the Borrower.

(c) **Legal Opinion**. Collateral Agent shall have received a duly executed legal opinion of Cooley LLP, counsel to Borrower, dated as of the Amendment Effective Date.

(d) **UK Security Documents**. Collateral Agent shall have received:

(i) duly executed copies of (a) a supplemental security deed in respect of that certain English-law Debenture dated 4 June 2019 between Apollo UK and Collateral Agent; and (b) a supplemental security deed in respect of that certain English-law Share Charge dated 4 June 2019 between Apollo Endo and Collateral Agent (the "**Supplemental Security Documents**");

(ii) a copy of the "PSC Register" (within the meaning of section 790C(10) of the Companies Act 2006) of Apollo UK; together with confirmation from a director of Apollo UK (i) that "no warning notice" or "restrictions notice" (in each case as defined in Schedule 1B of the Companies Act 2006) has been issued in respect of the Apollo UK shares pledged as Collateral and no circumstances exist at the time of such confirmation which allow such notice to be issued; or (ii) that Apollo UK is not required to comply with Part 21A of the Companies Act 2006;

(iii) copies of the articles of association and certificate of incorporation of Apollo UK;

(iv) resolutions adopted by Apollo UK's board of directors for the purpose of approving the transactions contemplated by the Supplemental Security Documents;

(v) resolutions adopted by the sole shareholder of Apollo UK for the purpose of approving the transactions contemplated by the Supplemental Security Documents;

(vi) a copy of the specimen signature of each person authorized by the resolutions delivered pursuant to Section 4(d)(iv) of this Amendment;

(vii) certificates (as customary in the jurisdiction of Apollo UK and containing specimen signatures) of a director confirming that guaranteeing or securing the Loans would not cause any guaranteeing or similar limit binding on Apollo UK to be exceeded and certifying that each copy document relating to it specified in Section 4(d)(ii)-(vi) are correct, complete and in full force and effect and has not been amended or superseded as at such date;

(viii) an English law legal opinion of English law counsel regarding only the capacity and due execution of Apollo UK to enter into the Supplemental Security Documents, addressed to the Loan Parties and dated as of the same date as the Supplemental Security Documents, in form and substance reasonably satisfactory to Collateral Agent; and

(ix) such other documents as Collateral Agent may reasonably request.

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

(i) The representations and warranties contained in Section 5 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

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

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

SECTION 6. Miscellaneous.

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

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 4, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

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

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

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

(e) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

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

(g) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES that would result in the application of any laws other than the laws OF the State of New York), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

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

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

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

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

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

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

BORROWER:

APOLLO ENDOSURGERY, INC.

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

APOLLO ENDOSURGERY INTERNATIONAL, LLC

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

APOLLO ENDOSURGERY US, INC.

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

LPATH THERAPEUTICS INC.

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

GUARANTOR:

APOLLO ENDOSURGERY UK LTD

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

GUARANTOR:

APOLLO ENDOSURGERY COSTA RICA S.R.L.

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

STATE OF) Texas
) ss.
COUNTY OF) Travis

On March 13, 2020, before me, the undersigned Notary Public, personally appeared Stefanie Cavanaugh (name of signer), personally known to me or proved to me on the basis of satisfactory evidence of identification, which were _(license), to be the person(s) whose name is signed on the preceding or attached document, and acknowledge to me that he/she/they signed it voluntarily and for its stated purpose.

SEAL

WITNESS my hand and official seal.

/s/ Margaret Rose Keller
_____

Notary Public in and for said State

COLLATERAL AGENT:

SOLAR CAPITAL LTD.

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

LENDER:

SOLAR CAPITAL LTD.

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

SCP PRIVATE CREDIT INCOME FUND SPV LLC

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

SCP PRIVATE CREDIT INCOME BDC SPV LLC

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

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

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

SCP SF DEBT FUND L.P.

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

SCHEDULE 1.1
Lenders and Commitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
SOLAR CAPITAL LTD.	$20,491,579.00	58.55%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$5,329,825.00	15.23%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$4,003,509.00	11.44%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$3,173,333.00	9.07%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$2,001,754.00	5.72%
TOTAL	**$35,000,000**	**100.00%**

Term B Loans

	Term Loan Commitment	Commitment Percentage
SOLAR CAPITAL LTD.	$5,854,736.00	58.55%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$1,522,807.00	15.23%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$1,143,860.00	11.44%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$906,667.00	9.07%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$571,930.00	5.72%
TOTAL	**$10,000,000**	**100.00%**

Term C Loans

	Term Loan Commitment	Commitment Percentage
SOLAR CAPITAL LTD.	$2,927,368.00	58.55%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$761,404.00	15.23%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$571,930.00	11.44%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$453,333.00	9.07%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$285,965.00	5.72%
TOTAL	**$5,000,000**	**100.00%**

Aggregate (all Term Loans)

	Term Loan Amount	Commitment Percentage
SOLAR CAPITAL LTD.	$29,273,683.00	58.55%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$7,614,036.00	15.23%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$5,719,299.00	11.44%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$4,533,333.00	9.07%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$2,859,649.00	5.72%
TOTAL	**$50,000,000**	**100.00%**

FIFTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT AND SECOND AMENDMENT TO FEE LETTER

THIS **FIFTH AMENDMENT AND LIMITED WAIVER TO LOAN AND SECURITY AGREEMENT AND SECOND AMENDMENT TO FEE LETTER** (this "**Amendment**"), dated as of April 30, 2020 (the "**Amendment Effective Date**"), is made by and among Apollo Endosurgery, Inc., a Delaware corporation ("**Parent**"), Apollo Endosurgery US, Inc., a Delaware corporation (" **Apollo Endo**"), Apollo Endosurgery International LLC, a Delaware limited liability company ("**Apollo International**"), Lpath Therapeutics Inc., a Delaware corporation (" **Lpath**"; together with Parent, Apollo Endo and Apollo International, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

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

The Borrower has informed Collateral Agent that it may be unable (i) to comply with the requirements contained in Section 6.2(a) of the Loan and Security Agreement to deliver to each Lender (x) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent (the "**Monthly Financial Statement Covenant**"), for the months beginning with March, 2020 through and including June, 2020 (the "**Monthly Financial Statement Specified Period**"), and (y) as soon as available, but no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent (the "**Quarterly Financial Statement Covenant**"), for the fiscal quarter ending March 31, 2020 (the "**Quarterly Financial Statement Specified Period**"), and (ii) to comply with the requirement contained in Section 7.13(b) of the Loan and Security Agreement to achieve Specified Product Revenue, measured on a trailing six-month basis on the last day of each month, of not less than the amount specified in Section 7.13(b) for each month (the "**Minimum Revenue Covenant**"; together with the Monthly Financial Statement Covenant and the Quarterly Financial Statement Covenant, the "**Specified Covenants**"), for the months beginning with April, 2020 through and including September, 2020 (the " **Minimum Revenue Covenant Specified Period**"; together with the Monthly Financial Statement Specified Period and the Quarterly Financial Statement Specified Period, each, a "**Specified Period**"), which inability to so comply, unless waived by Collateral Agent, would in each case constitute an Event of Default under Section 8.2(a) of the Loan and Security Agreement.

The Borrower has requested that Collateral Agent and the Lenders (i) waive Borrower's compliance with (a) the Monthly Financial Statement Covenant for the Monthly Financial Statement Specified Period, (b) the Quarterly Financial Statement Covenant for the Quarterly Financial Statement Specified Period and (c) the Minimum Revenue Covenant for the Minimum Revenue Covenant Specified Period, (ii) permit Borrower's incurrence of Indebtedness consisting of a loan under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act (the "**PPP Loan**") and (iii) agree to certain amendments to the Loan and Security Agreement and the Fee Letter. Collateral Agent and the Lenders have agreed to such requests, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation.

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

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

SECTION 2. Limited Waiver.

(a) Subject to the terms of this Amendment, Collateral Agent and the Lenders hereby waive the Borrower's compliance with each of the Specified Covenants for the applicable Specified Period; provided that:

(i) In lieu of delivering the financial statements as set forth in the Monthly Financial Statement Covenant for the Monthly Financial Statement Specified Period, Borrower shall instead deliver to each Lender during the Monthly Financial Statement Specified Period, as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating reports of cash, accounts payable, accounts receivable and revenue of Borrower and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent. Concurrently with the delivery of the foregoing, Borrower shall deliver to each Lender each of the deliverables set forth in Section 6.2(b) of the Loan and Security Agreement; and

(ii) Notwithstanding the terms of the Quarterly Financial Statement Covenant, Borrower shall deliver to each Lender as soon as available, but no later than June 29, 2020, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its consolidated Subsidiaries for the fiscal quarter ending March 31, 2020, certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent.

(b) Notwithstanding the terms of Section 7.4 of the Loan and Security Agreement, Borrower shall be permitted to incur Indebtedness consisting of the PPP Loan; provided that (i) such loan shall be unsecured and shall not contain any terms or conditions that are adverse to Collateral Agent's and the Lenders' rights under the Loan and Security Agreement, including with respect to collateral, priority, preference and repayment terms, (ii) such loan shall be subject to Collateral Agent's written approval in its reasonable discretion prior to the closing thereof so long as Borrower is provided an opportunity to notify Collateral Agent of the loan closing prior to such loan being funded and (iii) any material modification to such loan shall be subject to Collateral Agent's written approval.

(c) Collateral Agent's and the Lenders' agreement to waive the Borrower's compliance with the Specified Covenants (i) in no way shall be deemed an agreement by Collateral Agent or the Lenders to waive the Loan Parties' compliance with the Specified Covenants as of all other dates, (ii) shall not limit or impair Collateral Agent's or the Lenders' rights to demand strict performance of all other covenants as of all other dates and (iii) shall not limit or impair Collateral Agent's or the Lenders' right to demand strict performance of all other covenants as of any date. For the avoidance of doubt, Collateral Agent's and the Lenders' waiver of Borrower's compliance with the Specified Covenants shall apply only to the applicable Specified Period.

(d) The waivers set forth in this Section 2 are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (i) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document or (ii) otherwise prejudice any right or remedy which Collateral Agent or the Lenders may now have or may have in the future under or in connection with any Loan Document.

SECTION 3. Amendments to the Loan and Security Agreement and the Fee Letter.

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

(i) The definition of "Qualified Cash Amount" is hereby amended and restated in its entirety as follows:

"Qualified Cash Amount" means Seventeen Million Five Hundred Thousand Dollars ($17,500,000); provided that upon the earlier to occur of (i) August 14, 2020 and (ii) the date on which Borrower satisfies the covenant set forth in Section 6.13, the Qualified Cash Amount shall be Twenty Million Dollars ($20,000,000); provided, further, that upon Borrower's complete compliance with the covenant set forth in Section 7.13(b) for the months of October, 2020 and November, 2020, the Qualified Cash Amount shall, beginning on January 1, 2021, be Twelve Million Five Hundred Thousand Dollars ($12,500,000).

(ii) The definition of "Second Draw Conditions" is hereby amended and restated in its entirety as follows:

"Second Draw Conditions" are satisfaction of each of the following: (a) no Event of Default has occurred and is continuing, (b) Borrower has maintained complete compliance with the covenants set forth in Section 7.13(a) and Section 7.13(b) at all times through and including June 30, 2020 and (c) Borrower has achieved Specified Product Revenue, measured on a trailing six-month basis on the last day of each month, of greater than or equal to the following:

Month-End	Specified Product Revenue
January 2020	$19,628,818
February 2020	$20,006,809
March 2020	$22,100,000
April 2020	$20,036,421
May 2020	$19,319,545
June 2020	$22,500,000

(iii) Section 7.13(b) is hereby amended by amending and restating Section 7.13(b) in its entirety as follows:

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

Month-End	Specified Product Revenue
October 2020	$15,200,000
November 2020	$18,400,000
December 2020	$20,500,000
January 2021 and thereafter	80% of projected Specified Product Revenue in accordance with an annual plan submitted by Borrower to Lenders pursuant to Section 6.2(a)(iv), such plan to be approved by Borrower's board of directors and by Agent and Lenders in writing

(b) Section 2 of the Fee Letter is hereby amended by replacing "4.90%" in clause (B) thereof with "5.00%".

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

SECTION 4. Conditions of Effectiveness. The effectiveness of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 6(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by the Borrower.

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

(i) The representations and warranties contained in Section 5 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

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

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

SECTION 6. Miscellaneous.

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

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 4, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

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

(e) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

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

(g) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES that would result in the application of any laws other than the laws OF the State of New York), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

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

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

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

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

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

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

BORROWER:

APOLLO ENDOSURGERY, INC.

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

APOLLO ENDOSURGERY INTERNATIONAL, LLC

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

APOLLO ENDOSURGERY US, INC.

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

LPATH THERAPEUTICS INC.

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

GUARANTOR:

APOLLO ENDOSURGERY UK LTD

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

GUARANTOR:

APOLLO ENDOSURGERY COSTA RICA S.R.L.

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

COLLATERAL AGENT:

SOLAR CAPITAL LTD.

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

LENDER:

LENDER:

SOLAR CAPITAL LTD.

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

SCP PRIVATE CREDIT INCOME FUND SPV LLC

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

SCP PRIVATE CREDIT INCOME BDC SPV LLC

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

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

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

SCP SF DEBT FUND L.P.

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

PROMISSORY NOTE

Principal	Loan Date	Maturity	Loan No	Call / Coll	Account	Officer	Initials
$2,823,740.00	04-27-2020	04-27-2022	3749377202			RGB	

References in the boxes above are for Lender's use only and do not limit the applicability of this document to any particular loan or item.
Any item above containing "***" has been omitted due to text length limitations.

BORROWER: Apollo Endosurgery US, Inc.
1120 S Capital Texas Hwy, Building 1, Suite 300
Austin, TX 78746-6715

LENDER: Dallas Capital Bank, N.A.
PO Box 814810
Dallas, TX 75381
(972) 391-6800

Principal Amount: $2,823,740.00 Date of Note: April 27, 2020

PROMISE TO PAY. Apollo Endosurgery US, Inc. ("Borrower") promises to pay to Dallas Capital Bank, N.A. ("Lender"), or order, in lawful money of the United States of America, the principal amount of Two Million Eight Hundred Twenty-three Thousand Seven Hundred Forty & 00/100 Dollars ($2,823,740.00), together with interest on the unpaid principal balance from April 27, 2020, until maturity.

PAYMENT. Borrower will pay this loan in accordance with the following payment schedule, which calculates interest on the unpaid principal balances as described in the "INTEREST CALCULATION METHOD" paragraph using the interest rates described in this paragraph: If the current principal balance and all accrued but unpaid interest is not paid at the end of the six month (06) deferment period according to the SBA Guidelines, all the accrued unpaid interest for the first six months (06) will be added to the current principal balance effective October 24, 2020. Borrower will then make 17 estimated monthly consecutive principal and interest payments of $158,911.57 each, beginning November 27, 2020, with interest calculated on the unpaid principal balances using an interest rate of 1.000% per annum; and one estimated principal and interest payment of $158,911.57 on April 27, 2022, with interest calculated on the unpaid principal balances using an interest rate of 1.000% per annum. This estimated final payment is based on the assumption that all payments will be made exactly as scheduled; the actual final payment will be for all principal and accrued interest not yet paid, together with any other unpaid amounts under this Note. Unless otherwise agreed or required by applicable law, payments will be applied first to any accrued unpaid interest; then to principal; and then to any late charges. Borrower will pay Lender at Lender's address shown above or at such other place as Lender may designate in writing.

MAXIMUM INTEREST RATE. Under no circumstances will the interest rate on this Note exceed (except for any higher default rate shown below) the lesser of 18.000% per annum or the maximum rate allowed by applicable law.

INTEREST CALCULATION METHOD. Interest on this Note is computed on a 365/365 simple interest basis; that is, by applying the ratio of the interest rate over the number of days in a year (365 for all years, including leap years), multiplied by the outstanding principal balance, multiplied by the actual number of days the principal balance is outstanding. All interest payable under this Note is computed using this method.

PREPAYMENT. Borrower may pay without penalty all or a portion of the amount owed earlier than it is due. Prepayment in full shall consist of payment of the remaining unpaid principal balance together with all accrued and unpaid interest and all other amounts, costs and expenses for which Borrower is responsible under this Note or any other agreement with Lender pertaining to this loan, and in no event will Borrower ever be required to pay any unearned interest. Early payments will not, unless agreed to by Lender in writing, relieve Borrower of Borrower's obligation to continue to make payments under the payment schedule. Rather, early payments will reduce the principal balance due and may result in Borrower's making fewer payments. Borrower agrees not to send Lender payments marked "paid in full", "without recourse", or similar language. If Borrower sends such a payment, Lender may accept it without losing any of Lender's rights under this Note, and Borrower will remain obligated to pay any further amount owed to Lender. All Written communications concerning disputed amounts, including any check or other payment instrument that indicates that the payment constitutes "payment in full" of the amount owed or that is tendered with other conditions or limitations or as full satisfaction of a disputed amount must be mailed or delivered to: Dallas Capital Bank, N. A., Loan Department, PO Box 814810 Dallas, TX 75381-4810.

LATE CHARGE. If a payment is 10 days or more late, Borrower will be charged 5.000% of the regularly scheduled payment.

POST MATURITY RATE. The Post Maturity Rate on this Note is the lesser of (A) the maximum rate allowed by law or (B) 18.000% per annum. Borrower will pay interest on all sums due after final maturity, whether by acceleration or otherwise, at that rate.

DEFAULT. Each of the following shall constitute an event of default ("Event of Default") under this Note:

Payment Default. Borrower fails to make any payment when due under this Note.

Other Defaults. Borrower fails to comply with or to perform any other term, obligation, covenant or condition contained in this Note or in any of the related documents or to comply with or to perform any term, obligation, covenant or condition contained in any other agreement between lender and Borrower.

Default in Favor of Third Parties. Borrower or any Grantor defaults under any loan, extension of credit, security agreement, purchase or sales agreement, or any other agreement, in favor of any other creditor or person that may materially affect any of Borrower's property or Borrower's ability to repay this Note or perform Borrower's obligations under this Note or any of the related documents.

False Statements. Any warranty, representation or statement made or furnished to Lender by Borrower or on Borrower's behalf under this Note or the related documents is false or misleading in any material respect, either now or at the time made or furnished or becomes false or misleading at any time thereafter.

Death or Insolvency. The dissolution or termination of Borrower's existence as a going business or the death of any partner, the insolvency of Borrower, the appointment of a receiver for any part of Borrower's property, any assignment for the benefit of creditors, any type or creditor workout, or the commencement of any proceeding under any bankruptcy or insolvency laws by or against Borrower.

Creditor or Forfeiture Proceedings. Commencement or foreclosure or forfeiture proceedings, whether by judicial proceeding, self-help, repossession or any other method, by any creditor of Borrower or by any governmental agency against any collateral securing the loan. This includes a garnishment of any of Borrower's accounts, including deposit accounts, with Lender. However, this Event of Default shall not apply if there is a good faith dispute by Borrower as to the validity or reasonableness of the claim which is the basis of the creditor or forfeiture proceeding and if Borrower gives Lender written notice or the creditor or forfeiture proceeding and deposits with Lender monies or a surety bond for the creditor or forfeiture proceeding, in an amount determined by Lender, in its sole discretion, as being an adequate reserve or bond for the dispute.

Events Affecting Guarantor. Any of the preceding events occurs with respect to any guarantor, endorser, surety, or accommodation party of any of the indebtedness or any guarantor, endorser, surety, or accommodation party dies or becomes incompetent, or revokes or disputes the validity of, or liability under, any guaranty of the indebtedness evidenced by this Note.

Events Affecting General Partner of Borrower. Any of the preceding events occurs with respect to any general partner of Borrower or any general partner dies or becomes incompetent.

Change In Ownership. The resignation or expulsion of any general partner with an ownership interest of twenty-five percent (25%) or more in Borrower.

Adverse Change. A material adverse change occurs in Borrower's financial condition. or Lender believes the prospect of payment or performance of this Note is impaired.

Insecurity. Lender in good faith believes itself insecure.

Cure Provisions. If any default, other than a default in payment, is curable and if Borrower has not been given a notice of a breach of the same provision of this Note within the preceding twelve (12) months, it may be cured if Borrower, after Lender sends written notice to Borrower demanding cure of such default (1) cures the default within twenty (20) days; or (2) if the cure requires more than twenty (20) days, immediately initiates steps which Lender deems in Lenders sole discretion to be sufficient to cure the default and thereafter continues and completes all reasonable and necessary steps sufficient to produce compliance as soon as reasonably practical.

LENDER'S RIGHTS. Upon default, Lender may declare the entire indebtedness, including the unpaid principal balance under this Note, all accrued unpaid interest, and all other amounts, costs and expenses for which Borrower is responsible under this Note or any other agreement with Lender pertaining to this loan, immediately due, without notice, and then Borrower will pay that amount.

ATTORNEYS' FEES: EXPENSES. Lender may hire an attorney to help collect this Note if Borrower does not pay, and Borrower will pay Lender's reasonable attorneys' fees. Borrower also will pay Lender all other amounts Lender actually incurs as court costs, lawful fees for filing, recording, releasing to any public office any instrument securing this Note; the reasonable cost actually expended for repossessing, storing, preparing for sale, and selling any security; and fees for noting a lien on or transferring a certificate of title to any motor vehicle offered as security for this Note, or premiums or identifiable charges received in connection with the sale of authorized insurance.

JURY WAIVER. Lender and Borrower hereby waive the right to any jury trial in any action, proceeding, or counterclaim brought by either Lender or Borrower against the other.

GOVERNING LAW. This Note will be governed by federal law applicable to Lender and, to the extent not preempted by federal law, the laws of the State of Texas without regard to its conflicts of law provisions. This Note has been accepted by Lender in the State of Texas.

SBA PROVISION. "When SBA is the holder, this Note will be interpreted and enforced under Federal law, including SBA regulations. Lender or SBA may use state or local procedures for filing papers, recording documents, giving notice, foreclosing liens, and other purposes. By using such procedures, SBA does not waive any Federal immunity from state or local control, penalty, tax, or liability. As to this Note, Borrower may not claim or assert against SBA any local or state law to deny any obligation, defeat any claim of SBA, or preempt Federal law."

CHOICE OF VENUE. If there is a lawsuit, and if the transaction evidenced by this Note occurred in Dallas County, Borrower agrees upon Lender's request to submit to the jurisdiction of the courts of Dallas County, State of Texas.

RIGHT OF SETOFF. To the extent permitted by applicable law, Lender reserves a right of setoff in all Borrower's accounts with Lender (whether checking, savings, or some other account). This includes all accounts Borrower holds jointly with someone else and all accounts Borrower may open in the future. However, this does not include any IRA or Keogh accounts, or any trust accounts for which setoff would be prohibited by law. Borrower authorizes Lender, to the extent permitted by applicable law, to charge or setoff all sums owing on the debt against any and all such accounts, and, at Lender's option, to administratively freeze all such accounts to allow Lender to protect Lender's charge and setoff rights provided in this paragraph.

COLLATERAL. This loan is unsecured.

SUCCESSOR INTERESTS. The terms of this Note shall be binding upon Borrower, and upon Borrower's heirs, personal representatives, successors and assigns, and shall inure to the benefit of Lender and its successors and assigns.

GENERAL PROVISIONS. NOTICE: Under no circumstances (and notwithstanding any other provisions of this Note) shall the interest charged, collected, or contracted for on this Note exceed the maximum rate permitted by law. The term ”maximum rate permitted by law” as used in this Note means the greater of (a) the maximum rate of interest permitted under federal or other law applicable to the indebtedness evidenced by this Note, or (b) the higher, as of the date of this Note, of the ”Weekly Ceiling” or the ”Quarterly Ceiling” as referred to in Sections 303.002, 303.003 and 303.006 of the Texas Finance Code. If any part of this Note cannot be enforced, this fact will not affect the rest of the Note. Borrower does not agree or intend to pay, and Lender does not agree or intend to contract for, charge, collect, take, reserve or receive (collectively referred to herein as ”charge or collect”), any amount in the nature of interest or in the nature of a fee for this loan, which would in any way or event (including demand, prepayment, or acceleration) cause Lender to charge or collect more for this loan than the maximum Lender would be permitted to charge or collect by federal law or the law of the State of Texas (as applicable). Any such excess interest or unauthorized fee shall, instead of anything stated to the contrary, be applied first to reduce the principal balance of this Loan, and when the principal has been paid in full, be refunded to Borrower. The right to accelerate maturity of sums due under this Note does not include the right to accelerate any interest which has not otherwise accrued on the date of such acceleration, and Lender does not intend to charge or collect any unearned interest in the event of acceleration. All sums paid or agreed to be paid to lender for the use, forbearance or detention of sums due hereunder shall, to the extent permitted by applicable law, be amortized, prorated, allocated and spread throughout the full term of the loan evidenced by this Note until payment in full so that the rate or amount of interest on account of the loan evidenced hereby does not exceed the applicable usury ceiling. Lender may delay or forgo enforcing any of its rights or remedies under this Note without losing them. Borrower and any other person who signs, guarantees or endorses this Note, to the extent allowed by law, waive presentment, demand for payment, notice of dishonor, notice of intent to accelerate the maturity of this Note, and notice of acceleration of the maturity of this Note. Upon any change in the terms of this Note, and unless otherwise expressly stated in writing, no party who signs this Note, whether as maker, guarantor, accommodation maker or endorser, shall be released from liability. All such parties agree that Lender may renew or extend (repeatedly and for any length of time) this loan or release any party, partner, or guarantor or collateral; or impair, fail to realize upon or perfect Lender's security interest in the collateral without the consent of or notice to anyone. All such parties also agree that Lender may modify this loan without the consent of or notice to anyone other than the party with whom the modification is made. The obligations under this Note are joint and several.

PRIOR TO SIGNING THIS NOTE, BORROWER READ AND UNDERSTOOD ALL THE PROVISIONS OF THIS NOTE. BORROWER AGREES TO THE TERMS OF THE NOTE.

BORROWER ACKNOWLEDGES RECEIPT OF A COMPLETED COPY OF THIS PROMISSORY NOTE.

BORROWER:

APOLLO ENDOSURGERY US. INC.

By: /s/ Todd Newton
Todd Newton, Chief Executive Officer of Apollo Endosurgery US, Inc.

By: /s/ Stefanie Cavanaugh
Stefanie L. Cavanaugh, Secretary of Apollo Endosurgery US, Inc.

Exhibit 31.1

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

I, Todd Newton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Apollo Endosurgery, Inc.;

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

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

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

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

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

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

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

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

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

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

May 4, 2020

By: /s/ Todd Newton

Todd Newton
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Stefanie Cavanaugh, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Apollo Endosurgery, Inc.;

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

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

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

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

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

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

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

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

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

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

May 4, 2020

By: /s/ Stefanie Cavanaugh

Stefanie Cavanaugh
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

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

1. The Company's Report on Form 10-Q for the period ended March 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 4, 2020

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

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

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

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

1. The Company's Report on Form 10-Q for the period ended March 31, 2020, to which this Certification is attached as Exhibit 32.2 (the "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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 4, 2020

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

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

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.