

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 2022

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-35706

**APOLLO ENDOSURGERY, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**78746**  
(Zip Code)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☐

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

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

As of April 29, 2022, there were 40,250,402 shares of the issuer's \$0.001 par value common stock issued and outstanding.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**FOR THE QUARTER ENDED MARCH 31, 2022**  
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## PART I - FINANCIAL INFORMATION

### ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 81,730	\$ 90,691
Accounts receivable, net of allowance for doubtful accounts of \$345 and \$330, respectively	11,066	10,078
Inventory	13,251	11,966
Prepaid expenses and other current assets	2,451	1,965
Total current assets	108,498	114,700
Restricted cash	1,008	1,121
Property, equipment and right-of-use assets, net	5,768	5,593
Goodwill	5,290	5,290
Intangible assets, net of accumulated amortization of \$14,948 and \$14,814, respectively	4,028	4,400
Other assets	423	424
Total assets	<u>\$ 125,015</u>	<u>\$ 131,528</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,396	\$ 4,584
Accrued expenses	7,556	9,902
Total current liabilities	13,952	14,486
Long-term debt	33,594	33,473
Convertible debt	19,563	19,513
Long-term liabilities	2,873	2,819
Total liabilities	69,982	70,291
Commitments and contingencies		
Stockholders' equity:		
Common stock; \$0.001 par value; 100,000,000 shares authorized; 40,102,879 and 39,546,323 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	40	40
Additional paid-in capital	358,717	356,516
Accumulated other comprehensive income	2,145	2,136
Accumulated deficit	(305,869)	(297,455)
Total stockholders' equity	55,033	61,237
Total liabilities and stockholders' equity	<u>\$ 125,015</u>	<u>\$ 131,528</u>

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)

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenues	\$ 16,662	\$ 13,857
Cost of sales	7,289	6,350
Gross margin	9,373	7,507
Operating expenses:		
Sales and marketing	8,220	4,790
General and administrative	5,231	4,069
Research and development	2,713	1,928
Amortization of intangible assets	456	474
Total operating expenses	16,620	11,261
Loss from operations	(7,247)	(3,754)
Other (income) expenses:		
Interest expense, net	1,222	1,352
Other income, net	(242)	(564)
Net loss before income taxes	(8,227)	(4,542)
Income tax expense	187	59
Net loss	\$ (8,414)	\$ (4,601)
Other comprehensive (loss)/income:		
Foreign currency translation	9	(885)
Comprehensive loss	\$ (8,405)	\$ (5,486)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.17)
Shares used in computing net loss per share, basic and diluted	39,652,299	26,306,442

See accompanying notes to the condensed consolidated financial statements.

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

**Three Months Ended March 31, 2022 and 2021**

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Accumulated</b>	
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in</b>	<b>Other</b>	<b>Deficit</b>	<b>Total</b>
			<b>Capital</b>	<b>Comprehensive</b>		
				<b>Income</b>		
Balances at December 31, 2020	25,819,329	\$ 26	\$ 276,569	\$ 2,929	\$ (272,773)	\$ 6,751
Exercise of common stock options	21,493	—	60	—	—	60
Exchange of common stock for warrants	999,855	1	(1)	—	—	—
Issuance of restricted stock units	11,337	—	—	—	—	—
Issuance of common stock for convertible debt interest	161,184	—	572	—	—	572
Conversion of convertible debt	22,644	—	74	—	—	74
Stock-based compensation	—	—	720	—	—	720
Foreign currency translation	—	—	—	(885)	—	(885)
Net loss	—	—	—	—	(4,601)	(4,601)
Balances at March 31, 2021	<u>27,035,842</u>	<u>\$ 27</u>	<u>\$ 277,994</u>	<u>\$ 2,044</u>	<u>\$ (277,374)</u>	<u>\$ 2,691</u>
Balances at December 31, 2021	39,546,323	\$ 40	\$ 356,516	\$ 2,136	\$ (297,455)	\$ 61,237
Exercise of common stock options	8,216	—	32	—	—	32
Exercise of common stock warrants	450,842	—	—	—	—	—
Issuance of restricted stock and performance stock units	21,718	—	—	—	—	—
Issuance of common stock for convertible debt interest	75,780	—	613	—	—	613
Stock-based compensation	—	—	1,556	—	—	1,556
Foreign currency translation	—	—	—	9	—	9
Net loss	—	—	—	—	(8,414)	(8,414)
Balances at March 31, 2022	<u>40,102,879</u>	<u>\$ 40</u>	<u>\$ 358,717</u>	<u>\$ 2,145</u>	<u>\$ (305,869)</u>	<u>\$ 55,033</u>

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash flows from operating activities:		
Net loss	\$ (8,414)	\$ (4,601)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	741	904
Amortization of deferred financing costs	113	133
Non-cash interest	486	446
Provision for doubtful accounts receivable	26	(18)
Stock-based compensation	1,556	720
Unrealized foreign exchange on intercompany payables	(315)	(545)
Changes in operating assets and liabilities:		
Accounts receivable	(947)	(1,443)
Inventory	(1,279)	(236)
Prepaid expenses and other assets	(403)	(347)
Accounts payable and accrued expenses	(253)	678
Net cash used in operating activities	(8,689)	(4,309)
Cash flows from investing activities:		
Purchases of property and equipment	(467)	(221)
Purchases of intangibles and other assets	(84)	(76)
Net cash used in investing activities	(551)	(297)
Cash flows from financing activities:		
Proceeds from exercise of stock options	32	60
Net cash provided by financing activities	32	60
Effect of exchange rate changes on cash	134	(6)
Net change in cash, cash equivalents and restricted cash	(9,074)	(4,552)
Cash, cash equivalents and restricted cash at beginning of year	91,812	37,200
Cash, cash equivalents and restricted cash at end of period	\$ 82,738	\$ 32,648
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 410	\$ 775
Cash paid for income taxes	(8)	4
Right-of-use assets recognized in exchange for lease obligations (non-cash)	107	—
Issuance of common stock for convertible debt interest (non-cash)	613	572
Issuance of common stock from conversion of convertible debt (non-cash)	—	74

See accompanying notes to the condensed consolidated financial statements.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements**  
**(In thousands, except for share data)**

**(1) Organization and Business Description**

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

Apollo is a medical technology company primarily focused on the development of next-generation, less invasive medical devices to advance gastrointestinal therapeutic endoscopy. The Company develops and distributes devices that are used by surgeons and gastroenterologists for a variety of procedures related to gastrointestinal conditions including closure of gastrointestinal defects, managing gastrointestinal complications and the treatment of obesity.

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

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

**(2) Significant Accounting Policies**

**(a) Basis of Presentation**

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

The Company has made estimates and judgments affecting the amounts reported in its condensed consolidated financial statements and the accompanying notes. The actual results that the Company experiences may differ materially from the Company’s estimates. The accounting estimates that require the Company’s most significant, difficult and subjective judgments include revenue recognition and inventory valuation.

**(b) Unaudited Interim Results**

In management’s opinion, the unaudited financial information for the interim periods presented includes all adjustments necessary for a fair presentation of the results of operations, financial position, and cash flows. All adjustments are of a normal recurring nature unless otherwise disclosed. Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. This interim information should be read in conjunction with the audited consolidated financial statements in the Company’s [Annual Report on Form 10-K](#) for the year ended December 31, 2021.

**(c) Recent Accounting Pronouncements**

In August 2020, Accounting Standards Update (“ASU”) No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity* was issued, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. This ASU will become effective for the Company on January 1, 2024 and is not expected to have a material impact on the consolidated financial statements.

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

**(3) Concentrations**

Consolidated financial instruments that potentially subject the Company to a concentration of credit risk principally consist of cash and cash equivalents and accounts receivable. At March 31, 2022, the Company’s cash, cash equivalents and restricted cash are held in deposit accounts at four different banks totaling \$82,738. The Company has not experienced any losses in such accounts, and management does not believe the Company is exposed to any significant credit risk. Management further believes that credit risk in the Company’s accounts receivable is substantially mitigated by the Company’s evaluation process, relatively short collection terms, and the high level of

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

creditworthiness of its customers. The Company continually monitors the compliance of its customers with the Company's payment terms, but generally requires no collateral.

The Company had no concentrations greater than 10% of the Company's net accounts receivable as of March 31, 2022 or December 31, 2021. The Company had no single customer that comprised more than 10% of the Company's total revenues for the three months ended March 31, 2022 or 2021.

**(4) Inventory**

Inventory consists of the following as of:

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
	<b>(unaudited)</b>	
Raw materials	\$ 3,972	\$ 3,442
Work in progress	1,195	965
Finished goods	8,084	7,559
Total inventory	<u>\$ 13,251</u>	<u>\$ 11,966</u>

Finished goods included \$94 of consigned inventory at March 31, 2022.

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

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

	<b>Depreciable Lives</b>	<b>March 31, 2022</b>	<b>December 31, 2021</b>
		<b>(unaudited)</b>	
Equipment	5 years	\$ 7,747	\$ 7,472
Right-of-use assets	1-8 years	3,554	3,459
Furniture, fixtures and tooling	4-8 years	1,901	1,855
Computer hardware	3-5 years	1,560	1,444
Leasehold improvements	3-7 years	2,018	2,059
Construction in process		635	483
		<u>17,415</u>	<u>16,772</u>
Less accumulated depreciation		(11,647)	(11,179)
Property, equipment and right-of-use assets, net		<u>\$ 5,768</u>	<u>\$ 5,593</u>

The Company recorded depreciation expense of \$284 and \$429 for the three months ended March 31, 2022 and 2021, respectively. There were no impairment charges for the three months ended March 31, 2022 or 2021.

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

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

As of March 31, 2022, the maturities of the Company's operating lease liabilities are as follows:

2022	\$	628
2023		546
2024		449
2025		404
2026		416
Thereafter		756
Total lease payments		3,199
Less imputed interest		(686)
Total operating lease liabilities	\$	2,513

Operating lease liabilities of \$578 are included in accrued expenses and \$1,935 are included in long-term liabilities as of March 31, 2022. Operating lease expense and cash paid within operating cash flows for operating leases was \$255 and \$267 for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the weighted average remaining lease term was 4.5 years and the weighted average discount rate used to estimate the value of the operating lease liabilities was 8.9%. In June 2021, the Company extended the office lease in Texas for one year.

**(6) Accrued Expenses**

Accrued expenses consists of the following as of:

	March 31, 2022	December 31, 2021
	(unaudited)	
Accrued employee compensation and expenses	\$ 4,006	\$ 6,569
Accrued professional service fees	765	656
Lease liability	578	587
Accrued taxes	779	437
Accrued interest	307	613
Accrued returns and rebates	93	106
Other	1,028	934
Total accrued expenses	\$ 7,556	\$ 9,902

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

**(7) Long-Term Debt**

Long-term debt consists of the following as of:

	March 31, 2022	December 31, 2021
	(unaudited)	
Term loan facility	\$ 35,000	\$ 35,000
Deferred interest	64	6
Deferred financing costs	(1,470)	(1,533)
Long-term debt	<u>\$ 33,594</u>	<u>\$ 33,473</u>

**Term Loan Facility**

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

Interest expense on the Company’s long-term debt was \$750 and \$1,058 for the three months ended March 31, 2022 and 2021, respectively.

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

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

**(8) Convertible Debt**

Convertible debt consists of the following as of:

	March 31, 2022	December 31, 2021
	(unaudited)	
Convertible debt	\$ 20,446	\$ 20,446
Deferred financing costs	(883)	(933)
Total convertible debt	<u>\$ 19,563</u>	<u>\$ 19,513</u>

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

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

The Company issued 75,780 shares of the Company's common stock to holders of the Convertible Debt in January 2022 in fulfillment of accrued interest as of December 31, 2021. As of March 31, 2022, accrued interest on the Convertible Debt is \$307.

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

Interest expense on the Convertible Debt was \$357 for each of the three months ended March 31, 2022 and 2021.

**(9) Long-Term Liabilities**

Included in other long-term liabilities as of March 31, 2022 was \$938 for the estimated non-current portion of the exit fee obligation to Solar Capital Ltd., our previous lender, which was reclassified from long-term debt in December 2021. The Company remains obligated to pay \$1,925 upon the earlier to occur of (i) certain exit events specified in the Solar Term Facility or (ii) the Company's achievement of trailing twelve-month revenue of \$100,000. Interest expense on this long-term liability was \$122 for the three months ended March 31, 2022.

**(10) Warrants**

Warrants consist of the following as of March 31, 2022:

Warrant Expiration Date	Number of shares	Exercise price per share
No expiration	13,293,594	\$ 0.001

During the three months ended March 31, 2022, pre-funded warrants were exercised into 450,842 shares of common stock and 163,915 warrants expired.

**(11) Stock-Based Compensation**

A summary of the stock option activity as of March 31, 2022 is presented below.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding, December 31, 2021	3,482,883	\$ 5.04	8.0 years	\$ 12,307
Options granted	176,861	5.63		
Options exercised	(8,216)	3.84		
Options forfeited	(57,592)	3.59		
Options outstanding, vested and expected to vest, March 31, 2022	3,593,936	\$ 5.10	7.6 years	\$ 5,062
Options exercisable	1,834,282	\$ 4.71	6.5 years	\$ 3,522

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

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(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:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Risk free interest rate	1.9%	1.0%
Expected dividend yield	—%	—%
Estimated volatility	81.6%	81.0%
Expected life	6.1 years	6.1 years

The aggregate intrinsic value in the tables above represents the total pre-tax value of the options shown, calculated as the difference between the Company's closing stock price on March 31, 2022 and the exercise prices of the options shown, multiplied by the number of in-the money options. This is the aggregate amount that would have been received by the option holders if they had all exercised their options on March 31, 2022 and sold the shares thereby received at the closing price of the Company's common stock on that date. This amount changes based on the closing price of the Company's common stock.

Additional information regarding options is as follows:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Weighted-average grant date fair value of options granted during the period	\$ 3.96	\$ 4.12
Aggregate intrinsic value of options exercised during the period	\$ 21	\$ 57

Unrecognized compensation expense related to unvested options was approximately \$6,005 at March 31, 2022, with a weighted average remaining amortization period of 2.9 years.

A summary of the restricted stock unit activity, including performance-based stock units, under the Company's Equity Plans as of March 31, 2022 is presented below.

	Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding, December 31, 2021	1,194,432	\$ 5.67	\$ 10,069
Restricted stock units granted	996,929	5.63	
Restricted stock units released	(21,718)	6.02	
Restricted stock units forfeited	(66,355)	3.90	
Restricted stock units outstanding, March 31, 2022	<u>2,103,288</u>	\$ 5.70	\$ 12,725

In March 2021, the Company awarded 707,278 performance-based restricted stock units to the Company's chief executive officer in connection with the commencement of his employment. The performance-based restricted stock units vest in four equal tranches upon the achievement of revenue for the trailing four quarters equal to \$50,000, \$65,000, \$80,000, and \$95,000. The revenue milestone for the first and second tranche was achieved as of June 30, 2021 and March 31, 2022, respectively.

Unrecognized compensation expense related to unvested restricted stock units and performance-based stock units was approximately \$7,054 and \$1,610, respectively, at March 31, 2022, with a weighted average remaining amortization period of 3.2 years.

## **(12) Income Taxes**

The provision for income taxes for the three months ended March 31, 2022 and 2021 primarily consists of foreign income taxes.

The Company has established a valuation allowance due to uncertainties regarding the realization of deferred tax assets based on the Company's lack of earnings history and potential limitations pursuant to changes in ownership under Internal Revenue Code Section 382.

As of March 31, 2022, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

**(13) Net Loss Per Share**

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

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

	Three Months Ended March 31,	
	2022	2021
Warrants for common stock	13,293,594	15,617,335
Convertible debt	6,315,988	6,349,515
Common stock options	3,483,889	3,137,230
Restricted stock units	1,491,016	843,962
	<u>24,584,487</u>	<u>25,948,042</u>

**(14) Fair Value Measurements**

The carrying amounts of the Company's financial instruments, which primarily include cash, cash equivalents, and restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of the Company's long-term debt and Convertible Debt is estimated by management to approximate \$35,000 and \$20,400, respectively at March 31, 2022. 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.

**APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Interim Condensed Consolidated Financial Statements (continued)**  
(In thousands, except for share data)

**(15) Segment and Geographic Information**

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

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

	Three Months Ended March 31, 2022				Three Months Ended March 31, 2021			
	(unaudited)							
	U.S.	OUS	Total Revenues	% Total Revenues	U.S.	OUS	Total Revenues	% Total Revenues
ESS	\$ 7,220	\$3,511	\$ 10,731	64.4 %	\$ 5,395	\$ 3,244	\$ 8,639	62.4 %
IGB	2,064	3,667	5,731	34.4 %	1,470	3,493	4,963	35.8 %
Other	197	3	200	1.2 %	242	13	255	1.8 %
Total revenues	<u>\$ 9,481</u>	<u>\$7,181</u>	<u>\$ 16,662</u>	<u>100.0 %</u>	<u>\$ 7,107</u>	<u>\$ 6,750</u>	<u>\$ 13,857</u>	<u>100.0 %</u>
% Total revenues	56.9 %	43.1 %			51.3 %	48.7 %		

Total distributor sales were 48.9% and 43.7% of total OUS revenues for the three months ended March 31, 2022 and 2021, respectively. Sales in the next largest individual country outside the U.S. were 5.1% of total revenues for the three months ended March 31, 2022 compared to 6.8% for the three months ended March 31, 2021.

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

	March 31, 2022	December 31, 2021
	(unaudited)	
U.S.	\$ 2,116	\$ 1,855
Costa Rica	3,357	3,436
Other	295	302
Total property, equipment and right-of-use assets, net	<u>\$ 5,768</u>	<u>\$ 5,593</u>

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

*This quarterly report ("Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks, uncertainties and other important factors. In particular, statements, whether express or implied, concerning future operating results or the ability to generate sales, income or cash flow are forward-looking statements. They involve risks, uncertainties and assumptions that are beyond our ability to control or predict, including those discussed in [Part II, Item 1A](#), of this Quarterly Report, such as the continuing effects of the COVID-19 pandemic on our financial condition and results of operations. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements as predictions of future events. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.*

*The following discussion should be read in conjunction with the condensed consolidated financial statements and accompanying notes, and our [Annual Report on Form 10-K for the year ended December 31, 2021 filed on February 22, 2022](#) with the Securities and Exchange Commission ("SEC"). "Apollo", Orbera®, OverStitch®, X-Tack®, 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 development of next-generation, less invasive medical devices to advance gastrointestinal therapeutic endoscopy. Our Endoscopy product portfolio consists of the OverStitch® Endoscopic Suturing System, the OverStitch Sx® Endoscopic Suturing System, X-Tack® Endoscopic HeliX Tacking System (collectively "ESS") and ORBERA® IntraGastric Balloon ("IGB"). Our products are used by gastroenterologists and bariatric surgeons in a variety of settings to treat multiple gastrointestinal conditions including closure of acute perforations and chronic fistulas; tissue closure after the removal of abnormal lesions in the esophagus, stomach or colon (also known as endoscopic submucosal dissections, endoscopic mucosal resections and endoscopic full thickness resections); treatment of swallowing disorders (peroral endoscopic myotomy); and esophageal stent fixation and obesity.

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

Since its market introduction in 2008, over 80,000 OverStitch units have been sold for procedures worldwide. We estimate that approximately 60% of OverStitch uses in the United States were for advanced gastrointestinal therapies. The other uses were for endoscopic sleeve gastropasty ("ESG"), approximately 25%, and bariatric revision, approximately 15%. Outside the United States, we estimate that the majority of OverStitch uses, approximately 65%, were for ESG. The other uses outside the United States were for bariatric revision, approximately 20%, and for advanced gastrointestinal therapies, approximately 15%.

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

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

### **Impact of COVID-19 on Our Business**

After the COVID-19 pandemic began in March 2020, our business, financial condition, and results of operations were disrupted by the various measures imposed to contain the pandemic, primarily during 2020. Beginning in the latter half of 2020, our sales began to recover primarily as certain public health interventions implemented by various countries to reduce COVID-19 transmission risks were eased and procedures that use our products increased. Demand for our products and our business has generally recovered and been sustained over levels at the beginning of the COVID-19 pandemic in 2020, though there can be no assurance that recovery will continue or that current demand levels will be sustained. In particular, new variants or outbreaks of the virus, including the Omicron and other variants, have caused and may in the future cause health systems and other healthcare providers in our markets to restrict or limit procedures, which have harmed and may continue to harm our sales recovery or growth and result in fluctuation of our product sales. Despite growing availability of COVID-19 vaccines, the COVID-19 pandemic, including emerging variant strains of the virus, remains active and continues to represent uncertainty concerning our sales outlook and risk to our business operations, including due to reduced demand for or limitations on procedures that use our products and supply chain disruptions. Business challenges and periodic disruption resulting from COVID-19 will likely continue for the duration of the pandemic, which is uncertain. We cannot assure you that our recent recovery in sales will be indicative of future results or that we will not experience future sales or business disruptions due to COVID-19, including variants, which could be significant. See [Part II, Item 1A. Risk Factors—Risks Related to Our Business—Our business will be adversely affected by the effects of the recent COVID-19 outbreak.](#)

### **Financial Operations Overview**

#### ***Revenues***

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

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

#### ***Cost of Sales***

Cost of sales for purchased products consists of the actual purchase price from manufacturers plus an allocation of our internal manufacturing overhead cost. Cost of sales for products we manufacture include raw materials, labor, and manufacturing overhead. Raw materials used in our manufacturing activity are generally not subject to substantial commodity price volatility, and most of our manufacturing costs are incurred in U.S. dollars. Cost of sales also include royalties, shipping, excess and obsolete inventory charges, inspection and related costs incurred in making our products available for sale or use. In periods of reduced production volume, unabsorbed manufacturing overhead costs are charged to expense when incurred.

Manufacturing overhead as a percentage of revenue between periods can fluctuate as a result of manufacturing rates and the degree to which manufacturing overhead is allocated to production during the period. We expect to continue to improve gross margins as we complete certain identified gross margin improvement projects and improve capacity utilization of our manufacturing facility.

#### ***Sales and Marketing Expense***

Sales and marketing expense primarily consists of salaries, commissions, benefits and other related costs, including stock-based compensation, for personnel employed in sales, marketing and medical education. In addition, our sales and marketing expense includes costs associated with physician training, industry events, advertising and other promotional activities.

## General and Administrative Expense

General and administrative expense primarily consists of salaries, benefits and other related costs, including stock-based compensation, for personnel employed in corporate management, finance, legal, compliance, information technology and human resources. General and administrative expense also includes facility cost, insurance, audit fees, legal fees, bad debt expense and costs to develop and maintain our intellectual property portfolio.

## Research and Development Expense

Research and development expense includes product development, clinical trial costs, quality and regulatory compliance, consulting services, outside prototyping services, outside research activities, materials and other costs associated with development of our products. Research and development expense also includes salaries, benefits and other related costs, including stock-based compensation, for personnel dedicated to these activities. Research and development expense may fluctuate between periods depending on the activity associated with our various product development and clinical obligations.

## Amortization of Intangible Assets

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

## Critical Accounting Policies and Estimates

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

[Note 2, "Significant Accounting Policies" in Part I, Item 1](#) of this Form 10-Q and in the Notes to Consolidated Financial Statements in Part II, Item 8 of the Company's [Annual Report on Form 10-K for the year ended December 31, 2021](#) (the "2021 Form 10-K"), and "Critical Accounting Policies and Estimates" in Part II, Item 7 of the 2021 Form 10-K describe the significant accounting policies and methods used in the preparation of the Company's condensed consolidated financial statements. There have been no material changes to the Company's critical accounting policies and estimates since the 2021 Form 10-K.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31, 2022		Three Months Ended March 31, 2021	
	Dollars	% of Revenues	Dollars	% of Revenues
Revenues	\$ 16,662	100.0 %	\$ 13,857	100.0 %
Cost of sales	7,289	43.7 %	6,350	45.8 %
Gross margin	9,373	56.3 %	7,507	54.2 %
Operating expenses:				
Sales and marketing	8,220	49.3 %	4,790	34.6 %
General and administrative	5,231	31.4 %	4,069	29.4 %
Research and development	2,713	16.3 %	1,928	13.9 %
Amortization of intangible assets	456	2.7 %	474	3.4 %
Total operating expenses	16,620	99.7 %	11,261	81.3 %
Loss from operations	(7,247)	(43.4)%	(3,754)	(27.1)%
Interest expense, net	1,222	7.3 %	1,352	9.8 %
Other income, net	(242)	(1.5)%	(564)	(4.1)%
Net loss before income taxes	(8,227)	(49.2)%	(4,542)	(32.8)%
Income tax expense	187	1.1 %	59	0.4 %
Net loss	<u>\$ (8,414)</u>	<u>(50.3)%</u>	<u>\$ (4,601)</u>	<u>(33.2)%</u>

## Revenues

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

	Three Months Ended March 31, 2022			Three Months Ended March 31, 2021			% Increase/ (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	\$7,220	\$3,511	\$ 10,731	\$5,395	\$3,244	\$ 8,639	33.8 %	8.2 %	24.2 %
IGB	2,064	3,667	5,731	1,470	3,493	4,963	40.4 %	5.0 %	15.5 %
Other	197	3	200	242	13	255	(18.6)%	(76.9)%	(21.6)%
Total revenues	<u>\$9,481</u>	<u>\$7,181</u>	<u>\$ 16,662</u>	<u>\$7,107</u>	<u>\$6,750</u>	<u>\$ 13,857</u>	<u>33.4 %</u>	<u>6.4 %</u>	<u>20.2 %</u>
% Total revenues	56.9 %	43.1 %		51.3 %	48.7 %				

Total revenues for the three months ended March 31, 2022 were \$16.7 million, compared to \$13.9 million for the three months ended March 31, 2021, an increase of 20.2% due to improved demand for all our products, especially in our U.S. market where sales increased \$2.4 million or 33.4%. For the three months ended March 31, 2022, U.S. ESS sales grew 33.8%, as we continue to see higher demand for our X-Tack product which we launched in the first quarter of 2021, continued increase in our OverStitch product sales, and due to price increases. IGB also grew 40.4% in the U.S. due to higher demand for this elective procedure. Total OUS sales increased \$0.4 million or 6.4%, for the three months ended March 31, 2022 and was primarily driven by higher demand in our international distributor markets for both ESS and IGB products.

Direct market product sales remained relatively flat over 2021 and accounted for approximately 78.9% of total product sales for the three months ended March 31, 2022 compared to 78.7% for the same period in 2021, respectively.

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

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

Non-GAAP product sales percentage change in constant currency were as follows:

	Three Months Ended March 31, 2022	
	% Increase in Constant Currency	
	OUS	Total Revenues
ESS	12.4 %	25.8 %
IGB	8.4 %	17.9 %
Total revenues	10.1 %	22.1 %

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

## Cost of Sales

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

	Three Months Ended March 31, 2022		Three Months Ended March 31, 2021	
	Dollars	% Total Revenues	Dollars	% Total Revenues
Materials, labor and purchased goods	\$ 4,859	29.2 %	\$ 4,380	31.6 %
Overhead	1,510	9.0 %	1,320	9.5 %
Other indirect costs	920	5.5 %	650	4.7 %
Total cost of sales	<u>\$ 7,289</u>	<u>43.7 %</u>	<u>\$ 6,350</u>	<u>45.8 %</u>

## Gross Margin

Gross margin as a percentage of revenue was 56.3% for the three months ended March 31, 2022, compared to 54.2% for the same period in 2021. The increase in gross margin percentage was attributed to margin expansion in the U.S. on our ESS product sales, resulting primarily from improved overhead efficiencies, the impact of cost improvement projects in 2021, as well as moderate price increases for the three months ended March 31, 2022. The gross margin improvements in the U.S. were partially offset by a higher mix of distributor sales outside the U.S., which have a lower gross margin profile.

## Operating Expenses

*Sales and Marketing Expense.* Sales and marketing expense increased \$3.4 million for the three months ended March 31, 2022 primarily due to higher compensation, marketing spend, and increased travel in first quarter 2022 compared to first quarter 2021 as we continue to expand our salesforce headcount and invest in our marketing campaigns and initiatives. We expect our sales and marketing expenses to continue to increase in future periods as we continue to invest in our sales channel and marketing programs for sales growth.

*General and Administrative Expense.* General and administrative expense increased \$1.2 million for the three months ended March 31, 2022 when compared to the same period in 2021 primarily due to higher non-cash stock-based compensation expense in 2022 resulting from leadership team changes during 2021 as well as higher software spend.

*Research and Development Expense.* Research and development expense increased \$0.8 million for the three months ended March 31, 2022, primarily due to higher compensation in 2022 compared to 2021 as we expand our team to address key clinical needs and continued product development.

*Amortization of Intangible Assets.* Amortization of intangible assets remained unchanged for the three months ended March 31, 2022 when compared to the same period in 2021.

## Loss from Operations

Loss from operations for the three months ended March 31, 2022 of \$7.2 million increased \$3.5 million compared to \$3.8 million for the same period in 2021 due to higher operating expenses in 2022 compared to the prior year offset by higher revenues.

## Other (Income) Expenses

*Interest Expense, net.* Net interest expense decreased by \$0.1 million for the three months ended March 31, 2022 when compared to the same period in 2021 due to lower interest expense on our term loan.

*Other Income, net.* Other income primarily consists of realized and unrealized foreign exchange losses on short-term intercompany loans denominated in U.S. dollars payable by our foreign subsidiaries. Fluctuations in currency exchange rates resulted in an unrealized gain of \$0.3 million for the three months ended March 31, 2022 compared to unrealized gain of \$0.5 million for the three months ended March 31, 2021, respectively.

*Income tax expense.* Income tax expense related to foreign income taxes on income generated in our OUS tax jurisdictions was \$0.2 million for the three months ended March 31, 2022 compared to \$0.1 million in the same period in 2021.

## Liquidity and Capital Resources

We have experienced operating losses since inception and have an accumulated deficit of \$305.9 million as of March 31, 2022. To date, we have funded our operating losses and acquisitions through equity offerings, term loans, and the issuance of debt instruments. Our ability to fund future operations and meet debt covenant requirements will depend upon our level of future revenue and operating cash flow and our ability to access future draws on our existing credit facility, or additional funding through either equity offerings, issuances of debt instruments or both.

Management believes its existing cash and cash equivalents, cash from operations, additional term loans available upon certain thresholds under the Term Loans and access to financing sources will be sufficient to meet covenant, liquidity and capital requirements for the next twelve months and beyond. Management periodically evaluates our liquidity requirements, alternative uses of capital, capital needs and available resources. Any future cash requirements will depend on many factors including market acceptance of our products, the cost of our research and development activities, the cost and timing of additional regulatory clearance and approvals, the cost and timing of identified gross margin improvement projects, the cost and timing of clinical programs, the ability to maintain covenant compliance with our lending facility, and the cost of sales, marketing, and manufacturing activities. We may be required to seek additional equity or debt financing. As a result of this process, we have in the past, and may in the future, explore alternatives to finance our business plan, including, but not limited to, sales of common stock, preferred stock, convertible securities or debt financings, reduction of planned expenditures, or other sources, although there can be no assurances that such additional funding could be obtained. If we are unable to raise additional capital when desired, our business operating results and financial condition could be adversely affected.

There were no material changes to our cash requirements from contractual and other obligations for the three months ended March 31, 2022 from those disclosed in the [2021 Form 10-K](#).

### **Cash Flows**

The following table provides information regarding our cash flows:

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	\$ (8,689)	\$ (4,309)
Net cash used in investing activities	(551)	(297)
Net cash provided by financing activities	32	60
Effect of exchange rate changes on cash	134	(6)
Net change in cash, cash equivalents and restricted cash	<u>\$ (9,074)</u>	<u>\$ (4,552)</u>

### **Operating Activities**

Cash used in operating activities of \$8.7 million for the three months ended March 31, 2022 was primarily the result of a net loss of \$8.4 million offset by non-cash items of \$2.6 million, primarily related to depreciation, amortization, foreign exchange on intercompany loans, non-cash interest, and stock-based compensation. Cash used by operating assets and liabilities of \$2.9 million for the three months ended March 31, 2022 increased over cash used for the three months ended March 31, 2021 due to higher accounts receivable and increase in raw materials in correlation with the upward trend in sales and higher bonus payments.

Cash used in operating activities of \$4.3 million for the three months ended March 31, 2021 was primarily the result of a net loss of \$4.6 million offset by non-cash items of \$1.6 million primarily related to depreciation, amortization, foreign exchange on intercompany loans, non-cash interest and stock-based compensation. Additionally, cash used by operating assets and liabilities of \$1.3 million related to accounts receivable due to the increase in revenues.

### **Investing Activities**

Cash used in investing activities of \$0.6 million and \$0.3 million for the three months ended March 31, 2022 and 2021, respectively, were primarily related to equipment purchases and expansion of our Costa Rica manufacturing facility associated with our product development and gross margin improvement projects, as well as ongoing investments in our intellectual property portfolio.

### **Financing Activities**

Cash provided by financing activities for both the three months ended March 31, 2022 and March 31, 2021 was related to proceeds received from exercise of stock options.

### **Recent Accounting Pronouncements**

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

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

## ITEM 4. CONTROLS AND PROCEDURES

### *Disclosure Controls and Procedures*

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

### *Changes in Internal Control Over Financial Reporting*

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

### *Inherent Limitation on Effectiveness of Controls*

Our management, including our principal executive and principal financial officers, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by individuals' acts, by collusion of two or more people, or by management overriding the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

From time to time, we are involved in legal proceedings. The results of such legal proceedings and claims cannot be predicted with certainty, and regardless of the outcome, legal proceedings could have an adverse impact on our business because of defense and settlement costs, diversion of resources and other factors.

#### **Federal False Claims Act Action.**

As previously disclosed, 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. relating to the marketing of the Lap-Band System, including the web-based physician locator provided on the Lap-Band.com website. We cooperated fully with the investigation, and on August 21, 2017, we were notified by the Department of Justice that we were no longer a subject in such investigation. On February 5, 2021 the United States filed a declination to intervene in the underlying action that had prompted the investigation entitled United States of America ex rel. Mathew Fitzer M.D., et al., v. Allergan, Inc. et al., and also names the Company as a defendant. In April of 2021, the Company was served with the underlying action filed under qui tam provisions of the Federal False Claims act and related to the marketing of the Lap-Band System, including the web-based physician locator provided on the Lap-Band.com website during the period before and after our acquisition in December 2013 of the obesity intervention division of Allergan, Inc. In September of 2021, the court granted a motion to dismiss the qui tam claim for failing to state a claim. In October of 2021, Relator filed an amended complaint. In March of 2022, the court granted a motion to dismiss the qui tam claim for failing to state a claim. In April of 2022, Relator filed a motion to reconsider or, alternatively, to amend the pleading. We believe the claims are without merit, but we cannot predict the outcome of the legal proceedings or the effect on our business, but it is possible that the foregoing matter could result in a material adverse effect on our business, reputation, results of operation and financial condition.

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

#### **SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS**

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

- Our business has been and likely will continue to be adversely affected by the ongoing COVID-19 pandemic.
- We have incurred significant operating losses since inception and may not be able to achieve profitability.
- Our long-term growth depends on our ability to successfully develop the market for our Endoscopy products.
- A weakening of U.S. and international economic conditions may reduce consumer demand for our products, causing our sales and profitability to suffer.
- Our future growth depends on physician adoption and recommendation of procedures utilizing our products.
- Our future growth depends on patient awareness of and demand for procedures that use our products.
- Our future growth depends on developing clinical data that demonstrates the safety and efficacy of our products and the procedures that use our products.
- Our future growth depends on obtaining and maintaining adequate coverage and reimbursement for procedures performed with our products.
- If our products contribute to a serious injury or death, or malfunction in certain ways, we may be subject to liability claims and will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- The misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits and/or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.
- We are dependent on certain suppliers, vendors and manufacturers, and supply or service disruptions could materially adversely affect our business and future growth.

- We compete or may compete in the future against other companies, some of which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.
- If our facilities or the facility of a supplier become inoperable, we will be unable to continue to research, develop, manufacture and commercialize our products and, as a result, our business will be harmed.
- Our products are subject to extensive regulation by the FDA and foreign regulatory authorities, including the requirement to obtain premarket approval and the requirement to report adverse events and violations of the U.S. Federal Food, Drug and Cosmetic Act that could present significant risk of injury to patients. Even though we have received FDA approval of our PMA applications, 510(k) clearances and foreign regulatory approvals to commercially market our products, we will continue to be subject to extensive regulatory oversight from the FDA and foreign regulatory authorities.
- If we or our suppliers fail to comply with local, state or federal laws, rules or regulations, or with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.
- Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.
- We may in the future be a party to patent and other intellectual property litigation and administrative proceedings that could be costly and could interfere with our ability to sell our products.
- We have substantial indebtedness which contain restrictive covenants that may limit our operating flexibility and our failure to comply with the covenants and payment requirements of our indebtedness may subject us to increased interest expenses, lender consent and amendment costs or adverse financial consequences.
- We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.
- Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.
- Our business and operations would suffer in the event of system failures, security breaches or cyber-attacks.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section titled [“Risk Factors” in Part II, Item 1A](#), and the other information set forth in our [Annual Report on Form 10-K](#) for the year ended December 31, 2021, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also harm our business, financial condition, results of operations and future growth prospects.

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

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, 2021.

## **Risks Related to Our Business**

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

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

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

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

Continued restrictions on the ability to travel in certain jurisdictions, social distancing policies, orders and other restrictions, including those described above, and recommendations and fears of COVID-19 spreading within medical centers have caused and may continue to cause both patients and providers to delay or cancel procedures that use our devices, which has harmed our sales, results of operations and financial condition. Even as governmental restrictions begin to be relaxed or lifted and various jurisdictions gradually reopen, we are unable to accurately predict for how long they will remain relaxed or lifted, or whether such jurisdictions will remain open, including as COVID-19 variants continue to spread in certain jurisdictions. There can be no assurances that patients or providers will continue restarting procedures that use our devices following the lifting, relaxation or termination of these policies, orders and restrictions, particularly if there remains any continued community outbreak of COVID-19. Our distributors have periodically deferred and may continue to defer their purchases of our products due to the COVID-19 pandemic. Health systems and other healthcare providers in our markets that provide procedures that use our products have also suffered financially and operationally and may not be able to return to pre-pandemic levels of operations. New variants or outbreaks of the virus, including the Omicron variant outbreak, have caused health systems and other healthcare providers in our markets to restrict or limit procedures using our devices or have experienced reductions in or cancellations of planned procedures by patients, which have harmed and may continue to harm our sales and growth. Further, quarantines or government reaction or shutdowns for COVID-19 could disrupt our supply chain. Renewed travel and import restrictions may also disrupt our ability to manufacture or distribute our devices and may materially increase the cost of raw materials and finished goods. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products would restrict our ability to obtain raw materials, manufacture and ship products and harm our business, financial condition and results of operations. Our key personnel and other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce, including cost saving measures that we have previously instituted, could reduce the efficiency of our operations or prove insufficient.

In addition, the conduct of clinical trials required to maintain the regulatory status of certain of our products have been and may in the future be affected by the COVID-19 pandemic. For example, enrollment for our Orbera365 CE post approval study has been and likely will continue to be delayed due to the pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. COVID-19 restrictions may also delay the timing of regulatory reviews and approvals as regulators in various jurisdictions may have reduced staffing and capability. The presentation of the results of clinical trials may be delayed due to the cancellation or postponement of scientific meetings. In 2020, we had to prioritize key growth and operational projects over the others due to capital resource constraints resulting from our reduced sales levels and may in the future need to make similar choices, which may negatively impact our growth and operational projects.

Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers. While hospitals and healthcare providers have generally relaxed access restrictions, prior restrictions have harmed our sales and marketing efforts, and renewed restrictions, including due to variant strains of the virus, would have a negative impact on our sales and results of operations. An increase of COVID-19-related hospital admissions, including due to variant strains of the virus, may overload hospitals with unexpected patients, thereby delaying further procedures that use our devices but that are deemed elective by the hospital. Limited supplies of personal protective equipment and COVID-19 testing supplies may further reduce onsite access for our personnel and may delay the lifting of restrictions on elective procedures, including those that use our products.

The global outbreak of COVID-19, including the Delta and Omicron waves, continues to be volatile and rapidly evolving causing our business to be highly uncertain and unpredictable. We do not yet know the full extent of any impacts on our future business or the global economy as a whole, and the duration, continued spread and severity of the pandemic continues to be uncertain, including due to the spread of new variants or mutant strains of the virus as well as future spikes of COVID-19 infections. In addition, actions to contain the disease or treat its impact, the development, availability, and widespread acceptance of effective vaccines and treatments, further restrictions on travel, and the duration, timing and severity of the impact on customer spending, including any recession resulting from the pandemic, continue to be uncertain. However, these effects have harmed our business, financial condition and results of operations since the beginning of the pandemic and could have a material and negative impact on our future operations, sales and ability to continue as a going concern.

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

We have incurred net losses since our inception in 2005. For the three months ended March 31, 2022 and 2021, we had net losses of \$8.4 million and \$4.6 million, respectively. As of March 31, 2022, we had an accumulated deficit of \$305.9 million. To date, we have funded our operations primarily through equity offerings, the issuance of debt instruments, and from sales of our products. We have devoted substantially all of our resources to the acquisition of products, the research and development of products, sales and marketing activities and clinical and regulatory initiatives to obtain regulatory approvals for our products. Our ability to generate sufficient revenue from our existing products, and to transition to profitability and generate consistent positive cash flows is uncertain. We may need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all. We expect that our operating expenses may increase as we continue to build our commercial infrastructure, develop, enhance and commercialize our products and incur additional costs associated with being a public company. As a result, we may incur operating losses for the foreseeable future and may never achieve profitability.

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

It is important to our business that we continue to build a market for therapeutic endoscopy procedures within the gastroenterology and bariatric communities. Our Endoscopy products offer non-surgical and less-invasive solutions and technology that enable new options for physicians treating their patients who suffer from a variety of gastrointestinal conditions, including obesity. However, this is a new market and developing this market is expensive and time-consuming and may not be successful due to a variety of factors including lack of physician adoption, patient demand, or both. Many of our products are designed to work in cooperation with third party equipment such as flexible endoscopes whose design, specifications and continued availability is outside of our control. Changes to the design or specifications, withdrawals from the market, limited availability or other changes that limit the use and acceptance of such third party equipment may limit the market for our products or make our existing products obsolete. Even if we are successful in developing additional products in the Endoscopy market, the success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

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

If we are unsuccessful in developing and commercializing the therapeutic endoscopy market, our ability to increase our revenue will be impaired and our business, results of operations, financial condition and prospects will be materially adversely affected.

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

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

***Our future growth may depend on physician adoption and recommendation of procedures utilizing our products.***

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

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

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

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

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

- out of pocket cost for an elective procedure; and
- alternative treatments or competitive products that are perceived to be more effective or less expensive.

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

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

Further, with any clinical or pre-clinical study relating to our products, we cannot guarantee that the results of any such study will be timely finalized and made public or that the results of any study will be viewed as favorable by regulatory authorities, physicians, patients or payors. For example, in 2017, we entered into a clinical trial agreement with The Mayo Clinic in Rochester, Minnesota to undertake the MERIT trial to evaluate the long-term safety and efficacy of Endoscopic Sleeve Gastroplasty (“ESG”) compared to efficacy endpoints set forth in a consensus statement of the American Society for Gastrointestinal Endoscopy (“ASGE”) and the American Society of Metabolic Bariatric Surgery (“ASMBS”) and its impact on obesity related comorbidities in patients with obesity and BMI range of 30 to 45 kg/m<sup>2</sup>. ESG is an endoscopic procedure that involves the creation of plications in the stomach, through a series of stacked suture-based plications, to reduce stomach volume; the plications form a sleeve, which reduces stomach capacity and slows gastric emptying to induce weight loss. Adverse events that may occur during or following an ESG procedure include the following: pharyngitis/sore throat, nausea, vomiting, abdominal pain and/or bloating, hemorrhage, hematoma, conversion to laparoscopic or open procedure, stricture, infection, sepsis, pharyngeal and/or esophageal perforation, esophageal and/or pharyngeal laceration, intra-abdominal (hollow or solid) visceral injury, aspiration, acute inflammatory tissue reaction and death. Additional clinical risks may be identified as more clinical data on ESG is developed and analyzed. In June 2021, one of the principal investigators of the MERIT trial reported that, based on a preliminary analysis, the MERIT trial had achieved its primary end points for safety and efficacy, and outcomes data were published in the fourth quarter of 2021. These data have been submitted to the FDA through a De Novo request to create new devices specifically for ESG and bariatric revision procedures. However, we cannot assure you that such data will be timely reported or that the results will be viewed as favorable by physicians, patients, or regulatory agencies, including the FDA. A delay in making these outcomes results public or a failure to achieve favorable clinical outcomes would negatively impact our business.

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

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

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

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

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

Our future financial performance will depend in part on our ability to develop and manufacture new products or to acquire new products in a cost-effective manner, to introduce these products to the market on a timely basis and to achieve market acceptance of these products. Factors which may result in delays of new product introductions include capital constraints, research and development delays, lack of personnel with sufficient experience or competence, delays in acquiring regulatory approvals or clearances, including obtaining regulatory approval for new indications for use, delays in closing acquisition transactions, or delays in receiving necessary approval from a hospital or healthcare facility to introduce a new product or procedure. The ongoing COVID-19 pandemic may contribute to such delays, particularly as research and development may be narrowed to key projects and activities. Future product introductions may fail to achieve expected levels of market acceptance including physician adoption, patient awareness or both. Factors impacting the level of market acceptance include the timeliness of our product introductions, the effectiveness of medical education efforts, the effectiveness of patient awareness and educational activities, successful product pricing strategies, available financial and technological resources for product promotion and development, the ability to show clinical benefit from future products, the scope of the indicated use for new products and the availability of coverage and reimbursement for procedures that use future products.

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

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

Physicians may also misuse our products, use improper techniques, ignore or disregard product warnings, contraindications or other information provided in training materials or product labeling, fail to obtain adequate training, or fail to inform patients of the risks associated with procedures that utilize our products, potentially leading to injury and an increased risk of product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management’s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Some of our products have cleared indications for general use and the FDA or foreign regulatory bodies may request clinical evidence to support a specific intended use, or determine that promotional activity, educational materials or training relating to a specific intended use constitutes off-label promotion. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or we could be subject to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

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

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

also face disputes with our current or previous suppliers and vendors. In any of these cases, we could face a delay of several months to identify and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier or vendor transition plans. In addition, the failure of our third-party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products.

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

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

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

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

We create internal operational forecasts to determine requirements for components and materials used in the manufacture of our products and to make production plans. Our limited commercial experience, changes in the market or demand for our products, the launch of new products with no sales history, as well as the ongoing COVID-19 pandemic, may make it difficult for us to accurately predict future production requirements. If we forecast inaccurately, this may cause us to have shortfalls or backorders that may negatively impact our reputation with customers and cause them to seek alternative products, or could lead us to have excessive inventory, scrap or similar operational and financial inefficiency that could harm our business.

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

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

These industry participants may enjoy several competitive advantages, including:

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

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

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

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

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

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved or cleared for commercial sale by the FDA and manufactured in facilities regulated by the FDA, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products contribute to, or merely appear to or are alleged to have contributed to, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Further, because we provided certain transition services, including manufacturing support, to ReShape for our divested Surgical Product line through December 2020, we may be subject to product liability claims from sales of Surgical products by ReShape, over which we have limited to no control. Product liability claims may be brought against us by patients and their family members, health care providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

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

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

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

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

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

We believe that our continued success depends to a significant extent upon our efforts and ability to retain highly qualified personnel. Retaining and recruiting people with the appropriate skills is particularly challenging as the economy in general continues to recover from the COVID-19 pandemic resulting in competition for the human resources necessary to operate our business successfully. All of our officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel, including changes in our management team, likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business. For example, in March 2021, we implemented a planned CEO change. The failure to successfully execute this leadership transition and retain key employees could have negatively impacted our business and results of operations.

We cannot assure you we will be able to maintain our workforce or to replace any departing personnel on favorable or commercially reasonable terms, if at all. Loss of personnel may negatively impact our ability to support business activities in the future.

***If we are unable to manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue.***

Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales representatives fail to adequately promote, market and sell our products, our sales may suffer. In order to generate our anticipated sales, we will need to maintain a qualified and well-trained direct sales organization. As a result, our future success will depend largely on our ability to hire, train, retain and motivate skilled sales managers and direct sales representatives. Because of the competition for their services, we cannot assure you we will be able to hire and retain direct sales representatives on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales. Additionally, new hires require training and take time before they achieve full productivity. If we fail to train new hires adequately, new hires may not become as productive as may be necessary to maintain or increase our sales and we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition. In addition, we may change our sales approach in certain markets from direct sales to healthcare providers to sales to distributors who then resell our products. If we were to change our sales approach in a given market, our product sales price in the affected market would be reduced which would lower our revenue and gross margin and the resulting reduction in our operating expense may not be sufficient to offset this reduction in our gross margin.

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

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

A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. In the event that a material weakness is identified, we cannot assure you that we will be able to identify and implement measures that will be sufficient to remediate any such material weakness or that future material weaknesses will not occur.

If we fail to remediate an identified material weakness or identify new material weaknesses in our internal controls over financial reporting, investors may lack confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected regardless of whether material inaccuracies are determined to exist in our reported financial statements. If material inaccuracies are determined to exist in our financial statements or we are unable to report our financial statements on a timely basis, we could also become subject to investigations by Nasdaq, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

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

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

Our subsidiary that manages our European business is located in the U.K. and, thus, there are many ways in which our business operations may be impacted by Brexit, only some of which we can identify at this time. Our notified body in Europe was BSI based in the U.K., which will no longer have standing in the EU as a notified body. We subsequently transferred our notified body to BSI in the Netherlands which required that we change product labeling and packaging for all our products and may have other potential implications that have yet to be identified at this time. Financial markets could experience volatility which could negatively impact currency exchange rates and therefore the translated U.S. dollar value of our local currency sales to customers in the U.K. or Europe. We do not hedge our foreign currency transaction or translation risks. Our warehousing and distribution hub for Europe is in the Netherlands and distribution of our products in the U.K. market may be slowed or disrupted and our U.K. sales may suffer as a result.

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

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

**Risks Related to Regulatory Review and Approval of Our Products**

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

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

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. In addition, the FDA may deem certain uses of an existing cleared general use device, such as OverStitch, to be a high risk use and may require the submission of a PMA or a De Novo 510(k) prior to expanding the device's indication for such additional use. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. In addition, although FDA has granted PMA approval for our class III products, holding those approvals in good standing

requires ongoing compliance with FDA reporting requirements and conditions of approval including the completion of lengthy and expensive post market approval studies. The De Novo 510(k) process is also more costly, lengthy and uncertain than the 510(k) clearance process. Despite the time, effort and cost required to obtain approval, there can be no assurance that we will be able to meet all FDA requirements to maintain our PMA approvals or that circumstances outside of our control may cause the FDA to withdraw our PMA approvals.

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

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

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

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

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

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

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

In addition, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Affordable Care Act's provision commonly referred to as the federal Physician Payment Sunshine Act, as well as similar state and foreign laws, impose obligations on medical device manufacturers to annually report certain payments and other transfers of value provided, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. Failure to comply with any of these state, federal, or foreign transparency and disclosure requirements could subject us to significant fines and penalties. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

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

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

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

***Healthcare cost containment pressures could result in pricing pressure which could have an adverse effect on our business.***

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

Federal and state governments in the U.S. and outside the U.S. may enact legislation to modify the healthcare system which may result in increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. These reform measures may limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payors are willing to pay. The resulting pricing pressure from our hospital and ambulatory surgical center ("ASC") customers due to cost sensitivities resulting from healthcare cost containment pressures and reimbursement changes could decrease demand for our products, the prices that customers are willing to pay and the frequency of use of our products, which could have an adverse effect on our business.

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

***Restrictive reimbursement practices of third-party payors could decrease the demand for our products, the prices that customers are willing to pay and the number of procedures performed using our products, which could have an adverse effect on our business.***

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their healthcare treatment. Accordingly, market acceptance of our products is dependent on the extent to which third-party coverage and reimbursement is available from third-party payors, which can differ significantly from payor to payor and may change at any time. Adequate reimbursement coding, coverage, and payment may be required to support the future growth of some of our products. Inadequate coverage and negative reimbursement policies for our products could affect their adoption and our future revenue. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and thereafter maintain sufficient third-party coverage and reimbursement for our products and/or procedures in which our products are used, the commercial success of our products may be limited, and our financial condition and results of operations may be materially and adversely affected.

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

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

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

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

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

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

Expanding the indications for our products may require new regulatory approvals or clearances, including 510(k) or De Novo clearances or PMA approvals. We have current products such as OverStitch with clearance as a general use device but no procedure-specific indications for use. In the event that we pursue the approval of expanded indications for a product, the FDA or foreign regulatory authorities may require a separate filing such as a 510(k) or De Novo submission or may deem the desired indication for use to be of high enough risk to require a PMA or similar submission. For example, the investigators conducting the MERIT trial sought and received an Investigational Device Exemption following communication from the FDA which indicated that the FDA considered the ESG procedure for weight loss to be a high risk use. We have submitted a De Novo classification request to the FDA seeking 510(k) classification and clearance for the Apollo ESG™ and Apollo REVISE™ devices, which consist of the OverStitch® Endoscopic Suturing System and related components (e.g., tissue helix, sutures, cinches). Apollo ESG™ is intended for use in the endoscopic sleeve gastropasty procedure for weight loss and any futures cases and Apollo REVISE™ is intended for use in revision of bariatric surgery procedures. Obtaining clearances and approvals for such expanded uses can be a time consuming and costly process, and we may be unsuccessful in obtaining desired clearances and approvals, either of which could adversely affect our ability to market our products or delay efforts to obtain reimbursement coverage from payors.

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

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

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

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

We currently operate in the U.S., Costa Rica, Australia and various European countries and our products are approved for sale in over 75 different countries; our activities are subject to U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance.

Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. FCPA, as well as export control laws and economic sanctions laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant costs and disruption of business associated with an internal and/or government investigation, criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations present the same risks as presented by our U.S. operations plus unique risks inherent in operating in foreign jurisdictions. These unique risks include:

- foreign regulatory approval which could result in delays leading to possible insufficient inventory levels;
- foreign currency exchange rate fluctuations;
- reliance on sales people and distributors;
- pricing pressure and differing reimbursement regimes that we may experience internationally;
- competitive disadvantage to competitors who have more established business and customer relationships in a given market;
- reduced or varied intellectual property rights available in some countries;
- economic instability of certain countries or geopolitical events, including the ongoing conflict between Russia and Ukraine;
- 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;
- inflationary pressures;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on the Company; and
- laws and business practices favoring local companies.

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

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;

- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

Our products and operations are required to comply with standards set by foreign regulatory bodies, and those standards, types of evaluation and scope of review differ among foreign regulatory bodies. For example, audits are routinely performed by our Notified Body to ensure we are meeting by the Quality System requirements for Europe, which are organized in many other countries outside of Europe as well, notably Canada, Brazil, Australia and Japan. If we fail to comply with any of these standards adequately or if changes to our manufacturing or supply practices require additional regulatory approval, a foreign regulatory body may take adverse actions or cause delays within their jurisdiction similar to those within the power of the FDA. Any such action or circumstance may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

In addition, on May 25, 2017, the new EU Medical Devices Regulation ("MDR 2017") was published and was scheduled to become effective on May 26, 2020. On April 17, 2020, the European Parliament approved the delay of the effectiveness of MDR 2017 until May 26, 2021. MDR 2017 repeals and replaces the EU Medical Devices Directive ("MDD") and changes certain obligations of medical device manufacturers with product in the EU and subjects higher risk medical devices to additional scrutiny during the conformity assessment process. The new regulations will among other things:

- add new rules on placing devices on the market and reinforce post-market surveillance once they are available;
- establish explicit provisions on defining the responsibilities of EU economic actors (e.g., manufacturer, importer(s) and distributor(s)) for the follow-up of the quality, performance and safety of devices placed on the market;
- require the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;

- set up a central database (EUDAMED) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- add rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market;
- modify or increase clinical evidence requirements necessary to maintain existing CE marks

Accordingly, we are required to update our quality system to conform to certain requirements of MDR 2017 by May 2021. However, at this time only three of the six EUDAMED modules described by MDR 2017 are fully operational. Previously, the European Commission had stated that the EUDAMED database was expected to be fully operational by May 2022 but this seems unlikely and no updated timeline has been given by the European Commission. As such, the quality system updates required for us to comply with MDR 2017 cannot be fully implemented at this time. There remains uncertainty on how some new provisions are to be addressed.

Additionally, existing regulatory filings must be reviewed again by Notified Bodies as part of the transition of CE Mark certificates from the current MDD to the new MDR 2017 requirements. Industry-wide, Notified Bodies are experiencing much longer review times on these files and this creates additional uncertainty over the timely transition to MDR 2017. Our CE certificates under MDD are valid through November 2022 and we completed all submissions of our MDR 2017 documentation to our Notified Body review by the end of January 2022. However, there are no assurances that we will not experience delays or that our Notified Body will be able to conduct a timely review of this documentation nor that they will conclude our documentation is sufficient. Depending on the timing of the Notified Body review, we may not be able to supplement or correct our documentation prior to the expiration of our CE certificates. Our Notified Body could require changes to product labeling as part of the transition to MDR 2017. If that happens, it would likely result in additional filings globally to have those labeling changes approved in the various countries where we market and sell those products.

In order to continue to sell our products in Europe, we must maintain our CE marks and continue to comply with certain EU directives and, in the future with the MDR 2017. Our failure to continue to comply with applicable foreign regulatory requirements, including meeting additional clinical evidence requirements and complying with regulatory requirements administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the EU, such as the departure of the United Kingdom (Brexit), may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

We are also subject to regulations and periodic review from various regulatory bodies in other countries where our products are sold. Lack of regulatory compliance in any of these jurisdictions could limit our ability to distribute products in these countries. A number of countries outside of Europe consider the CE Mark status of a medical device when making their decisions to grant a license for said product. In many countries, we rely significantly on independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products.

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

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

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

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

production or a cessation of operations. We also expect that our operations may be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have a material adverse effect on our business.

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

We are subject to the U.S. FCPA, and other anti-bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates. We may face significant risks if we fail to comply with the FCPA and other similar foreign antibribery laws. Although we have implemented safeguards and training, including company policies requiring our employees, distributors, consultants and agents to comply with the FCPA and similar laws, our international operations nonetheless present a risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could have a material and adverse effect on our reputation, business, operating results and financial condition.

## **Risks Related to Our Intellectual Property**

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

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

### *Patents*

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

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

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

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

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

### *Trademarks*

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

### *Trade Secrets and Know-How*

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

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

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

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

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

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

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

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

### **Risks Related to Our Capital Requirements and Finances**

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

In December 2021, we borrowed \$35.0 million principal amount of debt under a term loan facility (“Term Loans”) with Innovatus Capital Partners, LLC (“Innovatus”). We used \$35.0 million of the proceeds to repay the existing senior secured credit facility. Our outstanding debt is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates without Innovatus’s consent. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent of the lender. In addition, we are required to prepare our financial statements and receive audits on our annual financial statements in a timely manner, meet certain financial ratio requirements and pay interest and principal when due. Furthermore, under the Innovatus Term Loans our interest rate is tied to the Wall Street Journal Prime Rate. We do not hedge this variable rate exposure to the Wall Street Journal Prime Rate and in the event of an increase in the Wall Street Journal Prime Rate, we will be required to pay greater interest expenses, which may be material and have an adverse effect on our net loss and financial condition.

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

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

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

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

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

- expand the commercialization of our products;
- fund our operations and clinical studies;

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

Any future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the scope, rate of progress and cost of our clinical studies;
- the cost of our research and development activities;
- the cost of filing, defending and enforcing our patent or other intellectual property rights, in litigation or otherwise and any claims that our product infringes third-party patents or other intellectual property rights;
- the cost of defending, in litigation or otherwise, products liability claims;
- the cost and timing of additional regulatory clearances or approvals;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the scope, rate of progress and cost to expand ongoing manufacturing activities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses;
- the costs of operating as a public company; and
- the ability of third-parties to pay future invoices and obligations.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs.

We cannot be certain that additional funding will be available on acceptable terms, if at all. In particular, the impact of the COVID-19 pandemic is highly uncertain as to the availability of additional funding and the underlying terms of such funding. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

### **Risks Related to Ownership of Our Common Stock**

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

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

- a slowdown in the medical device industry or the general economy, including due to the COVID-19 pandemic;

- inability to obtain adequate supply of the components for any of our products or inability to do so at acceptable prices;
- performance of third parties on whom we may rely, including for the manufacture of the components for our products, including their ability to comply with regulatory requirements;
- the results of our current and any future clinical trials of our devices;
- unanticipated or serious safety concerns related to the use of any of our products;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by us, our commercial partners or our competitors of new products or product enhancements, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- competition from existing technologies and products or new technologies and products that may emerge;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who may cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the high proportion of shares and convertible or exchangeable securities held by affiliates;
- exercises or conversions of our outstanding warrants or convertible notes, respectively;
- general economic and market conditions, including effects of inflationary pressures;
- changes in the structure of health care payment systems and insurance coverage related to our products and procedures that utilize our products; and
- period-to-period fluctuations in our financial results.

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

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

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

We will continue to incur significant legal, accounting and other expenses including costs associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, as well as new rules implemented by the SEC and The Nasdaq Stock Market LLC. Our executive officers, service providers and other personnel will need to devote substantial time to these rules and regulations. These rules and regulations require significant legal and financial compliance costs and make some other activities more time consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of the Company, which may adversely affect investor confidence and could cause our business or stock price to suffer.

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

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

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

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

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

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

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

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

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

As of March 31, 2022, a substantial number of the outstanding shares of our common stock was held by a relatively small number of stockholders. In addition, our officers, directors, and members of management acquire stock or have the potential to own stock through previously granted equity awards. Consequently, our common stock has a relatively small float and low average daily trading volume, which could affect a stockholder's ability to sell our stock or the price at which it can be sold. In addition, future sales of substantial amounts of our common stock in the public market by those larger stockholders, or the perception that these sales could occur, may adversely impact the market price of the stock and our stock could be difficult for a stockholder to liquidate.

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

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

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such

instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. Investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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

## **General Risk Factors**

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

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

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

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

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

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

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

We rely on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers and prospective product end-users. A security breach of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, may cause all or portions of our or our third-party providers' systems to be unavailable, create system disruptions or shutdowns, and lead to erasure of critical data and software or unauthorized disclosure of confidential information which could harm our business and which may not be effectively mitigated by our insurance programs.

We and our various third-party providers make investments and take measures to protect our systems and data, but there can be no guarantee that any such measures, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information, protected health information, or personal data of EU residents) could violate or subject us to remediation and liability under federal, state and foreign laws that protect personal data, resulting in increased costs or loss of revenue.

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

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

### Issuer Purchases of Equity Securities

None.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

None.

## ITEM 6. EXHIBITS

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule / Form	File Number	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	Form 8-K	001-35706	3.1	June 13, 2017
3.2	<a href="#">Amended and Restated Bylaws</a>	Form 8-K	001-35706	3.2	June 13, 2017
10.1+	<a href="#">2022 Bonus Plan</a>	Form 8-K	001-35706	10.1	February 22, 2022
31.1 *	<a href="#">Certification of Chief Executive Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934</a>				
31.2 *	<a href="#">Certification of Chief Financial Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934</a>				
32.1# *	<a href="#">Certification of Chief Executive Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934</a>				
32.2# *	<a href="#">Certification of Chief Financial Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934</a>				
101.INS *	Instance Document - the instance document does not appear in the Interactive data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH *	XBRL Taxonomy Extension Schema Document				
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

+ 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 May 3, 2022.

APOLLO ENDOSURGERY, INC.

/s/ Charles McKhann

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Charles McKhann

*President and Chief Executive Officer*

*(Principal Executive Officer)*

/s/ Jeffrey Black

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Jeffrey Black

Chief Financial Officer

*(Principal Financial Officer)*