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 September 30, 2019

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

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

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

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

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

As of October 25, 2019, there were 20,944,284 shares of the issuer's $0.001 par value common stock issued and outstanding.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
FOR THE QUARTER ENDED SEPTEMBER 30, 2019
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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)

	September 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 34,970	$ 23,996
Accounts receivable, net of allowance for doubtful accounts of $698 and $559, respectively	8,902	11,391
Inventory	10,833	9,932
Prepaid expenses and other current assets	3,350	2,801
Total current assets	58,055	48,120
Restricted cash	1,006	1,011
Property, equipment and right-of-use assets	6,999	5,897
Goodwill	5,290	5,290
Intangible assets, net of accumulated amortization of $11,029 and $9,455, respectively	8,340	9,859
Other assets	4,535	4,291
Total assets	$ 84,225	$ 74,468
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,157	$ 15,292
Accrued expenses	10,107	9,156
Total current liabilities	20,264	24,448
Long-term debt	34,276	21,190
Convertible debt	18,527	—
Long-term liabilities	1,209	—
Total liabilities	74,276	45,638
Commitments and contingencies		
Stockholders' equity:		
Common stock; $0.001 par value; 100,000,000 shares authorized; 20,934,969 and 21,899,522 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	21	22
Additional paid-in capital	250,186	249,115
Accumulated other comprehensive income	2,708	2,501
Accumulated deficit	(242,966)	(222,808)
Total stockholders' equity	9,949	28,830
Total liabilities and stockholders' equity	$ 84,225	$ 74,468

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	$ 11,259	$ 14,141	$ 38,724	$ 45,672
Cost of sales	5,826	6,400	18,884	19,560
Gross margin	5,433	7,741	19,840	26,112
Operating expenses:				
Sales and marketing	6,495	7,344	21,995	25,078
General and administrative	3,159	3,021	10,219	9,589
Research and development	2,128	3,671	8,245	9,281
Amortization of intangible assets	510	1,807	1,591	5,411
Settlement gain	—	—	(5,609)	—
Total operating expenses	12,292	15,843	36,441	49,359
Loss from operations	(6,859)	(8,102)	(16,601)	(23,247)
Other expenses:				
Interest expense, net	1,221	1,001	2,849	2,980
Other expense	498	620	655	1,085
Net loss before income taxes	(8,578)	(9,723)	(20,105)	(27,312)
Income tax expense	80	36	131	122
Net loss	$ (8,658)	$ (9,759)	$ (20,236)	$ (27,434)
Other comprehensive income (loss):				
Foreign currency translation	176	498	207	495
Comprehensive loss	$ (8,482)	$ (9,261)	$ (20,029)	$ (26,939)
Net loss per share, basic and diluted	$ (0.40)	$ (0.45)	$ (0.93)	$ (1.44)
Shares used in computing net loss per share, basic and diluted	21,401,044	21,885,158	21,743,218	19,080,400

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30, 2019 and 2018					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances at June 30, 2018	21,877,332	$ 22	$ 248,336	$ 1,792	$ (194,696)	$ 55,454
Exercise of common stock options	15,008	—	51	—	—	51
Issuance of restricted stock units	834	—	—	—	—	—
Stock based compensation	—	—	374	—	—	374
Foreign currency translation	—	—	—	498	—	498
Net loss	—	—	—	—	(9,759)	(9,759)
Balance at September 30, 2018	21,893,174	$ 22	$ 248,761	$ 2,290	$ (204,455)	$ 46,618
Balances at June 30, 2019	21,933,102	$ 22	$ 249,791	$ 2,532	$ (234,308)	$ 18,037
Exercise of common stock options	1,867	—	4	—	—	4
Exchange of common stock for warrants	(1,000,000)	(1)	1	—	—	—
Stock based compensation	—	—	390	—	—	390
Foreign currency translation	—	—	—	176	—	176
Net loss	—	—	—	—	(8,658)	(8,658)
Balances at September 30, 2019	20,934,969	$ 21	$ 250,186	$ 2,708	$ (242,966)	$ 9,949

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2019 and 2018					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2017	17,291,209	$ 17	$ 225,122	$ 1,795	$ (177,021)	$ 49,913
Exercise of common stock options	275,805	—	738	—	—	738
Issuance of restricted stock units	17,070	—	—	—	—	—
Stock based compensation	—	—	1,049	—	—	1,049
Issuance of common stock, net of issuance costs of $1,843	4,309,090	5	21,852	—	—	21,857
Foreign currency translation	—	—	—	495	—	495
Net loss	—	—	—	—	(27,434)	(27,434)
Balances at September 30, 2018	21,893,174	$ 22	$ 248,761	$ 2,290	$ (204,455)	$ 46,618
Balances at December 31, 2018	21,899,522	$ 22	$ 249,115	$ 2,501	$ (222,730)	$ 28,908
Exercise of common stock options	5,621	—	11	—	—	11
Exchange of common stock for warrants	(1,000,000)	(1)	1	—	—	—
Issuance of restricted stock units	29,826	—	—	—	—	—
Stock based compensation	—	—	1,059	—	—	1,059
Foreign currency translation	—	—	—	207	—	207
Net loss	—	—	—	—	(20,236)	(20,236)
Balances at September 30, 2019	20,934,969	$ 21	$ 250,186	$ 2,708	$ (242,966)	$ 9,949

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (20,236)	$ (27,434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Settlement gain	(5,609)	—
Depreciation and amortization	3,108	7,024
Amortization of deferred financing costs	470	269
Non-cash interest	214	291
Provision for doubtful accounts receivable	209	174
Inventory impairment	80	367
Stock based compensation	1,059	1,049
Unrealized foreign currency loss on short-term intercompany loans	950	906
Changes in operating assets and liabilities:		
Accounts receivable	2,074	1,088
Inventory	(1,042)	439
Prepaid expenses and other assets	(319)	(84)
Accounts payable and accrued expenses	97	(3,007)
Net cash used in operating activities	(18,945)	(18,918)
Cash flows from investing activities:		
Purchases of property and equipment	(466)	(1,965)
Purchases of intangibles and other assets	(181)	(754)
Proceeds from sale of equipment	18	—
Net cash used in investing activities	(629)	(2,719)
Cash flows from financing activities:		
Proceeds from exercise of stock options	11	738
Proceeds from long-term debt	35,000	—
Proceeds from convertible debt	20,000	—
Proceeds from issuance of common stock	—	21,857
Payments of deferred financing costs	(2,737)	(353)
Payment of long-term debt	(21,668)	(2,500)
Net cash provided by financing activities	30,606	19,742
Effect of exchange rate changes on cash	(63)	(69)
Net increase/(decrease) in cash, cash equivalents and restricted cash	10,969	(1,964)
Cash, cash equivalents and restricted cash at beginning of year	25,007	31,418
Cash, cash equivalents and restricted cash at end of period	$ 35,976	$ 29,454
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,634	$ 2,738
Cash paid for income taxes	132	36
Right-of-use assets recognized in exchange for new lease obligations (non-cash)	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 and surgeons in a variety of settings to provide interventional therapy to patients who suffer from various gastrointestinal conditions including obesity and the many co-morbidities associated with obesity.

The Company's core products include the OverStitch™ Endoscopic Suturing System ("ESS") and the Orbera® Intragastric Balloon System ("IGB"), which together comprise the Company's Endoscopy products.

We have offices in England, Australia, Italy, and Brazil that oversee commercial activities outside the U.S., a products manufacturing facility in Costa Rica and a device analysis lab in California. All other activities are managed and operated from facilities in Austin, Texas.

In December 2018, the Company sold its Surgical product line to ReShape Lifesciences, Inc. ("ReShape") for $10,000 in cash at closing and future cash consideration of $7,000. As additional consideration, the Company received substantially all of ReShape's assets exclusively related to ReShape's intragastric balloon product line. Effective December 31, 2018, the Company ceased sales of ReShape's intragastric balloon system.

(2) Significant Accounting Policies

(a) 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.

(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, 2018.

(c) Other Revenue

In connection with the December 2018 sale of the Surgical product line, the Company entered into a transition services agreement, supply agreement and distribution agreement pursuant to which the Company will provide specific transition services for designated periods of time for each service, manufacture Surgical products for up to two years, and serve as ReShape's distributor of Surgical product outside the U.S. for up to one year. Transition service revenue is recognized as the support is provided in accordance with the prices established in the transition services agreement. Supply agreement revenue is recognized when products are shipped at the net amount earned based upon the prices established in the supply agreement less the cost to produce the product. Transition service and supply agreement revenue are included in other revenue. Pursuant to the OUS distribution agreement, the Company will continue to sell products to customers and will continue to recognize OUS Surgical product sales at the amounts charged to customers and reflect the cost of these products in cost of sales.

(In thousands, except for share data)

(d) Leases

On January 1, 2019, the Company adopted the provisions of ASU 2016-02, *Leases* ("ASU 2016-02") under the modified retrospective approach, chose not to adjust comparative periods, and elected the package of practical expedients permitted under the transition guidance, which among other things, allowed us to carry forward the historical lease classification. The cumulative-effect adjustment made to the opening balance of retained earnings as of January 1, 2019 was $78. All significant lease arrangements are generally recognized at lease commitment. Operating lease right-of-use assets and liabilities are recognized at commencement, except for leases with an initial term of 12 months or less, for which lease expense is recognized as incurred over the lease term. Right-of-use assets represent the Company's right to use an underlying asset during the reasonably certain lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease terms may include options to extend or terminate the lease when its reasonably certain that the Company will exercise that option. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company primarily uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Operating lease right-of-use assets include any lease payments related to initial direct costs and prepayments and excludes lease incentives. Lease expense is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately.

(e) Recent Accounting Pronouncements

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

(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 September 30, 2019, the Company's cash, cash equivalents and restricted cash are held in deposit accounts at six different banks totaling $35,976. The Company has not experienced any losses in such accounts, and management does not believe the Company is exposed to any significant credit risk. Management further believes that the concentration of credit risk in the Company's accounts receivable is substantially mitigated by the Company's evaluation process, relatively short collection terms, and the high level of creditworthiness of its customers. The Company continually evaluates the status of each of its customers, but generally requires no collateral.

(4) Inventory

Inventory consists of the following as of:

	September 30, 2019	December 31, 2018
	(unaudited)	
Raw materials	$ 3,085	$ 3,806
Work in progress	539	352
Finished goods	7,209	5,774
Total inventory	$ 10,833	$ 9,932

The Company recorded inventory impairment charges of $40 and $80 for the three and nine months ended September 30, 2019 and $106 and $367 for the three and nine months ended September 30, 2018, respectively. Finished goods includes $200 of consigned inventory at September 30, 2019.

(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	September 30, 2019	December 31, 2018
		(unaudited)	
Equipment	5 years	$ 7,486	$ 7,510
Right-of-use assets	1-5 years	2,762	—
Furniture, fixtures and tooling	4-8 years	2,230	2,223
Computer hardware	3-5 years	1,334	1,326
Leasehold improvements	3-5 years	1,400	1,400
Construction in process		497	130
		15,709	12,589
Less accumulated depreciation		(8,710)	(6,692)
Property and equipment, net		$ 6,999	$ 5,897

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

As of September 30, 2019, the maturities of the Company's operating lease liabilities are as follows:

2019	$ 306
2020	1,015
2021	815
2022	137
2023	91
Thereafter	28
Total lease payments	2,392
Less imputed interest	(298)
Total operating lease liabilities	$ 2,094

Operating lease liabilities of $885 and $1,209 are included in accrued expenses and long-term liabilities, respectively, as of September 30, 2019. Operating lease expense and cash paid within operating cash flows for operating leases was $306 and $958 for the three and nine months ended September 30, 2019, respectively. The weighted average remaining lease term was 2.31 years and the weighted average discount rate used to estimate the value of the operating lease liabilities was 10.0%.

(6) Other Assets

Included in other assets as of September 30, 2019 and December 31, 2018 is $4,238 and $3,907 for the non-current portion of the receivable due from ReShape, respectively.

(In thousands, except for share data)

(7) Accrued Expenses

Accrued expenses consists of the following as of:

	September 30, 2019 (unaudited)	December 31, 2018
Accrued employee compensation and expenses	$ 3,116	$ 3,804
Accrued professional service fees	2,430	2,983
Settlement liability	1,625	—
Lease liability	885	—
Accrued insurance and taxes	276	625
Accrued returns and rebates	222	331
Other	1,553	1,413
Total accrued expenses	$ 10,107	$ 9,156

(8) Long-Term Debt

Long-term debt consists of the following as of:

	September 30, 2019 (unaudited)	December 31, 2018
Term loan facililty	$ 35,000	$ —
Senior secured credit facility	—	19,500
Payment-in-kind interest	347	2,142
Discount on long-term debt	—	(175)
Deferred financing costs	(1,071)	(277)
Long-term debt	$ 34,276	$ 21,190

Future minimum principal payments of long-term debt by year are as follows:

2019	$ —
2020	—
2021	11,667
2022	14,000
2023	9,333
Thereafter	—
	$ 35,000

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 LIBOR plus 7.5%. Interest only is payable in arrears until March 1, 2021 (or September 1, 2021 if certain revenue milestones are achieved). An additional 4.75% 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 Company is accruing for these additional fees as payment-in-kind interest which is included in long-term debt. The Credit Agreement provides that an additional $15,000 may be drawn upon the Company's 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 revenue requirement. The Company used $22,372 of the proceeds of the Credit Agreement to repay its previous senior secured credit facility in full including interest. Unamortized deferred financing costs and discount of $388 were written off in March 2019 in connection with the repayment.

In June 2019, the Company entered into the First Amendment to the Credit Agreement which adjusted the trailing six-month

(In thousands, except for share data)

Endoscopy revenue requirements for the periods ending June 30, July 31, and August 31, 2019 and increased the minimum liquidity covenant to $12,500.

In August 2019, the Company entered into the Second Amendment to the Credit Agreement to allow for the issuance of $20,000 aggregate principal amount of the Company's 6.0% unsecured convertible debentures due 2024 (the "Convertible Debt").

In October 2019, the Company entered into the Third Amendment to the Credit Agreement that adjusted the trailing six-month Endoscopy revenue requirements for the periods ending August 31, 2019 through December 31, 2019, as the Company was not in compliance with the minimum product revenue requirement. As of September 30, 2019, after considering the adjustments made pursuant to the Third Amendment to the Credit Agreement, the Company was in compliance with the financial covenants.

Interest expense on the Company's long term debt was $1,284 and $3,504 for the three and nine months ended September 30, 2019 and $1,152 and $3,279 for the three and nine months ended September 30, 2018, respectively.

(9) Convertible Debt

Convertible debt consists of the following as of:

	September 30, 2019 (unaudited)	December 31, 2018
Convertible debt	$ 20,000	$ —
Deferred financing costs	(1,473)	—
Total convertible debt	$ 18,527	$ —

In August 2019, the Company issued $20,000 aggregate principal amount of Convertible Debt, primarily to existing stockholders and officers of the Company. Interest on the Convertible Debt will be payable semi-annually in shares of the Company's 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 average 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.

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 $208 for the three and nine months ended September 30, 2019.

(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") (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.

A summary of the stock option activity under the Company's 2017 Plan and Prior Plans (collectively, the "Equity Plans") as of September 30, 2019 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2018	1,502,756	$5.63	7.7 years	$217
Options granted	781,705	$3.47		
Options exercised	(5,621)	$1.81		
Options forfeited	(228,346)	$4.45		
Options outstanding, vested and expected to vest, September 30, 2019	2,050,494	$4.95	7.7 years	$145
Options exercisable	978,853	$5.15	6.2 years	$130

(In thousands, except for share data)

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.

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

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Risk free interest rate	2.2 %	2.7 %
Expected dividend yield	— %	— %
Estimated volatility	64.6 %	63.3 %
Expected life	5.8 years	5.8 years

Additional information regarding options is as follows:

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Weighted-average grant date fair value of options granted during the period	$ 2.04	$ 3.95
Aggregate intrinsic value of options exercised during the period	$ 10	$ 923

The aggregate intrinsic value in the table above represents the total pre-tax value of the options shown, calculated as the difference between the Company's closing stock price on September 30, 2019 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 September 30, 2019 and sold the shares thereby received at the closing price of the Company's stock on that date. This amount changes based on the closing price of the Company's stock.

The total compensation cost recognized for stock-based awards was $390 and $1,059 for the three and nine months ended September 30, 2019 and $374 and $1,049 for the three and nine months ended September 30, 2018.

The Company has options outstanding to purchase 136,197 common shares that vest upon the achievement of certain revenue targets for calendar year 2019. Achievement of the performance targets deemed probable are included in total stock compensation expense.

Unrecognized compensation expense related to unvested options was approximately $2,836 at September 30, 2019, with a remaining amortization period of 2.7 years.

A summary of the restricted stock unit activity under the Company's Equity Plans as of September 30, 2019 is presented below.

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested units, December 31, 2018	94,940	$6.21	$328
Restricted stock units granted	200,009	$3.46	
Restricted stock units vested	(29,826)	$6.66	
Restricted stock units forfeited	(15,971)	$4.37	
Unvested units, September 30, 2019	249,152	$4.07	$820

Unrecognized compensation expense related to unvested restricted stock units was approximately $872 at September 30, 2019, with a remaining amortization period of 3.0 years.

(11) Income Taxes

The provision for income taxes for the three and nine months ended September 30, 2019 and 2018 includes both domestic and foreign income taxes at applicable statutory rates. The provision primarily consists of foreign income taxes.

The Company has established a valuation allowance equal to the total net domestic deferred tax asset due to uncertainties regarding the realization of deferred tax assets based on the Company's lack of earnings history.

(In thousands, except for share data)

As of September 30, 2019, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions.

(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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Warrants for common stock	736,980	251,189	383,858	251,189
Convertible debt	3,304,235	—	1,113,515	—
Common stock options	2,004,749	1,665,456	1,716,127	1,515,487
Restricted stock units	233,774	100,104	150,366	86,849
	6,279,738	2,016,749	3,363,866	1,853,525

In August 2019, the Company issued a pre-funded warrant ("Warrant"), to exchange up to 1,000,000 shares of the Company's common stock, at an exercise price of $0.001 per share, to an existing stockholder for 1,000,000 shares of common stock held by such stockholder. The common stock received in the exchange was subsequently retired. The Warrant may be exercised at any time until the Warrant is exercised in full. The holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would beneficially own more than 9.99% of the outstanding common stock in the aggregate immediately after exercise.

(13) Liquidity and Capital Resources

The Company has experienced operating losses since inception and debt covenant violations and has an accumulated deficit of $242,966 as of September 30, 2019. To date, the Company has funded its operating losses and acquisitions through equity offerings and the issuance of debt instruments. The Company's ability to fund future operations and meet debt covenant requirements will depend upon its level of future revenue and operating cash flow and its ability to access additional funding through either equity offerings, issuances of debt instruments or both.

In March 2019, the Company entered into the Credit Agreement with Solar Capital, Ltd. to borrow $35,000 of which $22,372 of the proceeds were used to repay the Company's previous senior secured credit facility. The Credit Agreement includes affirmative, negative and financial covenants, including maintenance of a minimum cash balance and minimum product revenue requirements. While the Company believes it will remain in compliance with these covenants, if it is unable to do so, the Company would seek covenant waivers which may or may not be granted by the lender and the lender could accelerate repayment of the Term Loan Facility.

In August 2019, the Company issued $20,000 aggregate principal amount of Convertible Debt. Interest on the Convertible Debt will be payable semi-annually in shares of the Company's 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 average 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 their terms.

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

(In thousands, except for share data)

(14) 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 convertible debt and long-term debt is estimated by management to approximate $20,000 and $35,000, respectively at September 30, 2019. 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.

(15) Segment and Geographic Information

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

Product sales by product group and geographic market, based on the location of the customer, whether the U.S. or outside the U.S. ("OUS") for the periods shown were as follows:

	Three Months Ended September 30, 2019				Three Months Ended September 30, 2018			
	(unaudited)							
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 3,711	$ 2,949	$ 6,660	59.2 %	$ 2,511	$ 2,698	$ 5,209	36.8 %
IGB	1,088	2,633	3,721	33.0 %	1,175	2,898	4,073	28.8 %
Total Endoscopy	4,799	5,582	10,381	92.2 %	3,686	5,596	9,282	65.6 %
Surgical	—	640	640	5.7 %	2,790	1,851	4,641	32.9 %
Other	228	10	238	2.1 %	210	8	218	1.5 %
Total revenues	$ 5,027	$ 6,232	$ 11,259	100.0 %	$ 6,686	$ 7,455	$ 14,141	100.0 %
% Total revenues	44.6 %	55.4 %			47.3 %	52.7 %		

(In thousands, except for share data)

	Nine Months Ended September 30, 2019				Nine Months Ended September 30, 2018			
	(unaudited)							
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	$ 10,498	$ 10,339	$ 20,837	53.8 %	$ 7,663	$ 8,793	$ 16,456	36.0 %
IGB	4,005	8,552	12,557	32.4 %	4,461	9,425	13,886	30.4 %
Total Endoscopy	14,503	18,891	33,394	86.2 %	12,124	18,218	30,342	66.4 %
Surgical	—	3,670	3,670	9.5 %	8,359	6,210	14,569	31.9 %
Other	1,632	28	1,660	4.3 %	735	26	761	1.7 %
Total revenues	$ 16,135	$ 22,589	$ 38,724	100.0 %	$ 21,218	$ 24,454	$ 45,672	100.0 %
% Total revenues	41.7 %	58.3 %			46.5 %	53.5 %		

Total distributor sales were 34.4% and 23.4% of total OUS revenues for the three months ended September 30, 2019 and 2018, respectively, and 31.8% and 21.8% for the nine months ended September 30, 2019 and 2018, respectively. The next largest individual country outside the U.S. was 6.8% and 7.2% of total revenues for the three months ended September 30, 2019 and 2018, respectively, and 8.2% and 7.8% of total revenues for the nine months ended September 30, 2019 and 2018, respectively.

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

	September 30, 2019	December 31, 2018
	(unaudited)	
United States	$ 3,158	$ 2,337
Costa Rica	3,359	3,347
Other	482	213
Total property, equipment and right-of-use assets, net	$ 6,999	$ 5,897

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. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this 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, 2018 filed on March 18, 2019 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 England, Australia, Italy, and Brazil that oversee commercial activities outside the U.S., a products manufacturing facility in Costa Rica and a device analysis lab in California. All other activities are managed and operated from facilities in Austin, Texas.

Divestiture of the Surgical Product Line

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

ReShape agreed to pay $17.0 million in cash ("Cash Purchase Price"), of which $10.0 million was paid at the closing of the transaction and an additional $2.0 million is payable on each of the first and second anniversary of the closing date and the remaining $3.0 million is payable on the third anniversary of the closing date. As additional consideration, we also received from ReShape substantially all of ReShape's assets exclusively related to their intragastric balloon product. As of December 31, 2018, we discontinued selling ReShape's intragastric balloon product.

Upon completion of the ReShape transaction, the parties entered into a transition services agreement, supply agreement and distribution agreement pursuant to which, among other things, we will manufacture the Surgical product for ReShape for up two years, serve as ReShape's distributor of the Surgical product outside of the U.S. ("OUS") for up to one year and provide other specified services for defined periods of time.

We and ReShape each made customary representations, warranties, covenants and indemnities in the Purchase Agreement. Subject to certain limitations, we each agreed to indemnify the other party for certain matters, including breaches of representations, warranties and covenants in the Purchase Agreement. ReShape also granted us a security interest in substantially all of ReShape's assets as security for the payment and performance when due of all of ReShape's obligations under the Purchase Agreement, including their remaining Cash Purchase Price obligations until the earlier of either the satisfaction of all obligations or the completion of one or more qualified financings that aggregate to $15.0 million. In October 2019, ReShape provided notice to us that it has completed their qualified financings.

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 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.

Following the divestiture of our Surgical product line, we agreed to sell Surgical products to customers OUS for the shorter of one year or until ReShape has transferred responsibility for selling in these markets. Our product sales will continue to include OUS Surgical product sales from these serviced markets at the amounts charged to customers and we will reflect the cost of these products in cost of sales.

Other revenue includes amounts recognized for our digital aftercare support program, transition and supply services we render to ReShape related to the divested Surgical product line and freight charged to customers. We offer a digital weight loss support system for patients both before and after weight loss procedures and recognize revenue over the term of each contract.

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 will continue to be 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.

Intangible Amortization

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, 2018 (the "2018 Form 10-K"), and "Critical Accounting Policies and Estimates" in Part II, Item 7 of the 2018 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 2018 Form 10-K.

Non-GAAP Financial Measures

To supplement our financial results we are providing a non-GAAP financial measure, percentage revenue change in constant currency, which removes the impact of changes in foreign currency exchange rates that affect the comparability and trend of revenues. Percentage revenue 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 and nine months ended September 30, 2019 and 2018

	Three Months Ended September 30, 2019		Three Months Ended September 30, 2018	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues [1]	$ 11,259	100.0 %	$ 14,141	100.0 %
Cost of sales	5,826	51.7 %	6,400	45.3 %
Gross margin	5,433	48.3 %	7,741	54.7 %
Operating expenses:				
Sales and marketing	6,495	57.7 %	7,344	51.9 %
General and administrative	3,159	28.1 %	3,021	21.4 %
Research and development	2,128	18.9 %	3,671	26.0 %
Amortization of intangible assets	510	4.5 %	1,807	12.8 %
Total operating expenses	12,292	109.2 %	15,843	112.0 %
Loss from operations	(6,859)	(60.9)%	(8,102)	(57.3)%
Interest expense, net	1,221	10.8 %	1,001	7.1 %
Other expense	498	4.4 %	620	4.4 %
Net loss before income taxes	(8,578)	(76.1)%	(9,723)	(68.8)%
Income tax expense	80	0.7 %	36	0.3 %
Net loss	$ (8,658)	(76.8)%	$ (9,759)	(69.0)%

[1] Revenue between periods declined $3.9 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.

	Nine Months Ended September 30, 2019		Nine Months Ended September 30, 2018	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues [1]	$ 38,724	100.0 %	$ 45,672	100.0 %
Cost of sales	18,884	48.8 %	19,560	42.8 %
Gross margin	19,840	51.2 %	26,112	57.2 %
Operating expenses:				
Sales and marketing	21,995	56.8 %	25,078	54.9 %
General and administrative	10,219	26.4 %	9,589	21.0 %
Research and development	8,245	21.3 %	9,281	20.3 %
Amortization of intangible assets	1,591	4.1 %	5,411	11.8 %
Settlement gain	(5,609)	(14.5)%	—	— %
Total operating expenses	36,441	94.1 %	49,359	108.1 %
Loss from operations	(16,601)	(42.9)%	(23,247)	(50.9)%
Interest expense, net	2,849	7.4 %	2,980	6.5 %
Other expense	655	1.7 %	1,085	2.4 %
Net loss before income taxes	(20,105)	(52.0)%	(27,312)	(59.8)%
Income tax expense	131	0.3 %	122	0.3 %
Net loss	$ (20,236)	(52.3)%	$ (27,434)	(60.1)%

[1] Revenue between periods declined $9.7 million due to the divestiture of the Surgical product line in December 2018. See the product sales table under "Revenues" for additional information for product group and geographic market.

Revenues

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

	Three Months Ended September 30, 2019			Three Months Ended September 30, 2018			% Increase/ (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 3,711	$ 2,949	$ 6,660	$ 2,511	$ 2,698	$ 5,209	47.8 %	9.3 %	27.9 %
IGB	1,088	2,633	3,721	1,175	2,898	4,073	(7.4)%	(9.1)%	(8.6)%
Total Endoscopy	4,799	5,582	10,381	3,686	5,596	9,282	30.2 %	(0.3)%	11.8 %
Surgical	—	640	640	2,790	1,851	4,641	(100.0)%	(65.4)%	(86.2)%
Other [1]	228	10	238	210	8	218	8.6 %	25.0 %	9.2 %
Total revenues	$ 5,027	$ 6,232	$ 11,259	$ 6,686	$ 7,455	$ 14,141	(24.8)%	(16.4)%	(20.4)%
% Total revenues	44.6 %	55.4 %		47.3 %	52.7 %				

[1] Other U.S. revenue includes $0.1 million of transition and manufacturing services provided to ReShape for the three months ended September 30, 2019.

	Nine Months Ended September 30, 2019			Nine Months Ended September 30, 2018			% Increase/ (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	$ 10,498	$ 10,339	$ 20,837	$ 7,663	$ 8,793	$ 16,456	37.0 %	17.6 %	26.6 %
IGB	4,005	8,552	12,557	4,461	9,425	13,886	(10.2)%	(9.3)%	(9.6)%
Total Endoscopy	14,503	18,891	33,394	12,124	18,218	30,342	19.6 %	3.7 %	10.1 %
Surgical	—	3,670	3,670	8,359	6,210	14,569	(100.0)%	(40.9)%	(74.8)%
Other [1]	1,632	28	1,660	735	26	761	122.0 %	7.7 %	118.1 %
Total revenues	$ 16,135	$ 22,589	$ 38,724	$ 21,218	$ 24,454	$ 45,672	(24.0)%	(7.6)%	(15.2)%
% Total revenues	41.7 %	58.3 %		46.5 %	53.5 %				

[1] Other U.S. revenue includes $1.2 million of transition and manufacturing services provided to ReShape for the nine months ended September 30, 2019.

Product sales percentage change in constant currency were as follows:

	Three Months Ended September 30, 2019		Nine Months Ended September 30, 2019	
	% Increase/Decrease in Constant Currency		% Increase/Decrease in Constant Currency	
	OUS	Total Revenues	OUS	Total Revenues
ESS	12.4 %	29.5 %	23.0 %	29.5 %
IGB	(6.8)%	(7.0)%	(4.9)%	(6.6)%
Total Endoscopy	2.4 %	13.5 %	8.5 %	13.0 %
Surgical	(63.7)%	(85.5)%	(37.3)%	(73.3)%
Other	46.7 %	9.7 %	21.1 %	118.3 %
Total revenues	(13.9)%	(19.1)%	(3.1)%	(12.8)%

Total revenues for the three months ended September 30, 2019 were $11.3 million, compared to $14.1 million for the three months ended September 30, 2018, a decrease of 20.4%. Total revenues for the nine months ended September 30, 2019 were $38.7 million, compared to $45.7 million for the nine months ended September 30, 2018, a decrease of 15.2%. The decline in total revenues was the result of the divestiture of our Surgical products in December 2018. Subsequent to this transaction, our management's focus is on the market development and commercialization of our Endoscopy products.

Total Endoscopy product sales increased to $10.4 million for the three months ended September 30, 2019 from $9.3 million in the same period for 2018, and to $33.4 million for the nine months ended September 30, 2019 from $30.3 million for the same period of 2018. In constant currency, Endoscopy sales increased 13.5% and 13.0% for the three and nine months ended September 30, 2019 when compared to the same period of 2018, respectively. Direct market Endoscopy product sales accounted for approximately 79.6% and 79.7% of total Endoscopy product sales for the three and nine months ended September 30, 2019, compared to 82.9% and 83.8% for the same period of 2018, respectively.

Total ESS product sales increased $1.5 million and $4.4 million, or 27.9% and 26.6%, for the three and nine months ended September 30, 2019, when compared to the same period of 2018, respectively. In constant currency, ESS product sales increased 29.5% for both the three and nine months ended September 30, 2019. U.S. ESS product sales increased $1.2 million and $2.8 million, or 47.8% and 37.0%, for the three and nine months ended September 30, 2019, when compared to the same period in 2018, respectively. OUS ESS product sales increased $0.3 million and $1.5 million, or 9.3% and 17.6%, for the three and nine months ended September 30, 2019 when compared to the same period of 2018, respectively. In constant currency, OUS ESS product sales increased 12.4% and 23.0% for the three and nine months ended September 30, 2019 when compared to the same period of 2018, respectively. Worldwide, ESS growth is due to increased sales volume from continued new user adoption and greater product utilization in our existing customer base.

Total IGB product sales decreased $0.4 million and $1.3 million, or 8.6% and 9.6%, for the three and nine months ended September 30, 2019, when compared to the same period of 2018, respectively. U.S. IGB product sales decreased $0.1 million and $0.5 million, or 7.4% and 10.2%, for the three and nine months ended September 30, 2019, when compared to the same period in 2018, respectively, due to lower consumer demand. OUS IGB product sales decreased $0.3 million and $0.9 million for the three and nine months ended September 30, 2019, or 9.1% and 9.3%, when compared to the same period in 2018, respectively, primarily due to lost market share in Brazil and negative currency rates. In constant currency, OUS IGB product sales decreased 6.8% and 4.9% for the three and nine months ended September 30, 2019, when compared to the same period of 2018, respectively.

Included in other revenues for the three and nine months ended September 30, 2019 is $0.1 million and $1.2 million, respectively, of transition and manufacturing services provided to ReShape that began in December 2018.

Cost of Sales

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

	Three Months Ended September 30, 2019		Three Months Ended September 30, 2018	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 4,354	38.7 %	$ 4,223	29.9 %
Overhead	806	7.2 %	1,551	11.0 %
Other indirect costs	666	5.8 %	626	4.4 %
Total cost of sales	$ 5,826	51.7 %	$ 6,400	45.3 %

	Nine Months Ended September 30, 2019		Nine Months Ended September 30, 2018	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 13,127	33.9 %	$ 13,045	28.5 %
Overhead	3,563	9.2 %	4,369	9.6 %
Other indirect costs	2,194	5.7 %	2,146	4.7 %
Total cost of sales	$ 18,884	48.8 %	$ 19,560	42.8 %

Gross Margin

Gross margin was 48.3% and 51.2% for the three and nine months ended September 30, 2019, compared to 54.7% and 57.2%, for the same period of 2018, respectively. The decline in gross margin this year is primarily due to a greater proportion of our overall product sales coming from our high growth, but lower gross margin, ESS products following the divestiture of the Surgical product line. Additionally, gross margins we realize on remaining OUS Surgical product sales have declined in 2019 as a result of the terms of the ReShape supply and distribution agreements. Gross margin for our Endoscopy products was 48.4% and 49.8% for the three and nine months ended September 30, 2019 compared to 43.9% and 47.4% for the same period of 2018, respectively.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense decreased $0.8 million and $3.1 million for the three and nine months ended September 30, 2019 compared to the same period in 2018, respectively, primarily due to lower U.S. direct consumer advertising costs, lower sales compensation, and benefits of bringing customer service in house in late 2018.

General and Administrative Expense. General and administrative expense increased $0.1 million and $0.6 million for the three and nine months ended September 30, 2019 when compared to the same period of 2018, respectively, primarily due to higher internal control audit fees incurred in the first quarter of 2019.

Research and Development Expense. Research and development expense decreased $1.5 million and $1.0 million for the three and nine months ended September 30, 2019 when compared to the same period for 2018, primarily due to less clinical trial enrollment activity in 2019.

Amortization of Intangible Assets. Amortization of intangible assets decreased $1.3 million and $3.8 million for the three and nine months ended September 30, 2019 compared to the same period in 2018, respectively, due to the disposition of intangible assets associated with the Surgical business in December 2018.

Settlement gain. Settlement gain of $5.6 million for the nine months ended September 30, 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 September 30, 2019 and 2018 was $6.9 million and $8.1 million, respectively. For the nine months ended September 30, 2019 and 2018, loss from operations was $16.6 million and $23.2 million, respectively. Excluding the settlement gain, the loss from operations for the nine months ended September 30, 2019 was $22.2 million. The increased loss from operations after excluding the one-time settlement gain was primarily due to the divestiture of our Surgical product line in December of 2018.

Other Expenses

Interest Expense, net. Net interest expense increased by $0.2 million for the three months ended September 30, 2019 when compared to the same period in 2018 primarily due to interest on the Convertible Debt. Net interest expense decreased by $0.1 million for the nine months ended September 30, 2019 when compared to the same period in 2018 primarily due to imputed interest income recognized on the receivable from ReShape related to the Surgical divestiture in December 2018.

Other Expense. Other expense primarily consists of realized and unrealized foreign exchange losses on the revaluation of short-term intercompany loans denominated in U.S. dollars payable by our foreign subsidiaries.

Liquidity and Capital Resources

We have experienced operating losses since inception and occasional debt covenant violations and have an accumulated deficit of $243.0 million as of September 30, 2019. 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. Management believes its existing cash and cash equivalents, product revenues and available debt and equity financing arrangements will be sufficient to meet covenant, liquidity and capital requirements for at least the next twelve months, although there can be no assurances that we will be able to do so. Management periodically evaluates our liquidity requirements, alternative uses of capital, capital needs and available resources. As a result of this process, we have in the past, and may in the future, explore alternatives to finance our business plan, including, but not limited to, sales of common stock, preferred stock, convertible securities or debt financings, reduction of planned expenditures, or other sources.

Term Loan Facility

In March 2019, we entered into the Credit Agreement with Solar Capital, Ltd. to borrow $35.0 million. The Credit Agreement matures on September 1, 2023, with principal payments beginning in March 2021, and bears interest at LIBOR plus 7.5%. Interest only is payable in arrears until March 1, 2021 (or September 1, 2021 if certain revenue milestones are achieved). Principal payments are due on a straight-line basis after the interest-only period concludes. An additional 4.75% 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 may borrow an additional $15.0 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 June 2019, we entered into the First Amendment to the Credit Agreement which adjusted the trailing six-month Endoscopy revenue requirements for the periods ending June 30, July 31, and August 31, 2019 and increased the minimum liquidity covenant to $12.5 million.

In August 2019, we entered into the Second Amendment to the Credit Agreement to allow for the issuance of up to $20.0 million aggregate principal amount of 6.0% convertible senior debentures due 2024 (the "Convertible Debt").

In October 2019, we entered into the Third Amendment to the Credit Agreement that adjusted the trailing six-month Endoscopy revenue requirements for the periods ending August 31, 2019 through December 31, 2019.

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 average 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.

Cash Flows

The following table provides information regarding our cash flows:

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (18,945)	$ (18,918)
Net cash used in investing activities	(629)	(2,719)
Net cash provided by financing activities	30,606	19,742
Effect of exchange rate changes on cash	(63)	(69)
Net change in cash, cash equivalents and restricted cash	$ 10,969	$ (1,964)

Operating Activities

Cash used in operating activities of $18.9 million for the nine months ended September 30, 2019 was primarily the result of a net loss of $20.2 million plus non-cash items of $0.5 million primarily related to the settlement gain of $5.6 million offset by depreciation, amortization, foreign currency on intercompany loans, and stock based compensation. The increase in net loss after adjusting for non-cash items was primarily due to the divestiture of our Surgical product line in December of 2018. Additionally, cash provided by operating assets and liabilities of $0.8 million related to working capital changes primarily related to accounts receivable offset by inventory purchases.

Cash used in operating activities of $18.9 million for the nine months ended September 30, 2018 was primarily the result of a net loss of $27.4 million, net of non-cash charges of $10.1 million primarily related to depreciation, amortization, foreign currency on intercompany loans and stock based compensation. Additionally, cash used by operating assets and liabilities of $1.6 million related to working capital changes primarily due to settlement of inventory purchases from the prior year offset by higher accounts receivable collections.

Investing Activities

Cash used for investing activities of $0.6 million for the nine months ended September 30, 2019 and $2.7 million for the nine months ended September 30, 2018 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 provided by financing activities of $30.6 million for the nine months ended September 30, 2019 was primarily related to the net proceeds of $13.3 million received from the Term Loan Facility refinancing, proceeds from the issuance of the Convertible Debt of $20.0 million and deferred financing costs of $2.7 million.

Cash provided by financing activities of $19.7 million for the nine months ended September 30, 2018 was primarily related to $21.9 million in net proceeds from the issuance of common stock in the June 2018 public offering offset by $2.5 million of principal payments on our previous senior secured credit facility.

Future Funding Requirements

As of September 30, 2019, we had cash, cash equivalents and restricted cash balances totaling $36.0 million. We believe our existing cash and cash equivalents, product revenues and available debt and equity financing arrangements will be sufficient to meet our liquidity and capital requirements for at least the next twelve months.

Any future capital requirements will depend on many factors including market acceptance of our products, the cost of our research and development activities, the cost and timing of additional regulatory clearances or approvals, the cost and timing of identified gross margin improvement projects, the cost and timing of clinical programs, the ability to maintain covenant compliance of our lending facility, and the costs and timing of sales, marketing, distribution and manufacturing activities. We may be required to seek additional equity or debt financing. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, operating results and financial condition could be adversely affected.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the 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(e) 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 not effective as of such date due to a material weakness in internal control over financial reporting related to control deficiencies within the Company's revenue recognition and recording processes that was disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

As disclosed under Item 9A., Controls and Procedures in our Annual Report on Form 10-K for the year ended December 31, 2018, management identified a material weakness in internal control over financial reporting relating to the Company's sales order to cash process. The material weakness did not result in any adjustments to our financial statements included in our Annual Report on Form 10-K. Nevertheless, we began implementing a remediation plan to address the material weakness identified. The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We expect that the remediation of this material weakness will be completed prior to December 31, 2019.

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, 2018.

Risks Related to Our Business

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

We have incurred net losses since our inception in 2005. For the years ended December 31, 2018 and 2017, we had net losses of $45.8 million and $27.3 million, respectively, and for the nine months ended September 30, 2019 we had a net loss of $20.2 million. As of September 30, 2019, we had an accumulated deficit of $243.0 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 community. 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 patients and educate them on the benefits of Endoscopy procedures;
- achieve procedure adoption in a timely manner;
- develop clinical data that demonstrate the safety and efficacy of the procedures that use our products;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- market new devices or modified products in compliance with the regulations of the FDA and other applicable regulatory authorities;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- train 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 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, 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 with our products;
- time and skill commitment that may be necessary to gain familiarity with a new product or new treatment;
- a perception that our products are unproven, unsafe, ineffective, experimental or too expensive;
- reluctance for a related hospital or healthcare facility to approve the introduction of a new product or procedure;
- a preference for an alternative procedure that may afford a physician or a related hospital or healthcare facility greater remuneration; and,
- the development of new weight loss treatment options, including pharmacological treatments, that are less costly, less invasive, or more effective.

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

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

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

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

Our future financial performance will depend in part on our ability to develop and manufacture new products or to acquire new products in a cost-effective manner, to introduce these products to the market on a timely basis and to achieve market acceptance of these products. Factors which may result in delays of new product introductions include capital constraints, research and development delays, lack of personnel with sufficient experience or competence, delays in acquiring regulatory approvals or clearances or delays in closing acquisition transactions. Future product introductions may fail to achieve expected levels of market acceptance including physician

adoption, patient awareness or both. Factors impacting the level of market acceptance include the timeliness of our product introductions, the effectiveness of medical education efforts, the effectiveness of patient awareness and educational activities, successful product pricing strategies, available financial and technological resources for product promotion and development, the ability to show clinical benefit from future products, the scope of the indicated use for new products and the availability of coverage and reimbursement for procedures that use future products.

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

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

Physicians may also misuse our products, use improper techniques, ignore or disregard information provided in training or fail to obtain adequate training, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. 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. As a result, our future success will depend largely on our ability to hire, train, retain and motivate skilled sales managers and direct sales representatives. Because of the competition for their services, we cannot assure you we will be able to hire and retain direct sales representatives on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales. Additionally, new hires require training and take time before they achieve full productivity. If we fail to train new hires adequately, new hires may not become as productive as may be necessary to maintain or increase our sales and we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition.

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

If the supply of materials from our suppliers were to be interrupted or if we experience delays or interruptions from our manufacturers, replacement or alternative sources might not be readily obtainable. In particular, the products which together comprise our ESS products are sourced from a variety of suppliers and manufacturers, and these suppliers and manufacturers further depend on many component providers. If our suppliers experience unanticipated quality issues or fail to supply components that meet design specifications 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 disruption for a variety of reasons and this has caused delays in our fulfillment of customer orders. If such a condition were to persist, our business could suffer as our reputation with customers could be damaged and eventually could lead to reduced future demand for our products. An inability to continue to source materials or components from any of our suppliers or manufacturers could be due to reasons outside of our direct control, such as regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier or manufacturer, labor disputes or shortages at the supplier and unexpected demands or quality issues.

Manufacturing of our products requires capital equipment and a well-trained workforce. The sourcing of new manufacturing or supply capacity can 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., Brazil, Australia and the Netherlands for product logistics, order fulfillment and distribution support that are owned and operated by third parties. Our ability to supply products to our customers in a timely manner and at acceptable commercial terms could be disrupted or continue to be disrupted by factors such as fire, earthquake or any other natural disaster, work stoppages or information technology system failures that occur at these third party warehouse and service providers.

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

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

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

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

These participants may enjoy several competitive advantages, including:

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

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

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

Our Surgical product line, which we recently divested, and our IGB product line were acquired December 2013. In the future, should we grow or acquire new assets or businesses, we expect to incrementally hire and train new personnel and implement appropriate financial and managerial controls, systems and procedures in order to effectively manage our growth and integrate newly acquired operations and processes.

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

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved or cleared for commercial sale by the FDA and manufactured in facilities regulated by the FDA, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be

subject to product liability claims if our products contribute to, or merely appear to or are alleged to have contributed to, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Further, because we are obligated to continue providing certain transition services, including manufacturing and distribution support, to ReShape for our divested Surgical Product line, we may be subject to product liability claims from sales of Surgical products by ReShape, over which we have limited to no control. Product liability claims may be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourself against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

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

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

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

Our computer systems, as well as those of various third-parties which we rely, including those of contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cyber criminals, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, or breaches. The risk of a security breach or disruption,

particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may in the future experience material system failures or security breaches that could cause interruptions in our operations or result in material disruption of our product development programs. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information we could incur liability.

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

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

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

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

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

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

Nonetheless, 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 and that our practices will be found to be non-compliant with this regulation. If so, this could result in government-imposed fines, orders or guidance requiring that we change our

data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

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

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

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

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

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

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

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

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 a portion of the Cash Purchase Price is due in future payments of $2.0 million on each of the first and second anniversary of the the closing date and $3.0 million payable on the third anniversary of the closing date. Any failure of ReShape to timely pay some or all of the remaining future payments will adversely affect our business and financial position.

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

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. We are implementing measures designed to improve our internal controls over financial reporting to remediate the identified material weakness. In addition, our independent registered public accounting firm, which audits our financial statements, issued an adverse opinion on the effectiveness of internal control over financial reporting as of December 31, 2018.

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

If we fail to remediate our existing material weakness or identify new material weaknesses in our internal controls over financial reporting, investors may lack confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected regardless of whether material inaccuracies are determined to exist in our reported financial statements.

If material inaccuracies are determined to exist in our financial statements or we are unable to report our financial statements on a timely basis, we could also become subject to investigations by Nasdaq, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

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

On June 23, 2016, the electorate in the United Kingdom ("U.K.") voted in favor of leaving the EU (commonly referred to as "Brexit"). On March 29, 2017, the U.K. government delivered to the European Council notice of its intention to leave the EU and, in the absence of an executed withdrawal agreement with the EU, the effective date of the U.K.'s withdrawal from the EU will be January 31, 2020. Our subsidiary that manages our European business is located in the U.K. and, thus, there are many ways in which our business operations may be impacted by Brexit, only some of which we can identify at this time. Our notified body in Europe was BSI which is based in the U.K., which will no longer have standing in the EU as a notified body. We transferred our notified body to BSI in the Netherlands which requires 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 translation risk. Our warehousing and distribution hub for Europe is in the Netherlands and distribution of our products in the U.K. market may be slowed or disrupted and our U.K. sales may suffer as a result. Our efforts to mitigate the risk of this supply disruption to our U.K. customers may not prove sufficient. Until the final terms of Brexit are known, impacts to relevant currencies and business operations will be difficult to predict.

Risks Related to Regulatory Review and Approval of Our Products

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

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

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Of our products, Orbera is a class III product and has been approved through the FDA's PMA process and our OverStitch products are class II and have been cleared through the 510(k) process. In addition, although FDA has granted PMA approval for our class III products, holding those approvals in good standing requires ongoing compliance with FDA reporting requirements and conditions of approval including the completion of lengthy and expensive post market approval studies. Despite the time, effort and cost required to obtain approval, there can be no assurance that we will be able to meet all FDA requirements to maintain our PMA approvals or that circumstances outside of our control may cause the FDA to withdraw our PMA approvals.

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

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these

circumstances, we rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

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

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

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

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

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

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

In certain cases, actions to pursue claims under the FCA may be brought by private individuals on behalf of the government. These lawsuits are known as "qui tam" actions and the individuals bringing such suits, sometimes known as "relators" or, more commonly, "whistleblowers" may share in any amounts paid by the entity to the government in fines or settlement. For example, in March 2017, we were informed by the Department of Justice that we were a subject in a federal False Claims Act investigation. The government's investigation concerned whether there had been a violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. related to our marketing of the Lap-Band System, including the web-based physician locator provided on our website Lap-Band.com. We cooperated fully with the investigation, and on August 21, 2017, we were notified by the Department of Justice that we were no longer a subject in such investigation.

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

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

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

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

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

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

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

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

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

Modifications to our products may require new regulatory approvals or clearances, including 510(k) or de novo clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA 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 from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. There is no guarantee that the FDA will grant PMA approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

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

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device were to recur. As required per the FDA Code of Federal Regulations (21 CFR) Part 803, we have established procedures and processes for documentation and evaluation of all complaints relative to reporting requirements. As with all device manufacturers, we have 30 days from "becoming aware" of an incident to submit to FDA a MDR for an event that reasonably suggests that a device has or may have caused or contributed to the incident, or five work days for an event designated by the FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health. As part of this assessment we conduct a complaint investigation of each reported Adverse Event. In the event that an investigation is inconclusive (i.e., the investigation cannot confirm whether or not our product was a cause of an Adverse Event), Apollo’s 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.

Our international operations must comply with local laws and regulations that present certain legal and operating risks, which could adversely impact our business, results of operations and financial condition.

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

Other laws and regulations that can significantly impact 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.

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

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

Moreover, 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 became effective on May 26, 2020. 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 procedure. MDR 2017 repeals and replaces the EU Medical

Devices Directive and intended to eliminate current differences in the regulation of medical devices among EEA Member States. 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.

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

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

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

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

Failure to comply with the U.S. FCPA and similar laws associated with any activities outside the U.S. could subject us to penalties and other adverse consequences.

We are subject to the U.S. FCPA, and other anti-bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates. We may face significant risks if we fail to comply with the FCPA and other similar foreign antibribery laws. Although we have implemented safeguards and training, including company policies requiring our employees, distributors, consultants and agents to comply with the FCPA and similar laws, our international operations nonetheless

present a risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could have a material and adverse effect on our reputation, business, operating results and financial condition.

Risks Related to Our Intellectual Property

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

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

Patents

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

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

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the U.S. or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to the Company, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

Trademarks

We rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. Our trademark applications may not be approved, however. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to

advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Trade Secrets and Know-How

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

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

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

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

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

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

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

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

Risks Related to Our Capital Requirements and Finances

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

In March 2019, we borrowed $35.0 million principal amount of debt under a term loan facility ("Solar Debt Facility") with Solar Capital, Ltd. ("Solar") under which we may borrow an additional $15.0 million upon our request subject to further credit approval. We cannot assure you that additional funding will be received. We used $22.4 million of the proceeds to repay the existing senior secured credit facility. Our outstanding debt is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates without Solar's consent. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent of the lender. In addition, we are required to prepare our financial statements and receive audits on our annual financial statements in a timely manner, meet certain financial ratio 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.

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

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

- expand the commercialization of our products;
- fund our operations and clinical studies;
- continue our research and development activities;
- support and expand ongoing manufacturing activities;
- defend 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.

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

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

- the cost of our research and development activities;
- the cost of filing, 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. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Risks Related to Ownership of Our Common Stock

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

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

- a slowdown in the medical device industry or the general economy;
- inability to obtain adequate supply of the components for any of our products, or inability to do so at acceptable prices;
- performance of third parties on whom we may rely, including for the manufacture of the components for our products, including their ability to comply with regulatory requirements;
- the results of our current and any future clinical trials of our devices;
- unanticipated or serious safety concerns related to the use of any of our products;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by us, our commercial partners or our competitors of new products or product enhancements, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- competition from existing technologies and products or new technologies and products that may emerge;
- the loss of key employees;

- changes in estimates or recommendations by securities analysts, if any, who may cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the low trading volume and the high proportion of shares 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 September 30, 2019, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders has the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

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

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

****Our amended and restated certificate of incorporation and amended and restated bylaws each designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.***

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. Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In addition, 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

The exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons. Moreover, if any court of competent jurisdiction were to find any exclusive-forum provision in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could harm our results of operations or financial condition.

****Our amended and restated bylaws designate the U.S. federal district courts as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations thereunder. We may be unable to enforce this provision.***

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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Our amended and restated certificate of incorporation does not contain a similar provision providing that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations thereunder because the provision is included in our amended and restated bylaws.

If any court of competent jurisdiction were to find this exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable, including due to its absence from our amended and restated certificate of incorporation, we may incur additional costs associated with resolving such matters in other jurisdictions. For example, if the Delaware Supreme Court does not ultimately overturn the Court of Chancery's recent determination that such a provision not enforceable, we may incur similar additional costs. Until a final resolution is reached on this matter, we will not attempt to enforce this provision of our amended and restated bylaws. As a result, we may incur additional costs associated with resolving disputes that would otherwise be restricted by that provision in other jurisdictions, which could harm our business.

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

Issuer Purchases of Equity Securities

The following table summarizes purchases of our shares of common stock made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Exchange Act during the period shown:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 - July 31, 2019	—	$ —	—	$ —
August 1 - August 31, 2019	1,000,000 [1]	$ — [1]	—	$ —
September 1 - September 30, 2019	—	$ —	—	$ —
Total	1,000,000	$ —	—	

[1] In August 2019, we issued the Warrant to exchange up to 1,000,000 shares of our common stock, at an exercise price of $0.001 per share, to an existing stockholder for 1,000,000 shares of common stock held by such stockholder. The common stock received in the exchange was subsequently retired. The Warrant may be exercised at any time until the Warrant is exercised in full. The holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would beneficially own more than 9.99% of the outstanding common stock in the aggregate immediately after exercise.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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 *	Third Amendment, dated October 25, 2019, to the Loan and Security Agreement, dated March 15, 2019, by and among Apollo Endosurgery, Inc., Solar Capital, Ltd., the guarantors party thereto, and the lenders.
31.1 *	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 *	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1# *	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2# *	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.Ins	Instance Document - the instance document does not appear in the Interactive data File because its XBRL tags are embedded within the Inline XBRL 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 October 30, 2019.

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)