SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Apollo Endosurgery, Inc.

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

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from to

Commission file number: 001-35706

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒
	Emerging growth company ☐

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed based on the adjusted close price of $7.89 as reported on the NASDAQ Stock Market on June 30, 2017 is $12,083,298. For purposes of this calculation, shares of common stock held by each officer and director and by each person or group who owns 5% or more of the outstanding common stock have been excluded from the calculation of aggregate market value as such persons or groups may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of October 20, 2017 , there were 17,290,347 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, 2017
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ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2017	December 31, 2016
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 34,553	$ 19,111
Accounts receivable, net of allowance for doubtful accounts of $435 and $479, respectively	12,327	10,509
Inventory, net	12,773	12,163
Prepaid expenses and other current assets	1,149	1,838
Total current assets	60,802	43,621
Restricted cash	946	930
Property and equipment, net of accumulated depreciation of $6,046 and $4,404, respectively	6,955	6,889
Goodwill	6,828	6,828
Intangible assets, net of accumulated amortization of $26,580 and $20,959, respectively	38,130	43,315
Other assets	341	541
Total assets	$ 114,002	$ 102,124
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 16,194	$ 13,650
Accrued expenses	7,792	6,630
Total current liabilities	23,986	20,280
Long-term debt	33,177	39,427
Total liabilities	57,163	59,707
Commitments and contingencies		
Stockholders' equity:		
Common stock; $0.001 par value; 100,000,000 shares authorized; 17,290,347 and 10,688,992 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	17	11
Additional paid-in capital	224,899	190,664
Accumulated other comprehensive income	1,629	1,471
Accumulated deficit	(169,706)	(149,729)
Total stockholders' equity	56,839	42,417
Total liabilities and stockholders' equity	$ 114,002	$ 102,124

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,	
	2017	2016	2017	2016
Revenues	$ 16,544	$ 15,786	$ 48,170	$ 49,319
Cost of sales	6,012	5,253	17,744	19,356
Gross margin	10,532	10,533	30,426	29,963
Operating expenses:				
Sales and marketing	7,978	6,832	24,832	23,541
General and administrative	2,858	3,842	10,293	8,808
Research and development	2,178	1,782	6,420	5,222
Amortization of intangible assets	1,803	1,799	5,444	5,399
Total operating expenses	14,817	14,255	46,989	42,970
Loss from operations	(4,285)	(3,722)	(16,563)	(13,007)
Other expenses:				
Interest expense, net	1,013	1,533	3,529	6,881
Other (income) expense	(451)	674	(283)	1,364
Net loss before income taxes	(4,847)	(5,929)	(19,809)	(21,252)
Income tax expense	55	4	168	203
Net loss	(4,902)	(5,933)	(19,977)	(21,455)
Current dividends on convertible preferred stock	—	(2,396)	—	(6,913)
Net loss attributable to common stockholders	$ (4,902)	$ (8,329)	$ (19,977)	$ (28,368)
Other comprehensive income (loss):				
Foreign currency translation	(227)	406	158	1,611
Comprehensive loss	$ (5,129)	$ (5,527)	$ (19,819)	$ (19,844)
Net loss per share, basic and diluted	$ (0.32)	$ (24.85)	$ (1.62)	$ (85.63)
Shares used in computing net loss per share, basic and diluted	15,481,872	335,172	12,310,426	331,288

See accompanying notes to the condensed consolidated financial statements.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
Nine Months Ended September 30, 2017
(In thousands, except for share data)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2016	10,688,992	$ 11	$ 190,664	$ 1,471	$ (149,729)	$ 42,417
Exercise of common stock options	58,902	—	119	—	—	119
Issuances of common stock, net of issuance costs of $2,400	6,542,453	6	33,578			33,584
Stock based compensation	—	—	538	—	—	538
Foreign currency translation	—	—	—	158	—	158
Net loss	—	—	—	—	(19,977)	(19,977)
Balances at September 30, 2017	17,290,347	$ 17	$ 224,899	$ 1,629	$ (169,706)	$ 56,839

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 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (19,977)	$ (21,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,260	6,747
Amortization of deferred financing costs	257	246
Non-cash interest expense	493	3,895
Change in fair value of warrant liability	—	(918)
Provision for doubtful accounts receivable	106	173
Change in inventory reserve	199	3,297
Stock based compensation	538	309
Foreign exchange on short-term intercompany loans	(592)	1,069
Changes in operating assets and liabilities:		
Accounts receivable	(1,414)	116
Inventory	(729)	(4,092)
Prepaid expenses and other assets	885	882
Accounts payable and accrued expenses	3,299	3,199
Net cash used in operating activities	(9,675)	(6,532)
Cash flows from investing activities:		
Purchases of property and equipment	(1,258)	(624)
Purchase of intangibles and other assets	(419)	(993)
Net cash used in investing activities	(1,677)	(1,617)
Cash flows from financing activities:		
Proceeds from exercise of stock options	119	45
Proceeds from issuance of common stock, net of issuance costs	33,584	—
Payment of debt	(7,000)	—
Payment of contingent consideration	—	(5,000)
Net cash provided by (used in) financing activities	26,703	(4,955)
Effect of exchange rate changes on cash	107	55
Net decrease in cash, cash equivalents and restricted cash	15,458	(13,049)
Cash, cash equivalents and restricted cash at beginning of year	20,041	22,586
Cash, cash equivalents and restricted cash at end of period	$ 35,499	$ 9,537
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,875	$ 3,694
Cash paid for income taxes	178	—
Supplemental disclosure of non-cash investing and financing activity:		
Accretion of dividends on preferred stock	$ —	$ 6,913

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 that can be used for the treatment of obesity. The Company develops and distributes minimally invasive surgical and non-surgical devices for bariatric and gastrointestinal procedures that are used by general surgeons, bariatric surgeons and gastroenterologists in a variety of settings to provide interventional therapy to patients who suffer from obesity and the many co-morbidities associated with obesity.

The Company's core products include the Orbera® intra-gastric balloon system, the OverStitch™ endoscopic suturing system and the Lap-Band® adjustable gastric banding system. All devices are regulated by the United States Food and Drug Administration (the "FDA") and equivalent regulatory bodies outside the United States. The Company's products are sold throughout the world with principal markets in the United States of America, Europe, Australia, Brazil and Canada. The Company also has a manufacturing facility located in Costa Rica.

(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 useful lives of intangible assets and long-lived assets, 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 our Annual Report on Form 10-K for the year ended December 31, 2016. Certain reclassifications of prior period amounts have been made to conform to the current presentation.

(c) Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 replaces most existing revenue recognition guidance in GAAP. In July 2015, the FASB approved a one-year deferral of this standard, with a revised effective date for annual and interim reporting in fiscal years beginning after December 15, 2017. In March 2016 and April 2016, the FASB issued ASU 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus Net*) and ASU 2016-10, *Identifying Performance Obligations and Licensing*, respectively. ASU 2014-09 permits the use of either the retrospective or modified retrospective (cumulative effect) transition method. While we are finalizing our assessment on the impact of the new standard, our revenue is primarily generated from the sale of finished product to customers. Those sales predominantly contain a single delivery element and revenue is recognized at a single point in time when ownership, risks and rewards transfer. These are largely unimpacted by the new standard. Therefore, we do not expect this new guidance to have a material impact on the Company's consolidated financial statements. The Company expects to adopt this new standard using the modified restrospective method and continues to review this guidance to complete its evaluation of the impact on its consolidated financial statements and disclosures. In addition, the Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact the Company’s current conclusions.

(In thousands, except for share data)

The Company has adopted the provisions of ASU 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"), which simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The adoption of ASU 2015-11 as of January 1, 2017 resulted in no material impact on the Company's consolidated financial statements.

The Company has adopted the provisions of ASU 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17") which requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The adoption of ASU 2015-17 as of January 1, 2017 resulted in no material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02") which requires a lessee to recognize assets and liabilities for leases with a maximum possible term of more than 12 months. A lessee would recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the leased asset (the underlying asset) for the lease term which will require companies to recognize most leases on the balance sheet, thereby increasing reported assets and liabilities. Extensive quantitative and qualitative disclosures, including significant judgments made by management, will be required. ASU 2016-02 requires adoption using a modified retrospective transition with application of the guidance at the beginning of the earliest comparative period presented. ASU 2016-02 will be effective for the Company on January 1, 2019. Early adoption is permitted. The Company is evaluating the effect that ASU 2016-02 will have on its consolidated financial statements.

The Company has adopted the provisions of ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), which contains guidance on accounting for certain aspects of share-based payments to employees. ASU 2016-09 requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. Furthermore, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. ASU 2016-09 also allows companies to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting, clarifying that all cash payments made on an employee's behalf for withheld shares should be presented as a financing activity in the consolidated statements of cash flows and provides an accounting policy election to account for forfeitures as they occur. The adoption of ASU 2016-09 as of January 1, 2017 resulted in no material impact on the Company's consolidated financial statements.

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 2 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. Early adoption is permitted. The effect of ASU 2017-04 on the Company's consolidated financial statements will be dependent on any future impairments.

(3) Acquisitions

On December 29, 2016, the Company completed a business combination with Lpath, Inc. ("Lpath"), a publicly held company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated September 8, 2016 (the "Merger").

The following summary pro forma condensed consolidated financial information reflects the Merger with Lpath as if it had occurred on January 1, 2016 for purposes of the statements of operations. This summary pro forma information is not necessarily representative of what the Company's results of operations would have been had the Merger in fact occurred on January 1, 2016, and is not intended to project the Company's results of operations for any future period.

Pro forma condensed consolidated financial information for the nine months ended September 30, 2016 (unaudited):

Pro forma combined revenues	$	49,362
Pro forma combined net loss	$	(25,827)
Pro forma combined loss per share	$	(2.43)

Pro forma combined net loss includes an adjustment to reduce historical interest expense by $3,937 for the nine months ended September 30, 2016 , due to the conversion of the convertible notes and the principal repayments of long-term debt of $11,000.

(In thousands, except for share data)

(4) Concentrations

Consolidated financial instruments that potentially subject the Company to a concentration of credit risk principally consist of cash and cash equivalents and accounts receivable. At September 30, 2017, the Company's cash and cash equivalents and restricted cash are held in deposit accounts at three different banks totaling $35,499. 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.

(5) Inventory

Inventory consists of the following as of:

	September 30, 2017	December 31, 2016
	(unaudited)	
Raw materials	$ 4,006	$ 5,031
Work in progress	609	346
Finished goods	10,889	10,520
Less inventory reserve	(2,731)	(3,734)
Total inventory, net	$ 12,773	$ 12,163

The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory and records a reserve for items identified. During the three and nine months ended September 30, 2017, the Company recorded an impairment charge of $30 and $199, respectively. During the nine months ended September 30, 2017 , the Company disposed of $1,202 of expired product which was fully reserved.

(6) Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2017	December 31, 2016
	(unaudited)	
Accrued employee compensation and expenses	$ 3,862	$ 3,040
Accrued professional service fees	657	1,521
Accrued returns and rebates	572	366
Accrued insurance, property and sales taxes	475	256
Accrued construction in progress	360	—
Other	1,866	1,447
Total accrued expenses	$ 7,792	$ 6,630

(7) Long-Term Debt

Long-term debt consists of the following as of:

	September 30, 2017	December 31, 2016
	(unaudited)	
Senior secured credit facility	$ 32,000	$ 39,000
Payment-in-kind interest	2,183	2,046
Long-term debt	34,183	41,046
Discount on long-term debt	(596)	(952)
Deferred financing costs	(410)	(667)
Long-term debt	$ 33,177	$ 39,427

On March 7, 2017, the Company entered into a Fifth Amendment (the "Fifth Amendment") to the senior secured credit facility (the "Credit Agreement") with its lender, Athyrium Opportunities II Acquisition LP ("Athyrium").

The Fifth Amendment (i) reduced the minimum cash balance requirement to $0 from $8,000, (ii) reduced the minimum quarterly revenue requirement to $13,000 from $18,000, (iii) increased the maximum debt-to-revenue ratio to 0.65 from 0.60 and (iv) required Apollo to make a principal repayment of $7,000. The minimum quarterly revenue requirement will increase by $1,000 quarterly over the remaining term of the facility, and the maximum debt-to-revenue ratio will decline gradually each quarter, from 0.65 to 0.25, over the remaining term of the facility. Unamortized deferred financing costs of $113 and unamortized discount of $162 were written off in March 2017 in connection with the principal repayment of $7,000.

As of September 30, 2017, the Company was in compliance with the financial covenants.

(8) Stock Based Compensation

On June 9, 2017, the 2017 Equity Incentive Plan (the "2017 Plan") was approved by the Company's shareholders and replaced the Company's 2016 Equity Incentive Plan (the "2016 Plan"), which was the successor to the 2006 Stock Option Plan ("the 2006 Plan"), and the Lpath Amended and Restated 2005 Equity Incentive Plan (the "Lpath Plan") (collectively with the 2016 Plan and the 2006 Plan, the "Prior Plans"). Grants will no longer be made under the Prior Plans, but the awards that remain outstanding will continue to be governed by the terms of the applicable Prior Plan and the applicable award agreement.

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

	Options (Number)	Weighted Average Exercise Price (Price)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000's)
Options outstanding, December 31, 2016	1,016,647	$2.94	7.0 years	$9,343
Options granted	663,006	$7.43		
Options exercised	(58,902)	$2.07		
Options forfeited	(43,067)	$5.74		
Options outstanding, September 30, 2017	1,577,684	$4.85	6.2 years	$1,649
Options vested and expected to vest	1,577,684	$4.85	6.2 years	$1,649
Options exercisable	629,738	$3.13	6.2 years	$1,107

Shares subject to awards granted under the 2017 Plan which expire, are repurchased, or are canceled or forfeited will again become available for issuance under the 2017 Plan. The shares available will not be reduced by awards settled in cash or by shares withheld to satisfy tax withholding obligations. Only the net number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise will be deducted from the shares available under the 2017 Plan.

(In thousands, except for share data)

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, 2017	Nine Months Ended September 30, 2016
Risk free interest rate	1.9%	1.3%
Expected dividend yield	—%	—%
Estimated volatility	65.1%	56.7%
Expected life	5.5 years	5.5 years

Additional information regarding options is as follows:

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Weighted-average grant date fair value of options granted during the period	$ 4.76	$ 0.99
Aggregate intrinsic value of options exercised during the period	$ 249	$ 15

The total compensation cost recognized for stock-based awards was $211 and $538 for the three and nine months ended September 30, 2017, respectively, and $102 and $309 for the three and nine months ended September 30, 2016, respectively.

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, 2017 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, 2017 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 Company has 400,351 options outstanding to purchase common shares that vest upon the Company's achievement of certain global revenue and EBITDA targets for calendar years 2016 and 2017. Achievement of the performance targets deemed probable are included in total stock compensation expense.

Unrecognized compensation expense related to unvested options was approximately $2,071 at September 30, 2017, with a remaining amortization period of less than four years.

In addition, the Company granted 39,348 time-based restricted stock units with a weighted-average grant date fair value of $6.50 during the nine months ended September 30, 2017. Intrinsic value of the restricted stock units was $310 and unrecognized compensation expense related to unvested restricted stock units was approximately $220 at September 30, 2017, with a remaining amortization period of less than four years.

(9) Income Taxes

The provision for income taxes for the three and nine months ended September 30, 2017 and 2016 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.

As of September 30, 2017, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions.

(10) Net Loss Per Share

The basic and diluted net loss per common share presented in the condensed consolidated statement 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. Net loss attributable to common stock is computed by deducting current dividends on convertible preferred stock from net loss. Potentially dilutive shares, which include convertible preferred stock, warrants for the purchase of common and preferred stock, options outstanding under the Company's equity incentive plans, and restricted stock units 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.

(In thousands, except for share data)

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares on a weighted-average basis):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Preferred stock	—	7,220,987	—	7,220,987
Warrants for common and preferred stock	251,934	495,144	254,902	495,144
Common stock options	1,547,354	993,525	1,539,562	979,100
Restricted stock units	39,348	—	27,826	—
	1,838,636	8,709,656	1,822,290	8,695,231

(11) Liquidity and Capital Resources

The Company has experienced operating losses since inception and occasional debt covenant violations and has an accumulated deficit of $169,706 as of September 30, 2017. 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 will depend upon its level of future operating cash flow and its ability to access additional funding through either equity offerings, issuances of debt instruments or both.

On July 25, 2017, the Company completed a public offering selling 6,542,453 shares at a price of $5.50 per share, including 853,363 shares sold to the underwriters upon the full exercise of their option to purchase additional shares, before the underwriting discount. The public offering generated net proceeds of approximately $33,584, after deducting the underwriting discount and related offering expenses.

In February 2015, the Company entered into the Credit Agreement which requires the Company to meet minimum revenue requirements and other covenants each quarter and provides a cure provision in the event this requirement is not met. If the Company is not able to meet its ongoing quarterly covenant requirements or utilize the remaining cure provision rights, the repayment of the Credit Facility could be accelerated at the lender's discretion. The Company believes its existing cash and cash equivalents and remaining cure provision rights will be sufficient to meet liquidity and capital requirements for at least the next twelve months.

(12) Fair Value Measurements

The carrying amounts of the Company's financial instruments, which primarily include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of the Company's long-term debt is estimated by management to approximate $31,000 at September 30, 2017. Management's estimates are based on comparisons of the characteristics of the Company's obligations, comparable ranges of interest rates on recently issued debt, and maturity. Such valuation inputs are considered a Level 3 measurement in the fair value valuation hierarchy.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

(In thousands, except for share data)

(13) 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, for the periods shown were as follows:

	Three Months Ended September 30, 2017 (unaudited)				Three Months Ended September 30, 2016 (unaudited)			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
Endo-bariatric	$ 3,281	$ 6,029	$ 9,310	56.3%	$ 3,266	$ 4,455	$ 7,721	48.9%
Surgical	4,422	2,605	7,027	42.5%	5,295	2,656	7,951	50.4%
Other	200	7	207	1.3%	111	3	114	0.7%
Total revenues	$ 7,903	$ 8,641	$ 16,544	100.0%	$ 8,672	$ 7,114	$ 15,786	100.0%
% Total revenues	47.8%	52.2%			54.9%	45.1%		

	Nine Months Ended September 30, 2017 (unaudited)				Nine Months Ended September 30, 2016 (unaudited)			
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
Endo-bariatric	$ 10,863	$ 15,300	$ 26,163	54.3%	$ 11,801	$ 12,547	$ 24,348	49.4%
Surgical	13,271	8,164	21,435	44.5%	16,245	8,374	24,619	49.9%
Other	551	21	572	1.2%	334	18	352	0.7%
Total revenues	$ 24,685	$ 23,485	$ 48,170	100.0%	$ 28,380	$ 20,939	$ 49,319	100.0%
% Total revenues	51.2%	48.8%			57.5%	42.5%		

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

	September 30, 2017 (unaudited)	December 31, 2016
United States	$ 3,034	$ 2,426
Costa Rica	3,633	4,195
Other	288	268
Total property and equipment, net	$ 6,955	$ 6,889

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, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks, uncertainties and other important factors. In particular, statements, whether express or implied, concerning future operating results or the ability to generate sales, income or cash flow are forward-looking statements. They involve risks, uncertainties and

assumptions that are beyond our ability to control or predict, including those discussed in Part II, Item 1A, of this 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, 2016 filed on March 24, 2017 with the Securities and Exchange Commission ("SEC"). "Apollo," Lap-Band®, 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 that can be used for the interventional treatment of obesity. We develop and distribute minimally invasive surgical products for bariatric and gastrointestinal procedures that are used by general surgeons, bariatric surgeons and gastroenterologists in a variety of settings to provide interventional therapy to patients who suffer from obesity and the many co-morbidities associated with obesity.

Our strategic focus and the majority of our future revenue growth is expected to come from our Endo-bariatric product portfolio, which consists of the Orbera and OverStitch systems. Historically, the majority of our revenues have come from Surgical product sales.

Financial Operations Overview

Revenues

Our principal source of revenues has come from and is expected to continue to come from sales of our Endo-bariatric products and our Surgical products. In our direct markets, product sales are made to end customers by our employed sales representatives or independent sales agents. In other markets, we sell our products to distributors who resell our products to end customers. Revenues between periods will be impacted by several factors, including physician procedure and therapy preferences, patient procedure and therapy preferences, other market trends, the stability of the average sales price we realize on products, the frequency of Endo-bariatric training courses and the amount of U.S. Orbera starter kit sales associated therewith, and changes in foreign exchange rates used to translate foreign currency denominated sales into U.S. dollars.

Cost of Sales

Historically, we have relied on third-party suppliers to manufacture our products. However, since June 2016 the products which comprise the majority of our revenue are manufactured in our Costa Rica facility. Our historical cost of sales primarily consist of costs of products purchased from our third-party suppliers, excess and obsolete inventory charges, royalties, shipping, inspection and related cost incurred in making our products available for sale or use. Prior to commencement of commercial manufacturing operations at our Costa Rica facility in June 2016, our historical cost of sales also included certain start-up costs associated with establishing our Costa Rica facility. As our Costa Rica facility begins manufacturing, costs include raw materials, labor, manufacturing overhead and other direct costs. Raw materials used to produce our products are generally not subject to substantial commodity price volatility, and most of our product manufacturing costs are incurred in U.S. dollars, but in many cases we only have one qualified supplier. Manufacturing overhead is a significant portion of our cost of sales. Cost of sales could vary as a percentage of revenue between periods as a result of manufacturing rates and the degree to which manufacturing overhead is allocated to production during the period. We expect overhead costs and the cost of certain raw material components we incur will be higher than the overhead and material costs allocated and charged to us by a third party under a previous manufacturing service agreement. Additionally, gross margin will be impacted by the shift in our revenue mix from low-growth but higher gross margin Surgical products to lower gross margin but high-growth Endo-bariatric products. Comparability of cost of sales between periods could also be affected by inventory valuation allowances related to obsolete or excess inventory.

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, industry events and other promotional activities.

General and Administrative Expense

General and administrative expense primarily consists of salaries, benefits and other related costs, including stock-based compensation, for personnel employed in corporate management, finance, legal, compliance, administrative, information technology and human resource departments. General and administrative expense also includes facilities cost, insurance, bad debt expense and costs related to the development and protection of our intellectual property portfolio. Our general and administrative expenses have increased in 2017 compared to 2016 as a result of activities required of us as a public company.

Research and Development Expense

Research and development expense include 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 related personnel and consultants' compensation and stock-based compensation expense. Research and development expense may fluctuate between periods dependent on the activity in the period 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. Intangible assets are amortized over the asset's estimated useful life.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which management has prepared in accordance with existing U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. Management evaluates estimates and judgments on an ongoing basis. Estimates relate to aspects of our revenue recognition, useful lives with respect to intangible and long-lived assets, inventory valuation, deferred tax asset valuation and allowances for doubtful accounts. We base our estimates on historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

The critical accounting policies addressed below reflect our most significant judgments and estimates used in the preparation of our condensed consolidated financial statements.

Revenue Recognition

Our principal source of revenues is from the sale of our products to hospitals, physician practices and distributors. We utilize a network of employee sales representatives in the U.S. and a combination of employee sales representatives, independent agents and distributors in markets outside the United States ("OUS"). Revenue is recognized when pervasive evidence of an arrangement exists, fees are fixed or determinable, collection of the fees is reasonably assured, and delivery or customer acceptance of the product has occurred and no other significant obligations remain. Generally, these conditions are met upon product shipment. Customers generally have the right to return or exchange products purchased from us for up to ninety days from the date of product shipment. Distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at the time of shipment. Our distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. At the end of each period, we determine the extent to which our revenues need to be reduced to account for expected rebates, returns and exchanges and a reserve is recorded against revenue recognized. Our policy is to classify shipping and handling cost billed to customers as revenue and the related expenses as cost of sales.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are at the invoiced amount less an allowance for doubtful accounts. On a regular basis, we evaluate accounts receivable and estimate an allowance for doubtful accounts, as needed, based on various factors such as customers' current credit conditions, length of time past due and the general economy as a whole. We write off receivables against the allowance when they are determined to be uncollectible.

Inventory

Inventory is stated at the lower of cost or market, net of any allowance. Charges for excess and obsolete inventory are based on specific identification of excess and obsolete inventory items and an analysis of inventory items approaching expiration date. We evaluate the carrying value of inventory in relation to the estimated forecast of product demand. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. When quantities on hand exceed estimated sales forecasts, we record estimated excess and obsolescence charges to cost of sales. Our inventories are stated using the weighted average cost approach, which approximates actual costs.

Intangible and Long-lived Assets

Definite-lived intangible assets consist of customer relationships, product technology, trade names, patents and trademarks which are amortized over their estimated useful lives.

Long-lived assets, including definite-lived intangible assets, are monitored and reviewed for impairment whenever events or circumstances indicate that the carrying value of any such asset may not be recoverable. The determination of recoverability is based on an estimate of undiscounted cash flows expected to result from the use of an asset and its eventual disposal. The estimate of undiscounted cash flows is based upon, among other things, certain assumptions about expected future operating performance. Our estimates of undiscounted cash flows may differ from actual cash flows. If the sum of the undiscounted cash flows is less than the carrying value of the asset, an impairment charge is recognized, measured as the amount by which the carrying value exceeds the fair value of the asset.

Income Taxes

We account for deferred income taxes using the asset and liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more-likely than-not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

In the ordinary course of business, there are many transactions for which the ultimate tax outcome is uncertain. We regularly assess uncertain tax positions in each of the tax jurisdictions in which we have operations and account for the related condensed consolidated financial statement implications. The amount of unrecognized tax benefits is adjusted when information becomes available or when an event occurs indicating a change is appropriate. We include interest and penalties related to our uncertain tax positions as part of income tax expense.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we provide certain non-GAAP financial measures including adjusted total revenues, excluding U.S. Orbera starter kit sales. Adjusted total revenues, excluding U.S. Orbera starter kit sales is a supplemental measure of our performance that is not required by, and is not determined in accordance with, GAAP.

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

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

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2017 and 2016

	Three Months Ended September 30, 2017		Three Months Ended September 30, 2016	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	$ 16,544	100.0 %	$ 15,786	100.0 %
Cost of sales	6,012	36.3 %	5,253	33.3 %
Gross margin	10,532	63.7 %	10,533	66.7 %
Operating expenses:				
Sales and marketing	7,978	48.2 %	6,832	43.3 %
General and administrative	2,858	17.3 %	3,842	24.3 %
Research and development	2,178	13.2 %	1,782	11.3 %
Amortization of intangible assets	1,803	10.9 %	1,799	11.4 %
Total operating expenses	14,817	89.6 %	14,255	90.3 %
Loss from operations	(4,285)	(25.9)%	(3,722)	(23.6)%
Interest expense, net	1,013	6.1 %	1,533	9.7 %
Other expense	(451)	(2.7)%	674	4.3 %
Net loss before income taxes	(4,847)	(29.3)%	(5,929)	(37.6)%
Income tax expense	55	0.3 %	4	— %
Net loss	$ (4,902)	(29.6)%	$ (5,933)	(37.6)%

	Nine Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	$ 48,170	100.0 %	$ 49,319	100.0 %
Cost of sales	17,744	36.8 %	19,356	39.2 %
Gross margin	30,426	63.2 %	29,963	60.8 %
Operating expenses:				
Sales and marketing	24,832	51.6 %	23,541	47.7 %
General and administrative	10,293	21.4 %	8,808	17.9 %
Research and development	6,420	13.3 %	5,222	10.6 %
Amortization of intangible assets	5,444	11.3 %	5,399	10.9 %
Total operating expenses	46,989	97.5 %	42,970	87.1 %
Loss from operations	(16,563)	(34.4)%	(13,007)	(26.4)%
Interest expense, net	3,529	7.3 %	6,881	14.0 %
Other expense	(283)	(0.6)%	1,364	2.8 %
Net loss before income taxes	(19,809)	(41.1)%	(21,252)	(43.1)%
Income tax expense	168	0.3 %	203	0.4 %
Net loss	$ (19,977)	(41.5)%	$ (21,455)	(43.5)%

Revenues

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

	Three Months Ended September 30, 2017			Three Months Ended September 30, 2016			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
Endo-bariatric, excluding U.S. Orbera starter kit sales	$ 3,155	$ 6,029	$ 9,184	$ 2,767	$ 4,455	$ 7,222	14.0 %	35.3 %	27.2 %
U.S. Orbera starter kit sales	126	—	126	499	—	499	(74.7)%	— %	(74.7)%
Total Endo-bariatric	3,281	6,029	9,310	3,266	4,455	7,721	0.5 %	35.3 %	20.6 %
Surgical	4,422	2,605	7,027	5,295	2,656	7,951	(16.5)%	(1.9)%	(11.6)%
Other	200	7	207	111	3	114	80.2 %	133.3 %	81.6 %
Total revenues	$ 7,903	$ 8,641	$ 16,544	$ 8,672	$ 7,114	$ 15,786	(8.9)%	21.5 %	4.8 %
% Total revenues	47.8%	52.2%		54.9%	45.1%				

	Nine Months Ended September 30, 2017			Nine Months Ended September 30, 2016			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
Endo-bariatric, excluding U.S. Orbera starter kit sales	$ 10,137	$ 15,300	$ 25,437	$ 8,101	$ 12,547	$ 20,648	25.1 %	21.9 %	23.2 %
U.S. Orbera starter kit sales	726	—	726	3,700	—	3,700	(80.4)%	— %	(80.4)%
Total Endo-bariatric	10,863	15,300	26,163	11,801	12,547	24,348	(7.9)%	21.9 %	7.5 %
Surgical	13,271	8,164	21,435	16,245	8,374	24,619	(18.3)%	(2.5)%	(12.9)%
Other	551	21	572	334	18	352	65.0 %	16.7 %	62.5 %
Total revenues	$ 24,685	$ 23,485	$ 48,170	$ 28,380	$ 20,939	$ 49,319	(13.0)%	12.2 %	(2.3)%
% Total revenues	51.2%	48.8%		57.5%	42.5%				

Reconciliation of GAAP to Non-GAAP Financial Information:

	Three Months Ended September 30,		% Increase / (Decrease)
	2017	2016	
Total revenues	$ 16,544	$ 15,786	4.8 %
Less: U.S. Orbera starter kit sales	(126)	(499)	(74.7)%
Adjusted total revenues, excluding U.S. Orbera starter kit sales	$ 16,418	$ 15,287	7.4 %

	Nine Months Ended September 30,		% Increase / (Decrease)
	2017	2016	
Total revenues	$ 48,170	$ 49,319	(2.3)%
Less: U.S. Orbera starter kit sales	(726)	(3,700)	(80.4)%
Adjusted total revenues, less U.S. Orbera starter kit sales	$ 47,444	$ 45,619	4.0 %

Total sales for the three months ended September 30, 2017 were $16.5 million compared to $15.8 million for the three months ended September 30, 2016 representing growth of 4.8%.

In the U.S., Endo-bariatric product sales, excluding U.S. Orbera starter kit sales were $3.2 million for the three months ended September 30, 2017 versus $2.8 million for the three months ended September 30, 2016 , an increase of 14.0%, and $10.1 million for the nine months ended September 30, 2017 versus $8.1 million for the nine months ended September 30, 2016 , an increase of 25.1%. As previously announced by the Company in August 2017, the FDA issued a letter to Health Care Professionals relating to potential risks with liquid-filled intragastric balloons. U.S. Endo-bariatric product sales increased at a slower rate in the third quarter compared to the first half of 2017, due to lower demand for Orbera in the aftermath of the FDA's letter. Overstitch sales growth remained consistent with its year to date trend.

In markets outside the United States (OUS), Endo-bariatric product sales were $6.0 million for the three months ended September 30, 2017 versus $4.5 million for the three months ended September 30, 2016 , an increase of 35.3%, and $15.3 million for the nine months ended September 30, 2017 versus $12.5 million for the nine months ended September 30, 2016 , an increase of 21.9% primarily due to higher OverStitch sales in our direct markets. Direct market sales were 72.9% and 70.4% of total OUS sales for the three and nine months ended September 30, 2017, respectively, compared to 53.2% and 66.9%, for the same periods in 2016, respectively.

Surgical product sales decreased $0.9 million, or 11.6%, and $3.2 million, or 12.9%, for the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016. In the U.S., Surgical product sales decreased $0.9 million or 16.5%, and $3.0 million or 18.3%, for the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016 due to reductions in gastric banding procedures being performed in the U.S. In OUS markets, Surgical product sales decreased by $0.1 million, or 1.9%, and $0.2 million, or 2.5%, for the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016.

Cost of Sales

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

	Three Months Ended September 30, 2017		Three Months Ended September 30, 2016	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 3,689	22.3%	$ 3,814	24.2%
Start-up costs	—	—%	786	5.0%
Overhead	1,627	9.8%	86	0.5%
Change in inventory reserve	30	0.2%	82	0.5%
Other indirect costs	666	4.0%	485	3.1%
Total cost of sales	$ 6,012	36.3%	$ 5,253	33.3%

	Nine Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	$ 11,642	24.2%	$ 10,312	20.9%
Start-up costs	—	—%	3,384	6.9%
Overhead	4,104	8.5%	852	1.7%
Change in inventory reserve	199	0.4%	3,297	6.7%
Other indirect costs	1,799	3.7%	1,511	3.1%
Total cost of sales	$ 17,744	36.8%	$ 19,356	39.2%

Gross margin as a percentage of revenues was 63.7% and 63.2% for the three and nine months ended September 30, 2017, respectively, compared to 66.7% and 60.8% for the same periods in 2016, respectively. Gross margin was impacted by the change in inventory reserve which decreased 0.3% and 6.3% as a percentage of total revenue for the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016. In June 2016, we recorded an inventory impairment charge related to expiring finished good inventory and excess raw materials transferred from Allergan that we were required to purchase in accordance with the transition services agreement. The remaining change in gross margin is due to the ongoing shift in our product sales mix from higher gross margin Surgical products to Endo-bariatric products that realize lower relative gross margins.

Operating Expenses

Sales and Marketing Expense. Sales and marketing expense increased $1.1 million and $1.3 million during the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016 due to higher incentive compensation, Orbera consumer marketing campaign costs and OverStitch physician training program costs.

General and Administrative Expense. General and administrative expense decreased $1.0 million for the three months ended September 30, 2017 due to transaction costs incurred during the third quarter of 2016 associated with the Lpath merger. General and administrative expense increased $1.5 million during the nine months ended September 30, 2017 due to costs incurred to meet our public company filing and corporate governance obligations.

Research and Development Expense. Research and development expense increased $0.4 million and $1.2 million during the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016 primarily due to costs associated with new product development efforts.

Other Expenses

Interest Expense. Interest expense decreased $0.5 million and $0.9 million during the three and nine months ended September 30, 2017, respectively, when compared to the same periods in 2016 primarily due to reduced cash interest on our senior secured credit facility after principal reductions. The additional decrease for the the nine months ended September 30, 2017 was due to the elimination of non-cash interest primarily associated with the convertible notes that converted to equity in December 2016.

Other Expense. Other expense primarily consists of realized and unrealized foreign exchange gains and losses. The decrease in other expense of $1.1 million and $1.6 million for the three and nine months ended September 30, 2017, respectively, compared to the same periods in 2016 was primarily caused by the movement in exchange rates on short-term intercompany loans denominated in U.S. dollars payable by Apollo's foreign subsidiaries. Realized foreign exchange losses were less than $0.1 million and $0.2 million for the three and nine months ended September 30, 2017, respectively, and $0.5 million and $0.3 million for the three and nine months ended September 30, 2016, respectively.

Liquidity and Capital Resources

We have experienced operating losses since inception and occasional debt covenant violations and have an accumulated deficit of $169.7 million as of September 30, 2017. 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 will depend upon our level of future operating cash flow and our ability to access additional funding through either equity offerings, issuances of debt instruments or both.

On July 25, 2017, we completed a public offering selling 6,542,453 shares at a price of $5.50 per share, including 853,363 shares sold to the underwriters upon the full exercise of their option to purchase additional shares. The public offering generated net proceeds of approximately $33.6 million, after deducting the underwriting discount and related offering expenses.

Senior Secured Credit Facility

In February 2015, we entered into the Credit Agreement to borrow $50.0 million which is due in February 2020. The facility bears interest at 10.5% annually including 3.5% payment-in-kind during the first year. An additional 2% of the outstanding amount will be due upon prepayment or repayment of the loan in full. We used the proceeds of this facility to refinance existing indebtedness incurred as part of our acquisition of the obesity intervention division of Allergan, Inc. in December 2013. This facility includes covenants and terms that place certain restrictions on our ability to incur additional indebtedness, incur additional liens, make investments, effect mergers, declare or pay dividends, sell assets, engage in transactions with affiliates or make capital expenditures. The facility also includes financial covenants including minimum consolidated quarterly revenue, and a consolidated debt to revenue ratio. We have not been in compliance with financial covenants in the past and received waivers or amendments from the lender in respect of these covenants. If we are not able to maintain compliance with our ongoing financial covenants or are otherwise unable to negotiate a waiver or amendment to the covenant requirements, the repayment of the facility could be accelerated at the lender's discretion.

In March 2017, we amended our senior secured credit facility pursuant to the Fifth Amendment to the Credit Agreement, the net effect of which is to improve our net liquidity by $1.0 million, reduce future interest expense and improve our financial covenants. Specifically, the Amendment (i) reduced the minimum cash balance requirement to $0.0 from $8.0 million, (ii) reduced the minimum quarterly revenue requirement to $13.0 million from $18.0 million, (iii) increased the maximum debt-to-revenue ratio to 0.65 from 0.60 and (iv) required us to make a principal repayment of $7.0 million. The minimum quarterly revenue requirement will increase by $1.0 million quarterly over the remaining term of the facility, and the maximum debt-to-revenue ratio will decline gradually each quarter, from 0.65 to 0.25, over the remaining term of the facility.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2017 and 2016, respectively:

	2017	2016
Net cash used in operating activities	$ (9,675)	$ (6,532)
Net cash used in investing activities	(1,677)	(1,617)
Net cash provided by (used in) financing activities	26,703	(4,955)
Effect of exchange rate changes on cash	107	55
Net change in cash, cash equivalents and restricted cash	$ 15,458	$ (13,049)

Operating Activities

Cash used in operating activities of $9.7 million for the nine months ended September 30, 2017 was primarily the result of a net loss of $20.0 million net of non-cash charges of $8.3 million primarily related to depreciation, amortization, non-cash interest expense and stock based compensation. Additionally, cash provided by operating assets and liabilities of $2.0 million related to working capital changes primarily due to an increase in accounts payable associated with higher inventory purchases offset by an increase in accounts receivable as a result of OUS revenue growth.

Cash used in operating activities of $6.5 million for the nine months ended September 30, 2016 was primarily the result of a net loss of $21.5 million net of non-cash charges of $14.8 million primarily related to depreciation, amortization, change in inventory reserve and non-cash interest expense.

Investing Activities

Cash used for investing activities of $1.7 million for both the nine months ended September 30, 2017 and 2016, primarily related to ongoing investments in our intellectual property portfolio and purchases of equipment for our manufacturing facility as we expand our manufacturing capability.

Financing Activities

Cash provided by financing activities of $26.7 million for the nine months ended September 30, 2017 related to the public offering which generated net proceeds of approximately $33.6 million offset by the repayment of $7.0 million in principal on the senior secured credit facility. Cash used for financing activities of $5.0 million for the nine months ended September 30, 2016 related to the contingent consideration payment to Allergan resulting from the FDA approval of Orbera.

Future Funding Requirements

As of September 30, 2017, we had cash, cash equivalents and restricted cash balances totaling $35.5 million. On July 25, 2017, the Company completed a public offering selling 6,542,453 million shares at a price of $5.50 per share, including 853,363 shares sold to the underwriters for the exercise of their option to purchase additional shares, before underwriting discounts and expense. The public offering generated net proceeds to the Company of approximately $33.6 million, after deducting underwriting discounts and estimated expenses. We believe our existing cash and cash equivalents, and product revenues, including our recent funding in July, 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 the 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 reimbursement initiatives, the ability to maintain covenant compliance of our current lending facility, and the costs of establishing additional sales, marketing, distribution and manufacturing capabilities. We may be required to seek additional equity or debt financing. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, operating results and financial condition could be adversely affected.

Off-balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 2(c) to the Condensed Consolidated Financial Statements in Part I, Item 1. of this Quarterly Report for a discussion of recently enacted accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This item has been omitted as we qualify as a smaller reporting company as defined by Rule 12b-2 of the Exchange Act.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the last quarter covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on Effectiveness of Controls

Our management, including our CEO and CFO, does not expect that our disclosure controls and internal controls will prevent all errors 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. Except as discussed below, our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our operations, financial conditions, or cash flows.

Federal False Claims Act Investigation

As previously disclosed in our Quarterly Report on Form 10-Q, for the three month period ended June 30, 2017, in March 2017, we were informed by the Department of Justice that we were a subject in a federal False Claims Act investigation concerning whether there had been a violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. related to the marketing of the Lap-Band System, including the web-based physician locator provided on our website Lap-Band.com, which we believe relates to the period before and after our acquisition in December 2013 of the obesity intervention division of Allergan, Inc. We have, and continue to cooperate 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.

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, 2016.

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, 2016 and 2015, we had net losses of $41.2 million and $27.4 million, respectively, and for the nine months ended September 30, 2017 we had a net loss of $20.0 million. As of September 30, 2017, we had an accumulated deficit of $169.7 million. To date, we have financed our operations primarily through private placements of our equity securities, certain debt-related financing arrangements 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 Endo-Bariatric market and successfully commercialize our Endo-Bariatric products.

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

- properly identify and anticipate physician and patient needs;
- effectively train physicians on how to use our products and achieve good patient outcomes;

- effectively communicate with patients and educate them on the benefits of Endo-Bariatric procedures;
- influence 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;
- be FDA-compliant with marketing of new devices or modified products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- successfully train the sales and marketing team to effectively support our market development efforts.

If we are unsuccessful in developing and commercializing the Endo-Bariatric market, our ability to increase our revenue will be impaired.

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

Adverse economic conditions in the U.S. and international markets may negatively affect our revenues and operating results. Our Endo-Bariatric products, such as the Orbera managed weight loss system, 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. The gastric banding procedure that uses our LapBand system is generally covered by most insurance programs that cover bariatric procedures, however, a gastric banding procedure is an elective procedure and may also require significant co-pay and other out of pocket expenses by the patient. Sales of our products may be negatively affected by adverse economic conditions impacting consumer spending, including among others, increased taxation, higher unemployment, lower consumer confidence in the economy, higher consumer debt levels, lower availability of consumer credit, higher interest rates and hardships relating to declines in the housing and stock markets which have historically caused consumers to reassess their spending choices and reduce their likelihood to pursue elective surgical procedures. Any reduced consumer demand due to adverse economic or market conditions could have a material adverse effect on our business, cause sales and profitability to suffer, reduce operating cash flow and result in a decline in the price of our common stock. Adverse economic and market conditions could also have a negative impact on our business by negatively affecting the parties with whom we do business, including among others, our business partners, creditors, third-party contractors and suppliers, causing them to fail to meet their obligations to us.

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

Our ability to sell our products depends on the willingness of our physician customers to adopt our products and to recommend corresponding procedures to their patients. Physicians may not adopt our product 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 or experimental;
- 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;
- 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 educate patients 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, unsafe, ineffective 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 and the availability of coverage and reimbursement for procedures that use future products.

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.

Our long-term growth and our cash flows depend on the ability to stabilize revenue from the sale of our surgical products.

Our surgical products consist of the Lap-Band System and related laparoscopic accessories. In the past two years, the majority of our revenue has come from our surgical products. Revenue from the surgical product portfolio has been decreasing over several years due to a shift in procedure mix to bariatric stapling procedures such as sleeve gastrectomy or gastric bypass procedures. It is important to our long-term growth and our cash flow to stabilize revenue from our surgical product business so that the decline of our surgical products business does not offset growth from other parts of our business.

There can be no assurance that we will be able to stabilize the declining revenue for our surgical products. Our surgical product revenue in 2016 was $32.5 million, compared with $47.6 million in 2015.

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

If the supply of materials from our suppliers were to be interrupted, replacement or alternative sources might not be readily obtainable. In particular, the products which together comprise our OverStitch Endoscopic Suturing System are sourced from a variety of suppliers and these suppliers further depend on many component providers. As OverStitch sales increase, we have experienced times of temporary supply disruption for a variety of reasons and this has caused delays in our fulfillment of customer orders. However, if such a condition were to persist, our business could suffer as our reputation with customers could be damaged and eventually could lead to reduced future demand for our products. An inability to continue to source materials or components from any of our suppliers 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, labor disputes or shortages at the supplier and unexpected demands or quality issues.

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. 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. Many of the companies developing or marketing bariatric surgical products are large divisions of publicly-traded companies including the Ethicon division of Johnson & Johnson and the Covidien division of Medtronic PLC. In addition, there are several other publicly-traded or privately-held companies with whom we compete, including Obalon Therapeutics, Inc., ReShape Lifesciences, Inc., Spatz Laboratories, Cousins BioTech and Medical Innovation Development. These companies 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 obesity that is less invasive or more effective than our current product offerings, including pharmacological treatment options, sales of our products would be significantly and adversely affected.

We may be unable to manage our growth effectively.

Our integration of the obesity intervention business of Allergan has provided, and our future growth may create, challenges to our organization. From the acquisition date of December 2, 2013, to December 31, 2016, the number of our employees increased from 50 to 193. In the future, should we grow, 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. As a public company, we will need to further expand our financial and potentially other resources to support our public company reporting and related obligations. If we fail to manage these challenges effectively, our business could be harmed.

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 cause, or merely appear to or are alleged to have caused, 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 it. 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.

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. Additionally, physicians or hospitals may misuse our products by disregarding the expiration labeling of a product. Use of an expired product could increase risk of injury to a patient or otherwise harm our reputation among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us 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 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 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.

If we experience significant disruptions in our 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 and inventory management. 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, we may experience difficulties in implementing and maintaining a resilient enough information technology infrastructure which could 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 as a result of the current implementation of 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.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into our information systems and may obtain our proprietary information.

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 indemnity 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.

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 FDC 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 extensive regulation by the FDA and various other federal, state and foreign governmental authorities. 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.

Although the FDA has granted 510(k) clearances for our Class II products, any modification to or deviation (including changes to design, manufacturing, materials, packaging and sterilization) that may affect the safety or effectiveness of a product or that constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending upon the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with the manufacturer's determination. If the FDA disagrees with our determination regarding the appropriateness of an action taken following the modification of an existing 510(k) cleared product, the FDA can require us to cease manufacturing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. In addition, FDA can impose regulatory fines or penalties for failure to undertake what FDA considers to be the appropriate action. With respect to modified 510(k) cleared products, there can be no assurance that 510(k) clearance or PMA applications for modified products will be approved or that FDA will agree with our determination that certain modifications do not require a new 510(k) clearance or a PMA application.

Our marketed products are subject to Medical Device Reporting, or MDR, obligations, which require that it report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. Adverse Events related to our products reported from any region in the world must be assessed for MDR reportability if the subject device is approved in the U.S. at the time the event occurred as part of Apollo's Global Product Surveillance Program. As of August 5, 2015 (date of the Orbera system PMA approval), any Adverse Event related to the Orbera system reported from any region in the world must be assessed for MDR reportability to the FDA. As part of this assessment Apollo conducts 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 an Apollo 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 Adverse Event reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by the device or to address a violation of the United States Food, Drug and Cosmetic Act, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

We are also required to keep internal records of any actions we take to correct a device or to address a violation that presents a risk to health. FDA may review these records and disagree with our risk determination or actions, and request that we retrospectively submit a notice of correction and removal.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, updates, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;

- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

If we fail to comply with U.S. federal and state healthcare regulatory laws, 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.*

There are numerous U.S. federal and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws and transparency laws. 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 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 even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil False Claims Act, 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 federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- 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, as amended ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the federal Foreign Corrupt Practices Act of 1997, 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, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

While we do not submit claims 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. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for 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 influence the ordering of and use our products in procedures they perform. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. The medical device industry's relationship with physicians is under increasing scrutiny by the Department of Health and Human Services Office of Inspector General ("OIG"), the

Department of Justice ("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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, physicians, hospitals, ambulatory surgery centers, group purchasing organizations and our independent distributors and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

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, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting off-label uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA in their professional medical judgment, we are prohibited from promoting products for off-label uses. We market our products and provide educational and promotional materials and training programs to physicians regarding the use of our products. If it is determined that our business activities, including our marketing, educational and promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In certain cases, actions to pursue claims under the False Claims Act 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.

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 ACA's provision commonly referred to as the Physician Payment Sunshine Act imposes annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. 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 United States 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 medical devices. Therefore, coverage or reimbursement for medical devices may decrease in the future.

Federal and state governments in the United States have enacted legislation to overhaul the nation's healthcare system that has resulted in increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. President Trump ran for office on a platform that supported the repeal of the ACA and one of his first actions after his inauguration was to sign an Executive Order commanding federal agencies to try to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that impose fiscal or regulatory burdens on states, individuals, families, the health-care industry and others. The Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the states more flexibility and control to create a more free and open healthcare market." At this time, it is not clear whether the ACA will be repealed in its entirety, whether it will be replaced in whole or in part by another plan, and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could 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 product candidates once approved or additional pricing pressures, 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.

U.S. legislative or FDA 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. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. 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 of 2016, the 21st Century Cures Act was enacted into law. The Act includes many provisions that impact the regulation of medical devices. For example, this 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
- Requiring additional validation data prior to marketing certain reusable medical devices
- Streamlining the review process for combination products
- Classifying software functions, not generally subject to regulation, as medical devices
- Emphasizing the least burdensome standard for device reviews

If we materially modify our FDA-approved or cleared products, we may need to seek and obtain new approvals or clearances, which, if not granted, would prevent us from selling our modified products.

A component of our strategy is to continue to modify and upgrade our products. Medical devices can be marketed only for the indications for which they are approved or cleared. FDA grants approvals or clearances based on the product information (e.g., design specifications, component suppliers / materials, manufacturing and quality control processes) provided for review in support of the 510(k) or PMA submission. We may not be able to obtain additional regulatory approvals or clearances for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future approvals or clearances would

adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. If we determine that a modification to a product does not require any additional approval or clearance, the FDA can review such decision and may disagree with our determination. The FDA may require a new 510(k) clearance or PMA approval, may require us to cease manufacturing or recall the modified product and may impose significant fines or penalties that would harm our business and reputation.

Our international operations 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 key European markets 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 the Company include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, 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 United States 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 United States 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 inspectional 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. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. *

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is 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 their respective jurisdictions in the event of material deficiencies or defects in the design or manufacture of our products. We may, under our own initiative, recall a product if any material deficiency in our products is found. The FDA requires that recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by the Company or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, 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 reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. 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 that we report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. For example, two fluid filled intragastric balloons, including our Orbera System, have been the subject of an FDA announcement that a) adverse event reports of spontaneous inflation and, in separate instances, b) adverse event reports of an occurrence of acute pancreatitis have been received. The FDA has also published an update to this announcement to alert health care providers of five reports of unanticipated deaths that occurred within one month of the placement of an intragastric balloon, four of which involved the Orbera Intragastic Balloon. The update further indicated that the root cause of patient death in these cases had not been found and the FDA was not able to definitively attribute instances of patient death to the balloon devices or their respective insertion procedures. If these adverse events occur more frequently or other serious adverse effects are detected in fluid filled intragastric balloons, our product may be subject to adverse FDA action or additional communications from the FDA, which could harm our business. In addition, the FDA could take enforcement action for failing to report any recalls when they were conducted.

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 support our PMA approvals. 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, 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 United States Foreign Corrupt Practices Act and similar laws associated with any activities outside the United States could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act ("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, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We may face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, some of which represent significant markets for us, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees, distributors, consultants and agents to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. There can be no assurance that our employees, distributors, consultants and agents, or those companies to which we outsource certain of our business operations will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage. 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 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 you 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, 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. For example, we currently intend to discontinue the payment of maintenance fees on approximately 2 U.S. patents and 67 foreign patents that we no longer consider material to our business.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act ("the Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office ("USPTO"), developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications.

We may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the United States 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 United States. 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. For example, we have pending LapBand trademark registration actions in Australia, Canada, Costa Rica, India, Norway, Switzerland and Thailand where the distinctiveness of the LapBand trademark has been challenged and where trademark registration may not be granted or maintained. 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 generally 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 market is extremely 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. Most of our intellectual property has not been tested in litigation. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

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

Risks Related to Our Capital Requirements and Finances

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 it to obtain additional financing to fund our operations. We may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations and clinical studies;
- continue our research and development activities;

- support and expand ongoing manufacturing activities;
- defend, in litigation or otherwise, any claims that it infringes third-party patents or other intellectual property rights;
- enforce our patent and other intellectual property rights;
- address legal or enforcement actions by the FDA or other governmental agencies and remediate underlying problems;
- commercialize our new products in development, if any such products receive regulatory clearance or approval for commercial sale; and
- acquire companies or products and in-license products or intellectual property.

We believe that our existing cash and cash equivalents, revenue, proceeds from prior funding and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations at least through December 2017. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the scope, rate of progress and cost of our clinical studies;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that our product infringes third-party patents or other intellectual property rights;
- the cost of defending, in litigation or otherwise, products liability claims;
- the cost and timing of additional regulatory clearances or approvals;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- 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, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company.

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.

Our outstanding debt financing arrangements contain restrictive covenants that may limit our operating flexibility.

Our outstanding debt facility 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. 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 lenders. 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.

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 the we may rely, including for the manufacture of the components for our product, including their ability to comply with regulatory requirements;
- the results of our current and any future clinical trials of our devices;
- unanticipated or serious safety concerns related to the use of any of our products;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by us, our commercial partners or our competitors of new products or product enhancements, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- competition from existing technologies and products or new technologies and products that may emerge;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who may cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the low trading volume and the high proportion of shares held by affiliates;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

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

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

We will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, 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 and other personnel will need to devote substantial time to these rules and regulations. These rules and regulations are expected to increase our legal and financial compliance costs and to make some other activities more time-consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of the Company, which may adversely affect investor confidence and could cause our business or stock price to suffer.

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

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

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

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

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

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, if certain of our existing stockholders sell, or indicate an intention to sell, substantial

amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

As of September 30, 2017, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders has the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

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

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

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

None.

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
31.1 *	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2 *	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1# *	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2# *	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

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+ Management contract or compensation plan or arrangement

* 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 26, 2017.

APOLLO ENDOSURGERY, INC.

/s/ Todd Newton

Todd Newton
Chief Executive Officer
(Principal Executive Officer)

/s/ Stefanie Cavanaugh

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

Exhibit 31.1

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

I, Todd Newton, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 26, 2017

By: /s/ Todd Newton

Todd Newton

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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

I, Stefanie Cavanaugh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 26, 2017

By: /s/ Stefanie Cavanaugh

Stefanie Cavanaugh

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

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

(1) The Company's Report on Form 10-Q for the period ended September 30, 2017, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: October 26, 2017

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

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

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

Exhibit 32.2

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

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

(1) The Company's Report on Form 10-Q for the period ended September 30, 2017, to which this Certification is attached as Exhibit 32.2 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: October 26, 2017

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

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

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