UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40919

MINERVA SURGICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-3422906**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4255 Burton Dr.	
Santa Clara, CA	95054
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (855) 646-7874

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, $ 0.001 par value	UTRS	NASDAQ Global Stock Market

Indicate by check mark whether the registrant (1) has 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 November 5, 2021, the registrant had 28,815,941 shares of common stock, $0.001 par value per share, outstanding.

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Item 1. Condensed Financial Statements

Minerva Surgical, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 6,128	$ 17,359
Restricted cash, current	7,283	7,203
Accounts receivable, net	6,758	8,379
Inventory	14,960	10,201
Prepaid expenses and other current assets	4,740	2,279
Total current assets	39,869	45,421
Restricted cash, net of current portion	524	604
Intangible assets, net	37,005	43,141
Property and equipment, net	3,791	2,880
Total assets	$ **81,189**	$ **92,046**
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current Liabilities:		
Accounts payable	$ 8,451	$ 3,506
Accrued compensation	2,859	2,889
Accrued liabilities	11,377	10,204
Contingent consideration liability, current	15,919	—
Delayed cash purchase consideration	15,000	15,000
Current portion of long-term debt	12,659	1,668
Total current liabilities	66,265	33,267
Redeemable convertible preferred stock warrant liability	577	42
Long-term debt	18,222	29,423
Convertible notes (includes $62.5 million at September 30, 2021 and $46.5 million at December 31, 2020, respectively, attributable to related parties)	88,960	66,196
Derivative liabilities (includes $14.4 million at September 30, 2021 and $23.6 million at December 31, 2020, respectively, attributable to related parties)	22,764	38,007
Contingent consideration liability, net of current portion	8,528	23,667
Total liabilities	205,316	190,602
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock, $0.001 par value, 121,732,397 shares authorized as of September 30, 2021 and December 31, 2020; 12,397,838 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation value of $136,168 as of September 30, 2021 and December 31, 2020	123,255	123,255
Stockholders' deficit:		
Common stock, $0.001 par value, 144,406,928 shares authorized as of September 30, 2021 and December 31, 2020; 3,149,777 and 1,192,299 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	3	1
Additional paid-in capital	12,968	6,269
Accumulated other comprehensive income	11	11
Accumulated deficit	(260,364)	(228,092)
Total stockholders' deficit	(247,382)	(221,811)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ **81,189**	$ **92,046**

The accompanying notes are an integral part of these financial statements.

Minerva Surgical, Inc.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues	$ 12,506	$ 12,280	$ 38,458	$ 24,219
Cost of goods sold	5,373	5,725	15,760	13,284
Gross profit	7,133	6,555	22,698	10,935
Operating expenses				
Sales and marketing	7,919	6,722	22,883	16,205
General and administrative	3,987	1,804	18,115	5,888
Research and development	1,367	1,200	4,191	2,151
Total operating expenses	13,273	9,726	45,189	24,244
Loss from operations	(6,140)	(3,171)	(22,491)	(13,309)
Interest income	—	—	—	80
Interest expense (includes $1.3 million to related parties in three months ended September 30, 2021 and 2020 and $4.2 million and $3.2 million to related parties in nine months ended September 30, 2021 and 2020, respectively)	(3,611)	(3,293)	(10,663)	(8,714)
Change in fair value of derivative liabilities	23,383	(859)	15,243	9,201
Bargain purchase gain	—	—	—	643
Loss on extinguishment of convertible notes	(16,853)	—	(16,853)	—
Gain on extinguishment of PPP loan	—	—	3,036	—
Other income (expense), net	(4)	(1)	(544)	75
Net loss before income taxes	(3,225)	(7,324)	(32,272)	(12,024)
Income tax benefit	—	—	—	132
Net Loss	$ (3,225)	$ (7,324)	$ (32,272)	$ (11,892)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.15)	$ (7.33)	$ (15.04)	$ (12.56)
Weighted-average shares used in computing net loss per share, basic and diluted	2,798,146	999,091	2,145,733	946,576

The accompanying notes are an integral part of these financial statements.

Minerva Surgical, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share amounts)
(Unaudited)

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount				
Balances, January 1, 2021	12,397,838	$ 123,255	1,192,299	$ 1	$ 6,269	$ 11	$ (228,092)	$ (221,811)
Issuance of common stock upon exercise of stock options	—	—	1,828,713	2	884	—	—	886
Stock-based compensation expense	—	—	—	—	131	—	—	131
Net Loss	—	—	—	—	—	—	(14,948)	(14,948)
Balances, March 31, 2021	12,397,838	123,255	3,021,012	3	7,284	11	(243,040)	(235,742)
Issuance of common stock upon exercise of stock options	—	—	66,288	—	40	—	—	40
Vesting of early exercised stock options	—	—	—	—	15	—	—	15
Stock-based compensation expense	—	—	—	—	4,478	—	—	4,478
Net Loss	—	—	—	—	—	—	(14,099)	(14,099)
Balances, June 30, 2021	12,397,838	123,255	3,087,300	3	11,817	11	(257,139)	(245,308)
Issuance of common stock upon exercise of stock options	—	—	62,477	—	37	—	—	37
Vesting of early exercised stock options	—	—	—	—	39	—	—	39
Stock-based compensation expense	—	—	—	—	1,075	—	—	1,075
Net Loss	—	—	—	—	—	—	(3,225)	(3,225)
Balances, September 30, 2021	**12,397,838**	**$ 123,255**	**3,149,777**	**$ 3**	**$ 12,968**	**$ 11**	**$ (260,364)**	**$ (247,382)**

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount				
Balances, January 1, 2020	11,066,427	$ 120,518	909,486	$ 1	$ 5,293	$ 11	$ (209,829)	$ (204,524)
Issuance of common stock upon exercise of stock options	—	—	57,569	—	24	—	—	24
Stock-based compensation expense	—	—	—	—	150	—	—	150
Net Income	—	—	—	—	—	—	5,732	5,732
Balances, March 31, 2020	11,066,427	120,518	967,055	1	5,467	11	(204,097)	(198,618)
Issuance of Series D redeemable convertible preferred stock in connection with business combination	1,331,411	2,737	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	2,977	—	42	—	—	42
Stock-based compensation expense	—	—	—	—	399	—	—	399
Net Loss	—	—	—	—	—	—	(10,300)	(10,300)
Balances, June 30, 2020	12,397,838	123,255	970,032	1	5,908	11	(214,397)	(208,477)
Issuance of common stock upon exercise of stock options	—	—	42,858	—	25	—	—	25
Stock-based compensation expense	—	—	—	—	205	—	—	205
Net Loss	—	—	—	—	—	—	(7,324)	(7,324)
Balances, September 30, 2020	**12,397,838**	**$ 123,255**	**1,012,890**	**$ 1**	**$ 6,138**	**$ 11**	**$ (221,721)**	**$ (215,571)**

The accompanying notes are an integral part of these financial statements.

Minerva Surgical, Inc.
Condensed Statements of Cash Flows
(in thousands, except share amounts)
(Unaudited)

	Nine Months Ended September 30, 2021	2020
Cash Flows From Operating Activities:		
Net loss	$ (32,272)	$ (11,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bargain purchase gain	—	(643)
Amortization of debt discount and debt issuance costs	3,342	2,213
Non-cash interest expense from long-term debt and convertible notes	5,395	5,130
Loss on extinguishment of convertible notes	16,853	—
Depreciation and amortization	7,948	4,415
Gain on extinguishment of PPP loan	(3,036)	—
Stock-based compensation expense	5,684	754
Change in fair value of redeemable convertible preferred stock warrant liability	535	(34)
Change in fair value of contingent consideration liability	780	—
Change in fair value of derivative liabilities	(15,243)	(9,201)
Deferred taxes	—	(132)
Net changes in operating assets and liabilities:		
Accounts receivable, net	1,621	(4,820)
Inventory	(6,600)	5,325
Prepaid expenses and other current assets	(2,461)	(1,914)
Accounts payable	4,951	(723)
Accrued liabilities	1,227	1,000
Accrued compensation	(30)	(48)
Net cash used in operating activities	(11,306)	(10,570)
Cash Flows From Investing Activities:		
Cash paid for business combination	—	(15,000)
Purchase of property and equipment	(888)	(726)
Net cash used in investing activities	(888)	(15,726)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock	963	91
Proceeds from issuance of convertible notes and borrowing under term loans, net of payment of lender fees and costs	—	17,959
Net cash provided by financing activities	963	18,050
Net decrease in cash, cash equivalents and restricted cash	(11,231)	(8,246)
Cash, cash equivalents and restricted cash at the beginning of the period	25,166	34,783
Cash, cash equivalents and restricted cash at the end of the period	$ 13,935	$ 26,537
Reconciliation of cash, cash equivalents and restricted cash to balance sheets		
Cash and cash equivalents	$ 6,128	$ 18,839
Restricted cash	7,807	7,698
Cash, cash equivalents and restricted cash in balance sheets	$ 13,935	$ 26,537
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$ 1,894	$ 1,338
Supplemental Disclosure of Non-cash Items:		
Forgiveness of PPP loan	$ (3,036)	$ —
Issuance of derivative instruments related to convertible notes	$ —	$ 6,849
Fair value of net assets acquired in business combination	$ —	$ 57,222
Fair value of contingent consideration in connection to business combination	$ —	$ 23,842
Fair value of delayed cash consideration in connection to business combination	$ —	$ 15,000
Issuance of Series D redeemable convertible preferred stock in connection to business combination	$ —	$ 2,737
Vesting of early exercised stock options	$ 54	$ —
Reclassification of inventory to property and equipment for customer usage agreements	$ 1,934	$ 264

The accompanying notes are an integral part of these financial statements.

1. Formation and Business of the Company

The Company

Minerva Surgical, Inc. ("the Company", "we", "our") was incorporated in the state of Delaware on November 3, 2008. The Company's headquarters are in Santa Clara, California. The Company is a medical device company that develops therapeutic devices that treat abnormal uterine bleeding in a minimally invasive manner. The Company commenced commercial introduction of its products in the United States in 2015 following the clearance by the U.S. Food and Drug Administration.

In May 2020, the Company acquired certain assets from Boston Scientific Corporation (BSC) to broaden its product offerings to its customers. The Company derives all of its revenue from sales to customers in the United States through a direct sales force.

Initial Public Offering

On October 21, 2021, the Company's registration statement on Form S-1 (File No. 333- 259832) relating to its initial public offering ("IPO") of common stock became effective. The Company issued and sold 6,250,000 shares of its common stock at a public offering price of $12.00 per share, for aggregate gross proceeds of $75.0 million. The Company received $69.8 million in net proceeds after deducting underwriting discounts and commissions. The total IPO offering costs other than underwriting discounts and commissions were $3.3 million. At September 30, 2021, $1.9 million of expenses incurred in connection with the Company's IPO had not yet been paid and are included in Accounts payable and accrued liabilities on the interim condensed balance sheet as of September 30, 2021.

In connection with the completion of its IPO, on October 21, 2021, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of $0.001 per share and 5,000,000 authorized shares of preferred stock with a par value of $0.001 per share. The unaudited interim condensed financial statements as of September 30, 2021, including share and per share amounts, do not give effect to the IPO, as it closed subsequent to September 30, 2021.

Immediately prior to the IPO, $79.2 million in aggregate outstanding principal and accrued interest of the convertible promissory notes converted into 7,006,297 shares of redeemable convertible preferred stock at a conversion price of $11.31 per share. Also, immediately prior to the closing, all outstanding shares of the Company's redeemable convertible preferred stock (including those issued upon conversion of the convertible promissory notes) converted into 19,404,135 shares of common stock which resulted in the reclassification of the carrying value of the preferred stock to common stock and additional paid-in capital.

Liquidity

The Company incurred a net loss of $32.3 million and $11.9 million during the nine months ended September 30, 2021 and 2020, respectively, and had an accumulated deficit of $260.4 million as of September 30, 2021. The Company had cash and cash equivalents of $6.1 million as of September 30, 2021.

We have incurred significant operational losses since inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Historically, the Company’s activities have been financed through private placements of equity securities and debt. On October 21, 2021, the Company completed an IPO in which the Company issued and sold 6,2500,000 shares of its common stock at a public offering price of $12.00 per share, for aggregate gross proceeds of $75 million. The Company received approximately $69.8 million in net proceeds after deducting underwriting discounts and commissions.

Management believes that the Company’s existing cash and cash equivalents, together with the net proceeds from the IPO, allow the Company to finance its operations for at least the next 12 months from the date of issuance of these unaudited interim condensed financial statements.

Impact of the COVID-19 pandemic

The COVID-19 pandemic and the resulting economic downturn have impacted business conditions in the industry in which the Company operates. Beginning in March 2020, the Company’s net sales were negatively impacted by the COVID-19 pandemic as hospitals and ambulatory surgical centers (ASCs) delayed or canceled elective procedures. In response to the pandemic, many state and local governments in the U.S. issued orders that temporarily precluded elective procedures in order to conserve scarce health system resources. The decrease in hospital and ASCs admission rates and elective surgeries reduced both the number of patients being evaluated for treatment with and demand for elective procedures using the Company's products.

In March 2020, the governor of California, where the Company's headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at the Company's headquarters (including manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events and have restricted the efforts of the Company's sales representatives, thereby significantly and negatively impacting the Company's operations. These orders and restrictions have significantly decreased the number of procedures performed using the Company's products and otherwise negatively impacted sales and operations.

The Company experienced a second wave of slower than expected revenue growth in the nine months ended September 30, 2021 when certain state governments responding to a second wave of COVID-19 infection rates, including the Delta variant, reinstated hospital and ASC closures for elective procedures.

The Company has taken necessary precautions to safeguard its employees, patients, customers, and other stakeholders from the COVID-19 pandemic, while maintaining business continuity to support its patients, customers and employees. The timing, extent and continuation of any increase in procedures, and any corresponding increase in sales of the Company's products, and whether there could be a future decrease in the current level of procedures as a result of the COVID-19 pandemic or otherwise, remain uncertain and are subject to a variety of factors.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate and will take further actions that we consider prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

The ultimate extent of the impact of the COVID-19 pandemic on us is highly uncertain and subject to change. This impact may result in a material, adverse impact on liquidity, capital resources, supply chain, operations, revenue and may affect third parties on which the Company relies and could worsen over time. The extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19 is unpredictable.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying financial statements have been prepared using accounting principles generally accepted in the United States of America (GAAP).

Reverse Stock Split

On October 14, 2021, the Company effected a 1-for-6.046 reverse stock split of its outstanding common stock and redeemable convertible preferred stock. Upon the effectiveness of the reverse stock split, all issued and outstanding shares of common stock options to purchase common stock, warrants, instruments convertible to shares, redeemable convertible preferred stock and related share data and per share amounts contained in the accompanying financial statements were retroactively revised to reflect this reverse stock split for all periods presented. The par value of the authorized stock was not adjusted as a result of the reverse stock split.

Unaudited interim financial information

The accompanying condensed balance sheet as of September 30, 2021, the condensed statements of operations, the condensed statements of redeemable convertible preferred stock and stockholders' deficit and condensed statements of cash flows for the three and nine months ended September 30, 2020 and 2021 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2021 and the results of its operations and its cash flows for the three and nine months ended September 30, 2020 and 2021. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2021 are also unaudited. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. The balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim condensed financial statements. These unaudited interim condensed financial statements should be read in conjunction with the audited annual financial statements and related notes. The significant accounting policies used in the preparation of the unaudited condensed financial statements for the three and nine months ended September 30, 2020 and 2021, are consistent with those discussed in Note 2 to the audited financial statements for the years ended December 31, 2019 and 2020 included in our audited financial statements and notes thereto for the year ended December 31, 2020, included in our prospectus dated October 21, 2021 filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933,

as amended (the “Prospectus”).There have been no significant changes in the significant accounting policies or critical accounting estimates since December 31, 2020.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include accounts receivable allowances, inventory allowances, recoverability of long-term assets, valuation of equity instruments and equity-linked instruments, valuation of common stock, stock-based compensation, valuation of the redeemable convertible preferred stock warrant liability and derivative liabilities, valuation and estimated useful lives of intangible assets, deferred tax assets and related valuation allowances, and impact of contingencies.

Fair value of financial instruments

The carrying amounts of the Company’s financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate their fair value due to the short-term nature of these assets and liabilities. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying values of the term loans approximate their fair values. Refer to Note 4 for further details.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation (FDIC) insured limits.

The Company earns revenue from sale of disposable devices and controllers to customers such as hospitals, ambulatory surgical centers and physician offices. The Company’s accounts receivable are derived from revenue earned from customers. The Company performs ongoing credit evaluations of its customers’ financial condition and generally requires no collateral from its customers. At September 30, 2021 and 2020, and for the periods then ended, no customer accounted for more than 10.0% of accounts receivable or revenue.

Concentration of suppliers

The Company purchases certain components of its products from a single or small number of suppliers. A change in or loss of these suppliers could cause a delay in filling customer orders and a possible loss of sales, which could adversely affect results of operations; however, management believes that suitable replacement suppliers could be obtained in such an event

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company’s initial public offering (IPO), are capitalized and recorded on the balance sheet. As of September 30, 2021, $2.5 million of deferred offering costs were recorded on the balance sheet under Prepaid expenses and other current assets. The Company successfully completed its IPO in October 2021.

Net loss per share attributable to common stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders, by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, redeemable convertible preferred stock warrants, convertible notes, common stock subject to repurchase, and common stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of redeemable convertible preferred stock do not have a contractual obligation to share in the Company’s losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for the nine months ended

September 30, 2021 and 2020, diluted net loss per common share is the same as basic net loss per common share for the two periods presented.

3. Revenue

Disaggregation of revenue

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Minerva ES	46.1 %	45.0 %	46.8 %	59.5 %
Genesys HTA	31.2 %	35.4 %	32.0 %	26.2 %
Symphion	22.0 %	18.7 %	20.2 %	13.6 %
Other	0.7 %	0.9 %	1.0 %	0.7 %
	100 %	100 %	100 %	100 %

For the three and nine-month periods ended September 30, 2021 and 2020, approximately 99.0% of the Company's revenue is subject to point-in-time recognition for single-use (disposable) products and capital equipment. Sale of extended warranties on capital equipment represents less than 1.0% of the Company's revenue. In addition, more than 95.0% of the Company's total revenue is derived from the sale of single-use (disposable) products; therefore, the Company did not include disaggregated revenue data to present the amounts attributed to capital equipment, associated warranties, and miscellaneous revenue separately.

Contract balances

The Company's contract balances consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accounts receivable	$ 6,758	$ 8,379
Contract liability—current	$ 262	$ 219

4. Fair value measurements

ASC 820, Fair Value Measurements and Disclosures, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis—Financial assets held by the Company measured at fair value on a recurring basis include money market funds which are classified as Level 1 within the fair value hierarchy as the inputs used to measure fair value are quoted prices in active markets for identical assets. Derivative liabilities, contingent considerations liability and redeemable convertible preferred stock warrant liabilities are remeasured at fair value as of each reporting period (see Note 10).

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Fair value of assets and liabilities

The following tables summarizes the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 5,640	$ —	$ —	$ 5,640
Total financial assets	$ 5,640	$ —	$ —	$ 5,640
Liability:				
Derivative liabilities	$ —	$ —	$ 22,764	$ 22,764
Contingent consideration liability	—	—	24,447	24,447
Redeemable convertible preferred stock warrant liability	—	—	577	577
Total financial liabilities	$ —	$ —	$ 47,788	$ 47,788

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 14,638	$ —	$ —	$ 14,638
Total financial assets	$ 14,638	$ —	$ —	$ 14,638
Liability:				
Derivative liabilities	$ —	$ —	$ 38,007	$ 38,007
Contingent consideration liability	—	—	23,667	23,667
Redeemable convertible preferred stock warrant liability	—	—	42	42
Total financial liabilities	$ —	$ —	$ 61,716	$ 61,716

The redeemable convertible preferred stock warrant liability is classified within Level 3 of the fair value hierarchy because it is valued using the Black-Scholes pricing model, which requires subjective unobservable inputs (See Note 10).

Contingent consideration related to the BSC development and revenue milestones is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios using a Monte Carlo simulation, and is subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in general and administrative expense, in the statements of operations.

The fair value of the mandatory prepayment derivative liability, as a result of a change in control, was calculated using the “with and without” methodology at loan issuance. The “with and without” methodology involves valuing the term loan on an as-is basis and then valuing the term loan without the embedded derivatives. The difference between the value of the term loan with the embedded derivatives and the value without each individual embedded derivative equals the fair value of the embedded derivative. On the subsequent dates, the Company used an income approach to value the term loan derivative liabilities, where the proceeds to the lenders were estimated, adjusted by the opportunity cost of the lenders for foregoing the debt portion of the instrument. As of September 30, 2021, the mandatory prepayment derivative liability was valued using estimated time to exit of 0.1 years and a discount rate of 18.5%. Changes in the estimated fair value of the bifurcated embedded derivative are reported as gains or losses in the statements of operations.

The Company valued the convertible notes derivative liabilities using the income approach, where the proceeds to the convertible noteholders were estimated under different future scenarios, adjusted by the opportunity cost of the convertible noteholders for foregoing the debt portion of the instrument. Each outcome was probability-weighted based on future estimates.

The convertible notes derivative liabilities were determined using the following assumptions:

	September 30, 2021	December 31, 2020
Expected exit date	10/31/2021	6/30/2022
Discount rate	19.1 %	21.0 %

The change in fair value of the redeemable convertible preferred stock warrant liability, derivative liabilities and contingent consideration liability are summarized below (in thousands)

	Redeemable convertible preferred stock warrant liability	Derivative liabilities	Contingent consideration liability
Beginning fair value, January 1, 2020	$ 75	$ 39,499	$ —
Recognition	—	6,848	23,842
Change in fair value	(33)	(8,340)	(175)
Ending fair value, December 31, 2020	$ 42	$ 38,007	$ 23,667

	Redeemable convertible preferred stock warrant liability	Derivative liabilities	Contingent consideration liability
Beginning fair value, January 1, 2021	$ 42	$ 38,007	$ 23,667
Change in fair value	582	6,121	(204)
Ending fair value, March 31, 2021	624	44,128	23,463
Change in fair value	(50)	2,019	1,121
Ending fair value, June 30, 2021	574	46,147	24,584
Change in fair value	3	(23,383)	(137)
Ending fair value, September 30, 2021	$ 577	$ 22,764	$ 24,447

5. Balance Sheet Components

Cash and cash equivalents

The Company’s cash and cash equivalents consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Cash	$ 488	$ 2,721
Cash equivalents:		
Money market funds	5,640	14,638
Total cash and cash equivalents	$ **6,128**	$ **17,359**

Inventory

Inventory consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Finished goods	$ 9,297	$ 5,068
Component materials	5,663	5,133
Total inventory	$ **14,960**	$ **10,201**

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Prepaid expenses	$ 1,794	$ 1,794
Deferred offering cost	2,505	—
Prepaid insurance	271	122
Other current assets	170	363
Total prepaid expenses and other current assets	$ **4,740**	$ **2,279**

Property and equipment, net

Property and equipment, net consist of the following (in thousands):

	Useful life (years)	September 30, 2021	December 31, 2020
Computers and software	2	$ 730	$ 653
Machinery and equipment	3	1,000	954
Furniture and fixtures	7	48	48
Tools and dies	2	941	936
Construction in progress	—	421	—
Equipment under customer usage agreements	3	9,282	7,918
Leasehold improvements	Lesser of useful life or lease term	155	155
		12,577	10,664
Less: accumulated depreciation and amortization		(8,786)	(7,784)
Property and equipment, net		$ **3,791**	$ **2,880**

Depreciation and amortization expense on property and equipment was $0.6 million and $0.5 million, for the three month periods ended September 30, 2021 and 2020, respectively and was $1.8 million and $1.3 million, for the nine month periods ended September 30, 2021 and 2020, respectively. Of this amount, $0.5 million, and $0.4 million, for the three month periods ended September 30, 2021 and 2020 and $1.6 million, and $1.1 million, for the nine month periods ended September 30, 2021 and 2020, respectively, was related to equipment under customer usage agreements recorded to cost of goods sold.

Intangible asset, net

Intangible asset, net consist of the following (in thousands):

	Useful life (years)	September 30, 2021	December 31, 2020
Trademarks	6.5	$ 3,969	$ 3,969
Developed technology	10	30,819	30,819
Customer relationships	3	13,466	13,466
		48,254	48,254
Less: accumulated depreciation and amortization		(11,249)	(5,113)
Intangible asset, net		**$ 37,005**	**$ 43,141**

Amortization expense on intangible assets was $2.0 million for the three month periods ended September 30, 2021 and September 30, 2020. Amortization expense on intangible assets was $6.1 million and $3.1 million, for the nine month periods ended September 30, 2021 and September 30, 2020, respectively.

Future amortization expense of intangible assets as of September 30, 2021 is as follows (in thousands):

Year Ending September 30,	
2021 (remaining three months)	$ 2,045
2022	8,182
2023	5,376
2024	3,693
2025	3,693
Thereafter	14,016
Total	$ 37,005

Accrued compensation

Accrued compensation consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued vacation	$ 1,379	$ 1,184
Accrued bonuses	857	831
Accrued commissions	528	828
Other accrued personnel related expenses	95	46
Total accrued compensation	$ **2,859**	$ **2,889**

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrual for litigation	$ 7,203	$ 7,203
Accrued professional fees	1,460	824
Accrued sales and use taxes	612	754
Deferred rent	322	445
Accrual for inventory in transit	658	602
Contract liability	262	219
Others	860	157
Total accrued liabilities	**$ 11,377**	$ **10,204**

6. Business Combination

On May 11, 2020, the Company completed its acquisition of certain Intrauterine Health products consisting of the Genesys HTA System, Symphion Tissue Removal System, and the Resectr Tissue Resection Device (the acquired IUH products) from BSC. This transaction was accounted for as a business combination.

The following table summarizes the finalized allocation of the purchase price based on the estimated fair values of the acquired assets and assumed liabilities as of May 12, 2020 (in thousands):

Net assets acquired:	
Inventory	$ 7,846
Other receivable	271
Property and equipment	999
Trade names	3,969
Customer relationships	13,466
Developed technology	30,819
Warranty liability	(16)
Deferred tax liability	(132)
Negative goodwill	(643)
Purchase price	$ 56,579

In May and September 2021, the Company amended the Asset Purchase Agreement with BSC to modify the delayed consideration payment and contingent consideration due as follows: (1) the timing of the delayed $15.0 million payment was deferred from May 11, 2021 to the earlier of 15 days post-IPO or November 1, 2021; (2) the timing of the $10.0 million Development Milestone payment was changed to 15 days post-IPO or, if the IPO has not been completed by November 1, 2021, upon the earlier of the closing of the Company's first financing after November 1, 2021 or the date that the first Revenue Milestone Payment is due and it was agreed that the Development Milestone payment was achieved; and (3) the first Revenue Milestone Payment was modified from either $5.0 million if net revenue from the acquired IUH products exceeds $26.0 million in 2021 or $10.0 million if net revenue exceeds $30.0 million in 2021, to either $5.0 million if revenue from acquired IUH products in 2021 is less than $30.0 million or $10.0 million if more than $30.0 million in 2021. As a result, fair value of contingent consideration has changed by $0.8 million which was recognized in general and administrative expense in the statement of operations for the nine month period ended on September 30, 2021.

Pro-forma financial information (unaudited)

The unaudited pro forma revenue and net loss for the nine-months ended September 30, 2020 assuming the acquisition had occurred on January 1, 2019 was $31.2 million and $12.0 million respectively. The revenue for IUH products for the nine-months ended September 30, 2020 was $9.9 million.

7. Debt

Ares term loan

On December 30, 2019, the Company entered into a Credit Agreement (the Ares Agreement) with Ares Capital Corporation and Ares Direct Finance I LP (collectively, Ares) to raise up to $40.0 million in debt financing (Ares Loan) consisting of $30.0 million advanced at the closing of the agreement (Tranche A), with the option to draw up to an additional $10.0 million (Tranche B) on or before December 31, 2020, which was conditioned upon achieving a minimum of $30.0 million in net revenues in the prior 12-month

period. The Ares Loan has a three-year term maturing on December 30, 2022, which includes eight quarters of interest-only payments followed by four quarters of equal payments of principal and interest. The interest-only period could be extended to ten quarters if the Company satisfied certain amortization period extension conditions prior to December 31, 2021. In May 2020, the Company satisfied one of the amortization period extension conditions and the interest-only period was extended to ten quarters.

Borrowings under the Ares Agreement, including the Ares Loan, bear interest at either the ABR plus 8.5% per annum or the Eurodollar Rate plus 9.5% per annum, as applicable. The ABR equals the greatest of (a) 3.0%, (b) the prime rate, (c) the federal funds rate plus 0.5% and (d) the three-month Eurodollar Rate plus 1.0%. The Eurodollar Rate equals the greater of (a) 2.0% and (b) the rate per annum appearing on Bloomberg Professional Service Page BBAM1 offered rate for deposits in U.S. dollars at approximately two business days prior to the first day of such interest period for a three (3) month term; multiplied by the Statutory Reserve Rate. The Statutory Reserve Rate is based on a fraction, the numerator of which is the number one and the denominator of which is the number one minus the applicable reserve percentage for that day. Payments of interest under Ares Loan are to be made quarterly commencing on March 31, 2020. Through December 31, 2021, the Company has the option to pay all accrued interest in cash or by paying up to 50.0% of accrued interest in kind (PIK interest) by increasing the principal amount of Ares Loan. On each payment date through June 30, 2021, the Company elected the PIK option, issuing PIK notes totaling $2.9 million. For three months ended September 30, 2021, the Company did not use PIK option and paid all interest in cash. As of September 30, 2021 and December 31, 2020, the Ares Loan had an annual effective interest rate of 24.9% and 22.7% per annum, respectively.

The Ares Loan is collateralized by substantially all of the Company’s assets. The Company may prepay the loan, subject to prepayment premium equal to 30.0% of the principal amount being prepaid less all interest payments and fees paid in cash on or prior to the date of such prepayment, provided that in no event shall the prepayment premium be less than zero.

The Ares Loan includes a fee upon repayment of the loan ranging from 4.0% to 10.0% of the aggregate principal amount being prepaid or repaid including all PIK notes added to the principal amount. The Ares Agreement includes customary restrictive covenants, financial covenants, events of default and other customary terms and conditions. The financial covenants in the Ares Agreement require the Company to have revenue for the four consecutive fiscal quarters period ending on March 31, 2020, and the last day of each June, September, December and March thereafter to be not less than the minimum revenue amount specified in the Ares Agreement and maintain a minimum cash and cash equivalents balance of $5.0 million at any time.

In January 2021, the Company entered into a waiver and amendment agreement to the Ares Agreement to receive a waiver for certain reporting covenants for which the Company was not in compliance. Additionally, the amendment extended the Tranche B availability date to June 30, 2021. The amendment was accounted for as a debt modification and no gain or loss was recognized. In March 2021, the Company entered into a second amendment to the Ares Agreement to extend the compliance period for certain reporting covenants. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In July 2021, the Company amended the terms of the Ares Agreement to waive a default in connection with the Company’s failure to satisfy a covenant relating to delivery of financial statements and modify that financial reporting covenant. The amendment also served to modify the fee due to Ares upon repayment of the loan from a variable amount based on equity value of the Company to a fixed exit fee of 6.25% of the principal amount of the Loans funded under the Ares Agreement. In addition, the timing for delivery of the Company’s annual audited financial statements was amended to 210 days from the end of the fiscal year for the year ended December 31, 2020. The amendment was accounted for as a debt modification and no gain or loss was recognized.

The Company may be required to make mandatory prepayments of the Ares Loan upon the occurrence of specified prepayment trigger events, including the occurrence of any event of default or the occurrence of a change in control event. Upon the prepayment of all or any of the outstanding principal balance, the Company shall pay, in addition to such prepayment, the prepayment premium noted above. As Ares may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The mandatory prepayment derivative liability had a fair value of $4.3 million upon entering into the Ares Agreement, which was accounted for as a debt discount.

On October 8, 2021, the Company used most of the proceeds of the Canadian Imperial Bank of Commerce (CIBC) Loan to repay the Company’s entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of $35.5 million. Refer to Note 15 for further details.

The Ares Loan consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Term loan principal	$ 32,846	$ 31,878
Less: Debt issuance cost and debt discount	(2,710)	(4,120)
Add: Exit fee	745	312
Term loan	$ 30,881	$ 28,070

The Company paid $1.4 million in fees to the lender and third parties which is reflected as a discount on the Ares Loan and is being accreted over the life of the term loan using the effective interest method.

During the three months ended September 30, 2021 and 2020 the Company recorded interest expense related to debt discount, debt issuance costs and exit fee of the Ares Loan of $0.8 million and $0.5 million. The Company recorded interest expense of $1.9 million and $1.4 million, for the nine months ended September 30, 2021 and 2020, respectively.

Interest expense on the Ares Loan was $1.7 million and $1.4 million during the three months ended September 30, 2021 and September 30, 2020, respectively, and $4.7 million and $4.1 million during the nine months ended September 30, 2021 and September 30, 2020, respectively.

As of September 30, 2021 and December 31, 2020 the estimated fair value of the aggregate outstanding derivative instrument associated with the Ares loan was $2.2 million and $4.5 million, respectively.

Paycheck Protection Program

In April 2020, the Company received $3.0 million from a Federal Small Business Administration (SBA)loan under the Paycheck Protection Program (the PPP Loan). The PPP Loan bore interest at 1.0% per year on the outstanding principal amount and was scheduled to mature 24 months from the date of the note. No payments were due for initial six-month period beginning on the date of the note. Afterwards, payments of principal and interest were due over the following 18 months. In June 2021, the Company received formal notification from the SBA that the Company's PPP Loan and interest had been formally forgiven in the principal amount of $3.0 million, plus interest of less than $0.1 million. As a result, the Company recognized $3.0 million a gain on extinguishment of PPP loan in the statement of operations for the nine-month period ended on September 30, 2021.

Convertible notes

In March and December 2018, the Company entered into Second Lien Loan and Security Agreements (the 2018 Note Agreements) with certain investors, for up to $20.0 million and $10.0 million in convertible notes, respectively. The convertible notes under these 2018 Note Agreements are subordinated to the term loan with Silicon Valley Bank and are also collateralized by assets, including cash and cash equivalents, accounts receivable, and property and equipment. Under the 2018 Note Agreements, the investors agreed to make one or more convertible notes (the 2018 Notes) to the Company during the period beginning in March and December 2018, respectively, and ending on the one-year anniversary of the 2018 Note Agreements, the maturity date.

In May and November 2019, the Company entered into additional Second Lien Loan and Security Agreements (the 2019 Note Agreements) with certain investors, each for up to $10.5 million in convertible notes. With the exception of the issuance date of offering and maturity date, all remaining contractual terms of the 2019 Note Agreement are similar to the 2018 Note Agreements. Under the 2019 Note Agreements, the investors agreed to make one or more convertible notes to the Company during the period beginning in May and November 2019 (the 2019 Notes) and ending on the one-year anniversary of the 2019 Note Agreement, the maturity date.

In December 2019, the Company and the Investors entered into an amendment to the 2018 Notes and 2019 Notes (the Amendment), which extended the maturity of the 2018 Notes and 2019 Notes to June 2023. Moreover, the 2018 Notes and 2019 Notes were subordinated to the term loan with Ares Capital Corporation, and collateralized by assets, including cash and cash equivalents, accounts receivable, and property and equipment. The Amendment was accounted for as a debt extinguishment, and the Company recognized a $1.8 million extinguishment gain to additional paid-in capital (APIC), as the transaction was with stockholders of the Company, as well as a $7.7 million extinguishment loss in other income (expense), net in the statement of operations for the year ended December 31, 2019.

In May 2020, the Company entered into another Second Lien Loan and Security Agreement (the 2020 Note Agreement) with certain investors, for up to $30.0 million in convertible notes. The convertible notes under the 2020 Note Agreement are subordinated to the term loan with Ares Capital Corporation and are also collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment. Under the 2020 Note Agreement, the investors agreed to make one or more convertible notes to the Company during the period beginning in May 2020 (the 2020 Notes), and ending on June 30, 2023, the maturity date.

On September 3, 2021, the Company amended the 2018 Note Agreements, 2019 Note Agreements, and 2020 Note Agreement to modify the maturity dates to December 31, 2026 and to automatically convert all principal and interest owing on our outstanding convertible promissory notes into shares of common stock if either (i) the offering price per share of our IPO is greater than $5.61 and the aggregate gross proceeds to the Company from the IPO are greater than $50.0 million or (ii) the Company receives a written request from the holders of at least 66 2/3% of the redeemable convertible preferred stock to convert all outstanding redeemable convertible preferred stock to common stock. The Amendment was accounted for as a debt extinguishment, and the Company recognized a $16.9 million extinguishment loss in the statement of operations for the three months and nine months ended September 30, 2021.

The 2018 Notes, 2019 Notes, and 2020 Notes (collectively, the Notes) accrue interest at a fixed rate of 8.0% per annum. Interest accrues until the Note is converted to stock or paid in full. Each Note is evidenced by a separate Secured Convertible Promissory Note.

The Notes converted to Series D redeemable convertible preferred stock upon the conversion of all of our preferred stock to common stock in connection with the IPO in October 2021.

The Company borrowed $29.2 million in 2018, $21.0 million in 2019, and $15.0 million in 2020 under the Second Lien Loan and Security Agreements with investors. At September 30, 2021, the Company retained the ability to draw up to an additional $15.0 million under the 2020 Note Agreement in order to satisfy certain deferred payment obligations due to BSC.

The Notes contain embedded features – a qualified financing put, non-qualified financing put, and change of control put features that were bifurcated and accounted as derivative liabilities and recorded as debt discount. Debt discount is reported as a direct deduction to the carrying amount of the Notes and amortized using the effective interest rate over the life of the Notes as interest expense. The derivative liability is recognized at fair value at each reporting period, and classified as either short-term, or long-term, consistent with their respective host contract.

The Company valued the Notes derivative liabilities using the income approach, where the proceeds to the convertible noteholders were estimated under different future scenarios, adjusted by the opportunity cost of the convertible noteholders for foregoing the debt portion of the instrument as well as accrued interest through the maturity date.

As of September 30, 2021 and December 31, 2020, the estimated fair value of the aggregate outstanding derivative instrument associated with the convertible notes was $20.6 million, and, $33.5 million, respectively.

During the three and nine months ended September 30, 2021, the Company reported amortization of debt premium and discount of $0.4 million and $1.4 million, respectively. During the three and nine months ended September 30, 2020, the Company reported amortization of debt premium and discount of $0.5 million and $0.9 million, respectively.

The convertible note consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Principal	$ 78,377	$ 69,245
Less: debt issuance costs	—	(38)
Debt premium (discount)	10,120	(8,145)
Accrued interest	463	5,134
Convertible notes	$ 88,960	$ 66,196

During the three and nine months ended September 30, 2021, the Company recorded interest expense of $1.9 million and $5.9 million on the 2018, 2019 and 2020 Notes. As of September 30, 2021, the 2018, 2019 and 2020 Notes had accrued interest of $0.5 million.

During the three and nine months ended September 30, 2020, the Company recorded interest expense of $1.9 million and $4.6 million on the 2018, 2019 and 2020 Notes.

Contractual maturities of financing obligations

As of September 30, 2021, the aggregate future payments under the Ares Loan and Convertible Notes (including interest payments) are as follows (in thousands):

2021 (remaining three months)	$	493
2022		38,827
2023		—
2026		118,188
Total		157,508
Net of unamortized debt premium (discounts) and issuance costs		6,061
Less: interest		(43,727)
Term loan and convertible notes	$	119,842

8. Commitments and Contingencies

Operating lease

The future minimum rental obligations required under non-cancellable lease at September 30, 2021 are as follows (in thousands):

2021 (remaining three months)	$	218
2022		846
2023		358
Total minimum lease payments	$	1,422

Total rent expense was approximately $0.2 million, for each of the three months ended September 30, 2021 and 2020.

Total rent expense was approximately $0.3 million and $1.0 million, for the nine months ended September 30, 2021 and 2020, respectively.

Indemnification

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners and contractors. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The terms of these indemnification agreements are generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions.

Litigation

The Company regularly evaluates its exposure to threatened or pending litigation and other business contingencies. Because of the uncertainties related to the amount of loss from litigation and other business contingencies, the recording of losses relating to such exposures requires significant judgment about the potential range of outcomes. As additional information about current or future litigation or other contingencies becomes available, the Company will assess whether such information warrants the recording of additional expense.

In November 2015, Hologic, Inc. and Cytyc Surgical Products, LLC (collectively Hologic) filed a complaint against the Company alleging infringement of four patents (complaints against two of four infringement of patents later were dropped by Hologic). On July 27, 2018, a Delaware jury returned a verdict finding the Company did not willfully infringe on the patents and awarded Hologic $4.8 million in damages for lost profits and for royalties not included in the lost profits. Based on the result of the trial in July 2018 with Hologic, the Company recorded an accrual for potential legal losses of $4.8 million as of December 31, 2017 with a corresponding expense within general and administrative expenses. After the completion of post-trial motions and after the final orders from the courts, in July 2019, the Company filed a motion of appeal with the U.S. District Court for the District of Delaware. At the time of filing the appeal, the updated damages calculation totaled $7.1 million and the related cash balance was restricted from withdrawal. A surety bond was generated and filed along with the appeal documents and included in restricted cash in the balance sheet. The additional damages were accrued for as of December 31, 2018. On April 22, 2020, the Court of Appeals for the Federal Circuit affirmed the verdict of the $7.1 million in total damages. In September 2020 the Company filed a petition with the U.S. Supreme Court on the matter of verdict of the legal case. The Company's petition was heard in late April 2021 and an opinion was issued in June 2021 (see below).

On July 8, 2020, Hologic sued the Company for willful infringement of the Hologic patent in the U.S. District Court for the District of Delaware, alleging that the new Minerva ES Handpiece infringed the now expired patent. The Company has answered, denying infringement and willfulness and alleges that the patent was invalid prior to expiry. Due to COVID-19, the case was stayed twice for 60 days. On January 22, 2021, Minerva filed a motion to stay this case until such time that the U.S. Supreme Court decides the matter to be heard in April, 2021 (see above). The court's response to the Company's motion to stay was granted. On June 29, 2021, the U.S. Supreme Court vacated and remanded the Federal Circuit's decision that the Company cannot challenge the validity of the '348 patent due to assignor estoppel. A decision from the Federal Circuit on remand as to the invalidity of the '348 patent is expected to take a few months.

In April 2017, the Company sued Hologic for willful infringement of a Company patent in the U.S. District Court for the Northern District of California. Hologic has answered, denying infringement and willfulness and alleging invalidity of the patent. The Company sought a preliminary injunction and that motion was denied. This matter was transferred to the U.S. District Court for the District of Delaware, where it has been assigned to the same judge presiding over the Hologic complaint. Due to COVID-19, the July 2020 trial date was delayed. On July 20, 2021, the district court granted Hologic's Daubert motion excluding certain expert opinions regarding infringement. On July 23, 2021, the district court found on summary judgment that Minerva's '208 patent is invalid, dismissed the case and entered judgment. On August 24, 2021, the Company filed a Notice of Appeal with the Court of Appeals for the Federal Circuit.

9. Income Taxes

The Company did not record an income tax provision for the three and nine months ended September 30, 2021 and the three months ended September 30, 2020. For the nine months ended September 30, 2020, the Company recorded an income tax benefit of $0.1 million related to a valuation allowance release in connection with its acquisition of assets from BSC. The Company's net deferred tax assets are fully offset by a valuation allowance, as the Company believes it is more likely than not the benefit will not be realized.

10. Redeemable Convertible Preferred Stock Warrants

Warrants for Series D redeemable convertible preferred stock

A summary of the outstanding redeemable convertible preferred stock warrants is as follows (in thousands, except per share and share amounts):

	September 30, 2021			
	Exercise price per share	Shares	Fair value of liability	Expiration date
Series D redeemable convertible preferred stock warrants	$ 11.31	77,842	$ 577	June 2029

	December 31, 2020			
	Exercise price per share	Shares	Fair value of liability	Expiration date
Series D redeemable convertible preferred stock warrants	$ 11.31	77,842	$ 42	June 2029

The redeemable convertible preferred stock warrant liability was valued using the following assumptions under the Black-Scholes option-pricing model:

	September 30, 2021	December 31, 2020
Expected dividends	0%	0%
Expected volatility	51.3% -55.0%	48.2% -52.4%
Risk-free interest rate	1.1% -1.4%	0.6% -0.8%
Expected warrant life	5.6-7.8 years	6.4-8.6 years

11. Stockholders' Deficit

Common stock

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 144,406,928 shares of common stock.

In connection with the completion the IPO on October 21, 2021, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of $0.001 per share and 5,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

Shares reserved for future issuance

The Company has reserved shares of common stock for future issuances as follows:

	September, 30 2021	December, 31 2020
Series A redeemable convertible preferred stock outstanding	450,692	450,692
Series B redeemable convertible preferred stock outstanding	675,397	675,397
Series C redeemable convertible preferred stock outstanding	2,223,888	2,223,888
Series D redeemable convertible preferred stock outstanding	9,047,861	9,047,861
Warrants to purchase Series D redeemable convertible preferred stock	77,842	77,842
Convertible notes*	—	—
Common stock options issued and outstanding	2,170,894	2,466,594
Common stock available for future grants	59,187	67,010

* At September 30, 2021 and December 31, 2020, the conversion of the convertible notes into redeemable convertible preferred stock was dependent on the outstanding loan balance including accrued interest and the conversion stock per share price at the date of qualified equity financing, non-qualified equity financing, or a change of control event. These factors were not estimable and the number of redeemable convertible preferred stock was not determinable. There were no conversions of convertible notes to preferred stock for the nine month period ended September 30, 2021 and twelve month period ended December 31, 2020.

2008 Stock Plan, as amended (the Plan)

Options

A summary of stock option activity is set forth below (in thousands, except share and per share data):

	Number of Shares Available for Grant	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2021	67,010	2,466,594	$ 0.61	5.21	—
Options authorized	1,653,955	—			
Options granted	(1,784,086)	1,784,086	$ 11.25		
Options exercised	—	(1,957,478)	$ 0.61		
Options forfeited or cancelled	122,308	(122,308)	$ 1.48		
Outstanding, September 30, 2021	59,187	2,170,894	$ 9.31	8.86	$ 8,283
Shares exercisable September 30, 2021		1,451,709	$ 9.28	8.57	$ 5,579
Vested and expected to vest, September 30, 2021		2,170,894	$ 9.31	8.86	$ 8,283

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company’s common stock for stock options that were in-the-money at September 30, 2021.

During the three and nine months ended September 30, 2021, the aggregate intrinsic value of stock options exercised was $0.7 million and $1.5 million, respectively. The aggregate intrinsic value of stock options exercised was zero, for each of three and nine months ended September 30, 2020.

The total fair value of options that vested during the nine months ended September 30, 2021 and 2020 was $5.1 million and $0.5 million, respectively. The options granted during the nine months ended September 30, 2021 and 2020 had a weighted-average per share grant-date fair value of $7.07 and $0.36 per share, respectively. As of September 30, 2021, the total unrecognized stock-based compensation expense related to unvested stock options was $10.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.76 years.

Early exercise of stock options

The terms of the Plan permit the exercise of certain options granted under the Plan prior to vesting, subject to required approvals. The shares are subject to the Company’s lapsing repurchase right upon termination of employment at the original purchase price. The proceeds initially are recorded in accrued current liabilities from the early exercise of stock options and are reclassified to additional paid-in capital as the Company’s repurchase right lapses. During the nine months ended September 30, 2021 and September 30, 2020, the Company had no repurchases of common stock. As of September 30, 2020, there were no shares subject to repurchase. As of September 30, 2021 and December 31, 2020, there were 410,788 and 136,032 shares that were subject to repurchase, respectively. The

aggregate exercise prices of early exercised shares as of September 30, 2021 and December 31, 2020 was $0.3 million and $0.1 million, respectively, which were recorded in other current liabilities on the balance sheets.

Stock-based compensation associated with awards to employees and non-employees

On April 9, 2020, the Company's Board of Directors approved the repricing of all outstanding stock options for employees, officers and consultants. The Company has treated the repricing as a modification of terms of the options outstanding. The fair value of the modification was determined as the difference in the fair value of each option immediately before and after the repricing using the Black-Scholes option pricing model.

The repricing resulted in an incremental compensation cost of less than $0.1 million and $0.3 million for the nine months ended September 2021 and 2020, respectively.

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of goods sold	$ 66	$ 46	$ 236	$ 116
Sales and marketing	406	49	1,701	256
Research and development	8	1	127	7
General and administrative	595	109	3,620	375
Total	$ 1,075	$ 205	$ 5,684	$ 754

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2021	2020
Expected volatility	72.9%-75.9%	61.6% - 75.2%
Risk-free interest rate	0.6%-1.1%	0.3%-0.7%
Dividend yield	0%	0%
Expected term	5-6.1 years	5-6.1 years

12. Net Loss Per Share Attributable To Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period.

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except share and per share amounts)	2021	2020	2021	2020
Numerator				
Net loss attributable to common stockholders	$ (3,225)	$ (7,324)	$ (32,272)	$ (11,892)
Denominator:				
Weighted-average common stock outstanding	2,798,146	999,091	2,145,733	946,576
Net loss per share attributable to common stockholders, basic and diluted	$ (1.15)	$ (7.33)	$ (15.04)	$ (12.56)

The following potentially dilutive securities outstanding in common stock equivalent shares have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss:

	Nine Months Ended September 30,	
	2021	2020
Redeemable convertible preferred stock	12,397,838	12,397,838
Redeemable convertible preferred stock warrants	77,842	77,842
Unvested early exercised common stock options	410,788	—
Options to purchase common stock	2,170,894	2,573,122
Convertible notes*	—	—

* At September 30, 2021 and 2020, the conversion of the convertible notes into redeemable convertible preferred stock was dependent on the outstanding loan balance including accrued interest and the conversion stock per share price at the date of qualified equity financing, non-qualified equity financing, or a change of control event. These factors were

not estimable and the number of redeemable convertible preferred stock was not determinable. There were no conversions of convertible notes to preferred stock for the three and nine month periods ended September 30, 2021 and 2020.

13. Employee Benefit Plan

In 2012, the Company implemented a tax deferred savings plan, commonly referred to as a 401(k) plan. Employee contributions are withheld from standard payroll checks and are automatically withdrawn from the Company checking account and deposited into individual employee retirement accounts a few days following each payroll period. There has been no Company matching of employee contributions to the plan through September 30, 2021.

14. Related Party Transactions

A former member of the Company's Board of Directors owns 100% of Apical Instruments, Inc. (Apical). Apical supplies the Company with the RF Controllers used with its devices. During the nine months ended September 30, 2021 and 2020 fees charged by Apical for products purchased were $0.1 million. As of September 30, 2021 and 2020, amounts owed to Apical were zero and de minimis, respectively.

A former member of the Company's Board of Directors owns 90.0% of Hermes Innovations, LLC (Hermes). Hermes provides consulting services to the Company. During the nine months ended September 30, 2021 and 2020, expenses charged by Hermes for services were zero and de minimis. As of September 30, 2021 and 2020, amounts owed to Hermes were zero and de minimis.

The Company has issued convertible notes to certain redeemable convertible preferred stock holders (see Note 7).

15. Subsequent Events

CIBC Loan

On October 8, 2021, the Company entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce (CIBC), which provides for a senior secured term loan in an aggregate principal amount of $40.0 million (the CIBC Loan), the full amount of which was funded at the closing of the CIBC Agreement. Most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of $35.5 million.

The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the final obligations due and payable in full on October 8, 2026. The CIBC Loan accrues interest at a floating rate equal to 2.5% above the prime rate, and the interest is payable monthly in arrears. The Company may prepay the CIBC Loan in whole or in part, subject to a prepayment premium ranging from 0.0% to 3.0% of the principal amount of the CIBC Loan that is prepaid, depending on the timing of the prepayment. The Company became obligated to pay CIBC a success fee of $0.4 million upon certain change of control events, including upon the IPO in October 2021.

Obligations under the CIBC Agreement are secured by substantially all of the Company's assets. The CIBC Agreement contains customary affirmative and negative covenants, including, among other requirements, financial statement reporting requirements, limitations on the incurrence of certain indebtedness and liens, limitations on the disposition of assets, restrictions on certain transactions with affiliates, limitations on dividends and stock repurchases and a material adverse change event of default. The CIBC Agreement also contains financial covenants that require the Company to maintain minimum revenue and minimum cash.

The CIBC Agreement contains customary events of default subject to customary cure periods for certain defaults that include, among others, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, cross-defaults to certain other material indebtedness, bankruptcy and insolvency events with respect to the Company, and material judgements. Upon the occurrence and during the continuance of an event of default, CIBC may accelerate the Company's obligations under the CIBC Agreement, increase the applicable interest rate by 5.0% and exercise other remedies provided for under the CIBC Agreement and applicable law.

Initial Public Offering

In October 2021, upon the closing of the IPO, the Company issued and sold 6,250,000 shares of its common stock, at a public offering price of $12.00 per share. The Company received net proceeds of $ 69.8 million after deducting underwriting discounts and commissions. The total IPO offering costs other than underwriting discounts and commissions were $3.3 million. At September 30, 2021, $1.9 million of expenses incurred in connection with our IPO had not yet been paid and are included in Accounts payable and accrued liabilities on the interim condensed balance sheet as of September 30, 2021.

In connection with the completion of its IPO, on October 21, 2021, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of $0.001 per share and 5,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

Immediately prior to the closing of the IPO, $79.2 million in aggregate outstanding principal and accrued interest of the convertible promissory notes converted into 7,006,297 shares of redeemable convertible preferred stock at a conversion price of $11.31 per share. Also immediately prior to the closing, all outstanding shares of the Company's redeemable convertible preferred stock (including those issued upon conversion of the convertible promissory notes) converted into 19,404,135 shares of common stock which resulted in the reclassification of the carrying value of the preferred stock to common stock and additional paid-in capital.

Delayed Cash Purchase and Contingent Consideration

In November 2021, the Company paid BSC $15.0 million and $10.0 million for the delayed purchase obligation and Development Milestone payment, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q (Quarterly Report) and with our audited financial statements and notes thereto for the year ended December 31, 2020, included in our prospectus dated October 21, 2021 filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus").

Forward-Looking Statements

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview

We are a commercial-stage medical technology company focused on developing, manufacturing, and commercializing minimally invasive solutions to meet the distinct uterine healthcare needs of women. We have established a broad product line of commercially available, minimally invasive alternatives to hysterectomy, which are designed to address the most common causes of abnormal uterine bleeding (AUB) in most uterine anatomies. Our solutions can be used in a variety of medical treatment settings and aim to address the drawbacks associated with alternative treatment methods and to preserve the uterus by avoiding unnecessary hysterectomies.

We offer a broad suite of products for the treatment of structural and non-structural causes of AUB in most uterine anatomies. Our devices are utilized by obstetrician-gynecologists (OB/GYNs) across a variety of medical treatment settings, including hospitals, ambulatory surgical centers (ASCs), and physician offices.

Prior to May 2020, we sold only one product, the Minerva ES Endometrial Ablation System (Minerva ES) for women with AUB attributed to a non-structural cause. In May 2020, we acquired certain assets from Boston Scientific Corporation (BSC), including all rights to the Genesys HTA Endometrial Ablation System (Genesys HTA), Symphion Tissue Removal System (Symphion), and Resectr Tissue Resection (Resectr) product lines. The assets acquired included all future value associated with the developed products and rights of ownership for the products. We did not assume any liabilities associated with BSC's product activities, except for an immaterial warranty liability for installed Genesys HTA controllers. In addition to a deferred payment of $15.0 million due upon the earlier of 15 days following the consummation of the IPO or in November 2021, we expect to be liable for future variable milestone obligations to BSC, in the maximum amount of $30.0 million in total as described in our financial statements and notes based on future sales of the BSC products in 2021 and 2022 and a development based milestone with respect to certain Symphion controller improvements.

We utilize contract manufacturers for a significant portion of our products. This includes all of our controllers and significant subcomponents of our disposable devices. BSC manufactures the Genesys HTA and its ProCerva procedure set at its facility. In connection with the BSC product acquisition, we entered into a supply agreement with BSC relating to the Genesys HTA system and certain of its components. Pursuant to the supply agreement, BSC will supply us with systems and procedure sets until the earlier of February 2022 or such time as we have successfully transferred manufacturing to a third-party manufacturer. The Symphion and Resectr products were previously manufactured for BSC by various third-party manufacturers. We intend to rely on the same manufacturers to supply us with these products and we are in the process of assuming those relationships directly.

We market and sell our products through a direct sales force in the United States. Our target customer base includes approximately 19,000 OB/GYNs practicing in hospitals, ASCs, and physician offices. As of September 30, 2021, our commercial team consisted of approximately 80 field-based personnel that call on OB/GYNs in all major U.S. markets. Our sales and marketing programs focus on

educating physicians regarding the use of our products and on providing materials to help them educate their patients about our procedures. We also provide online patient-oriented educational materials about AUB and our products and procedures, which patients may use to consider and then discuss treatment options with their physicians.

Since our inception, we have generated significant losses. To date, we have financed our operations primarily through private placements of equity securities, debt financing arrangements, and sales of our products. In February, May and November 2019, we raised a total of $21.0 million through the sale and issuance of convertible promissory notes. In May 2020, we raised $15.0 million through the sale and issuance of additional convertible promissory notes. In December 2019, we entered into a Credit Agreement (the Ares Agreement) with Ares Capital Corporation and Ares Direct Finance I LP (collectively, Ares) providing for an aggregate of up to $40.0 million in debt financing, including an initial term loan of $30.0 million (the Ares Loan). We used part of the proceeds from the Ares Loan to repay the principal, interest, and fees due under our previously existing term loan with Silicon Valley Bank (SVB).

For the three months ended September 30, 2021, we generated revenue of $12.5 million, with a gross margin of 57.0% and a net loss of $3.2 million compared to revenue of $12.3 million, with a gross margin of 53.4% and a net loss of $7.3 million for the three months ended September 30, 2020.

For the nine months ended September 30, 2021, we generated revenue of $38.5 million, with a gross margin of 59.0% and a net loss of $32.3 million compared to revenue of $24.2 million, with a gross margin of 45.2% and a net loss of $11.9 million for the nine months ended September 30, 2020.

As of September 30, 2021, we had an accumulated deficit of $260.4 million, cash and cash equivalents of $6.1 million, $32.8 million outstanding under the Ares Agreement before debt discount, exit fees and issuance cost, and $78.8 million of convertible notes, including interest and before debt premium and issuance costs.

Impact of the COVID-19 pandemic

The global COVID-19 pandemic presents significant volatility, uncertainty and risks to us and has had, and continues to have, far reaching impacts on our business, operations, and financial results and condition, directly and indirectly. The access to many hospitals and other customer sites may be or may periodically be, depending on the current COVID-19 infection rates in the applicable location, restricted to essential personnel, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and other surgery centers have in the past suspended, and may suspend or continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers are located. Quarantines, shelter-in-place and similar government orders have also impacted and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in manufacturing and limited support functions continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our other employees and their families from potential exposure to COVID-19, until recently all other staff in our Santa Clara headquarters were requested to work from home. Certain of these other employees had begun to return to our headquarters full or part-time during the third quarter of 2021, although we are reviewing the impact of the delta variant of COVID-19 on employee safety. We continue to limit non-essential travel to protect the health and safety of our employees and customers.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that we consider prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

The Company experienced a second wave of slower than expected revenue growth in the nine months ended September 30, 2021 when certain state governments responding to a second wave of COVID-19 infection rates, including the Delta variant, reinstated hospital and ASC closures for elective procedures.
The ultimate extent of the impact of the COVID-19 pandemic on us is highly uncertain and subject to change. This impact may result in a material, adverse impact on liquidity, capital resources, supply chain, operations, revenue and may affect third parties on which the Company relies, and could worsen over time. The extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19 is unpredictable. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

Key Financial Data

We measure out business using both financial and operating data and use the following metrics and measures to assess the performance of our overall business, including identifying trends affecting our business, formulating business plans, making strategic decisions and assessing operational efficiencies.

Non-GAAP Financial Measures

Adjusted EBITDA and Adjusted EBITDA Margin

To provide additional information regarding our financial results, we have disclosed adjusted EBITDA and EBITDA here and elsewhere in this Quarterly Report. EBITDA and Adjusted EBITDA are key performance measures that our management uses to assess our financial performance and are also used for internal planning and forecasting purposes. We believe that these non-GAAP financial measures are useful to investors and other interested parties in analyzing our financial performance because they provide a comparable overview of our operations across historical periods. In addition, we believe that providing EBITDA and Adjusted EBITDA, together with a reconciliation of net loss to each such measure, helps investors make comparisons between our company and other companies that may have different capital structures, different tax rates, and/or different forms of employee compensation.

EBITDA and Adjusted EBITDA are used by our management team as an additional measure of our performance for purposes of business decision-making, including managing expenditures, and evaluating potential acquisitions. Period-to-period comparisons of EBITDA and Adjusted EBITDA help our management identify additional trends in our financial results that may not be shown solely by period-to-period comparisons of net income or income from continuing operations. Each of EBITDA and Adjusted EBITDA has inherent limitations because of the excluded items, and may not be directly comparable to similarly titled metrics used by other companies.

We calculate EBITDA as net income (loss) adjusted to exclude depreciation and amortization, interest expense and income tax benefit. We calculate Adjusted EBITDA by further excluding stock-based compensation expenses, bargain purchase gain, loss on extinguishment of long-term debt and convertible notes, gain on extinguishment of PPP loan, change in fair value of redeemable convertible preferred stock warrant liability, change in fair value of contingent consideration liability and change in fair value of derivative liabilities. EBITDA margin represents EBITDA as a percentage of revenue. Adjusted EBITDA margin represents Adjusted EBITDA as a percentage of revenue. EBITDA and Adjusted EBITDA should be viewed as measures of operating performance that are supplements to, and not substitutes for, operating (income) loss, net (income) loss and other U.S. GAAP measures of income andloss.

(in thousands, except percentage figures)	**Three months ended September 30,**		**Nine months ended September 30,**	
	2021	**2020**	**2021**	**2020**
	(unaudited)		**(unaudited)**	
Net Loss	$ (3,225)	$ (7,324)	$ (32,272)	$ (11,892)
Depreciation and amortization	2,614	2,554	7,948	4,415
Interest (income) expense	3,611	3,293	10,663	8,634
Income tax benefit	—	—	—	(132)
EBITDA	$ 3,000	$ (1,477)	$ (13,661)	$ 1,025
EBITDA margin	24.0 %	(12.0 %)	(35.5 %)	4.2 %
Net loss margin	(25.8 %)	(59.6 %)	(83.9 %)	(49.1 %)
Adjustments:				
Bargain purchase gain	—	—	—	(643)
Loss on extinguishment of convertible notes	16,853	—	16,853	—
Gain on extinguishment of PPP loan	—	—	(3,036)	—
Stock-based compensation expense	1,075	205	5,684	754
Change in fair value of redeemable convertible preferred stock warrant liability	3	(1)	535	(34)
Change in fair value of contingent consideration liability	(137)	—	780	—
Change in fair value of derivative liabilities	(23,383)	859	(15,243)	(9,201)
Adjusted EBITDA	$ (2,589)	$ (414)	$ (8,088)	$ (8,099)
Adjusted EBITDA margin	(20.7 %)	(3.4 %)	(21.0 %)	(33.4 %)

Components of our results of operations

Revenue

We currently derive substantially all our revenue from the sale of our products to hospitals, ASCs, and physician offices in the United States. We market and sell our products through a direct sales force. Nearly 99.0% of our revenue is point-in-time recognition for single-use (disposable) products and capital equipment. Sale of extended warranties on capital equipment represents less than 1.0% of

revenue. Further, more than 95.0% of our total revenue is derived from the sale of single-use (disposable) products and therefore revenue from the sale of capital equipment, associated warranties and miscellaneous revenue is not disaggregated in our financial statements.

Cost of goods sold

Cost of goods sold consists primarily of costs related to materials, components and subassemblies, payroll, and personnel-related expenses for our manufacturing and quality assurance employees, including expenses related to stock-based compensation, manufacturing overhead, charges for excess, obsolete and non-sellable inventories, and royalties. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision, and management personnel, an allocation of facilities and information technology expenses, including rent and utilities, and equipment depreciation. We record adjustments to our inventory valuation for estimated excess, obsolete, and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes, and overall market conditions. We expect cost of goods sold to increase in absolute dollars as more of our products are sold.

Gross margin

We calculate gross margin as gross profit divided by revenue. Our gross margin has been, and will continue to be, affected by a variety of factors, including production volumes, the cost of direct materials, product mix, manufacturing costs, product yields, headcount, and cost-reduction strategies. We expect our gross margin percentage to increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. However, we expect our gross margin to fluctuate from period to period based upon the factors described above and seasonality.

Operating expenses

Our operating expenses consisted of sales and marketing costs, general and administrative costs, and research and development costs. We expect to continue to invest in these activities.

Sales and marketing

We have made significant investments in building our commercial field organization and intend to make significant investments in sales and marketing activities in the future. Sales and marketing expense consist primarily of payroll and personnel-related costs for our sales and marketing personnel, including sales variable compensation, stock-based compensation expense, travel expenses, consulting, direct marketing, customer education, trade shows, and promotional expenses. Sales and marketing expenses also includes expenses related to the amortization of the value of customer relationships acquired from BSC.

We anticipate that our sales and marketing expenses will increase as we strategically invest to expand our business. We expect to hire additional sales personnel and related account management and sales support personnel to capture an increasing amount of our market opportunity. We also expect to continue our brand awareness and targeted marketing campaigns. As we scale our sales and marketing activities, we expect these expenses to increase.

General and administrative expenses

General and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense, professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses. We also recognize the change in value of the contingent consideration liability due to BSC for the potential future milestone payments in general and administrative expenses.

Research and development expenses

Research and development expenses have included clinical studies to demonstrate the safety and efficacy of our products, as well as obtain and retain FDA approval. Current research and development expenses consist primarily of costs incurred for the development of our products. These costs consist of engineering and research programs associated with our products under development and improvements to our existing products. These costs include prototype materials, laboratory supplies, regulatory expenses, and an allocation of facility overhead costs. Research and development expenses also include payroll and personnel-related costs and stock-based compensation expense for our research and development employees and consultants and acquisition of technology with no alternative future uses. We also recognize the amortization cost of intangible assets acquired from BSC for developed technology and patents and trademarks in research and development expenses beginning in May 2020. We expense research and development costs as incurred. We intend to continue making significant investments in research and development, clinical studies, and regulatory affairs to support future regulatory submissions for retaining and expanding indications of our products, support continuous improvements to our products, and develop future products that address abnormal uterine bleeding in a minimally invasive manner.

Interest expense and income

Interest expense consists primarily of interest expense related to our term loan facilities and convertible notes, including amortization of debt discount and issuance costs. Interest income is predominately derived from investing surplus cash in money market funds.

Other income and expenses

Other income and expenses primarily consist of changes in the fair value of derivative liabilities and redeemable convertible preferred stock warrant liability, gain/loss in loan extinguishment of debt, and bargain purchase gain. Upon exercise or expiration of the warrants, the final fair value of the warrant liability will be reclassified to stockholders' (equity)/deficit and we will no longer record any related periodic fair value adjustment. We will continue to adjust the derivative liabilities for changes in fair value at each balance sheet date until the convertible notes are converted or repaid, with any changes in fair value recognized in the statements of operations.

Results of operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our unaudited results of operations for the periods indicated:

	Three months ended September 30,			
	2021	2020	Change	% Change
Revenue	$ 12,506	$ 12,280	$ 226	1.8 %
Cost of goods sold	5,373	5,725	(352)	(6.1 %)
Gross profit	7,133	6,555	578	8.8 %
Operating expenses				
Sales and marketing	7,919	6,722	1,197	17.8 %
General and administrative	3,987	1,804	2,183	121.0 %
Research and development	1,367	1,200	167	13.9 %
Total operating expenses	13,273	9,726	3,547	36.5 %
Loss from operations	(6,140)	(3,171)	(2,969)	93.6 %
Interest expense	(3,611)	(3,293)	(318)	9.7 %
Change in fair value of derivative liabilities	23,383	(859)	24,242	(2,822.1 %)
Loss on extinguishment of convertible notes	(16,853)	—	(16,853)	100.0 %
Other income (expense), net	(4)	(1)	(3)	300.0 %
Net Loss	(3,225)	(7,324)	4,099	(56.0 %)
Net loss margin	(25.8 %)	(59.6 %)		

Revenue

Revenue increased by $0.2 million, or 1.8%, to $12.5 million during the three months ended September 30, 2021, compared to $12.3 million during the three months ended September 30, 2020. The increase in revenue was primarily attributable to the increase in volume of Genesys HTA and Symphion products as a result of a slight increased demand from our customers, partially offset by a decrease in revenue for Minerva ES products.

For the three months ended September 30, 2021 and 2020, sales of Minerva ES contributed 46.1% and 45.0% of revenue, respectively; sales of the Genesys HTA contributed 31.2% and 35.4% of revenue, respectively; sales of Symphion contributed 22.0% and 18.7% of revenue, respectively; and sales of other products and warranties contributed 0.7% and 0.9% of revenue, respectively.

Revenue was negatively impacted in the three months ended September 30, 2020 because elective procedures were restricted at ASCs across the country as a result of the COVID-19 pandemic. These restrictions were lifted in most ASCs across the country towards the end of the third quarter of 2020. Revenue growth was slower than expected in the three months ended September 30, 2021 when certain state governments responded to a second wave of COVID infection rates and reinstated hospital and ASC closures for elective procedures.

Cost of goods sold

Cost of goods sold decreased by $0.4 million, or 6.1%, to $5.4 million during the three months ended September 30, 2021, compared to $5.7 million during the three months ended September 30, 2020. The decrease was primarily due to growth in the sales volume of our Genesys HTA and Symphion products, which have lower costs.

Gross margin

Our gross margin increased from 53.4% for the three months ended September 30, 2020 to 57.0% for the three months ended September 30, 2021. The increase in gross margin was primarily due to the sales mix of our product portfolio, as described above.

Sales and marketing expenses

Sales and marketing expenses increased by $1.2 million, or 17.8%, to $7.9 million during the three months ended September 30, 2021, compared to $6.7 million during the three months ended September 30, 2020. The increase was primarily due to a $0.8 million increase in compensation and personnel related expenses due to growth in salesforce and a $0.4 million increase in case coverage and travel and entertainment expenses due to increase of in-person sales activities, $0.4 million increase in consulting, recruiting, website and other marketing related costs, partially offset by a $0.1 million decrease in commission expenses and $0.3 million decrease in distribution costs.

General and administrative expenses

General and administrative expenses increased by $2.2 million, or 121.0%, to $4.0 million during the three months ended September 30, 2021, compared to $1.8 million during the three months ended September 30, 2020. The increase was primarily due to a $1.1 million increase in compensation and personnel related expenses due to increases in headcount and stock-based compensation expenses, a $1.0 million increase in legal expenses in connection with our patent infringement lawsuit with Hologic, a $0.2 million increase in consulting, accounting, tax, and other services, and was partially offset by a $0.1 million decrease in expenses due to the change in value of the contingent consideration liability due to BSC for the milestones.

Research and development expenses

Research and development expenses increased by $0.2 million, or 13.9%, to $1.4 million during the three months ended September 30, 2021, compared to $1.2 million during the three months ended September 30, 2020. The increase was primarily due to a $0.1 million increase in controller and prototype expenses and $0.1 million increase in consulting and other services.

Interest expense and income

Interest expense increased by $0.3 million, or 9.7%, to $3.6 million during the three months ended September 30, 2021, compared to $3.3 million during the three months ended September 30, 2020, primarily due to higher average outstanding balances of our convertible notes and term loans during the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

Other income and expenses

	Three months ended September 30,			
(in thousands, except percentage figures)	**2021**	**2020**	**Change**	**% Change**
Change in fair value of derivative liabilities	$ 23,383	$ (859)	$ 24,242	(2822.1%)
Change in fair value of redeemable convertible preferred stock warrant liability	(3)	1	(4)	(400.0%)
Loss on extinguishment of convertible notes	(16,853)	—	(16,853)	100.0%
Other income (expense), net	(1)	(2)	1	(50.0%)
Total	$ 6,526	$ (860)	$ 7,386	(858.8%)

Changes in fair value of derivative liabilities increased by $24.2 million, or 2,822.1%, to $23.4 million of other income during the three months ended September 30, 2021, compared to $0.9 million of other expenses during the three months ended September 30, 2020, primarily due to management's view on the key assumptions that changed the probabilities of a qualified financing, change of control, non-qualified financing, and all other events that do not trigger put rights resulting in a gain on the change in fair value of $23.4 million. Additionally, the amendment of the 2018 Note Agreements and the 2019 Note Agreements (the Amendment) was

accounted for as a debt extinguishment, which resulted in a $16.9 million loss on extinguishment in other expenses for the three months ended September 30, 2021.

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our unaudited results of operations for the periods indicated:

	Nine months ended September 30,			
	2021	2020	Change	% Change
Revenue	$ 38,458	$ 24,219	$ 14,239	58.8 %
Cost of goods sold	15,760	13,284	2,476	18.6 %
Gross profit	22,698	10,935	11,763	107.6 %
Operating expenses				
Sales and marketing	22,883	16,205	6,678	41.2 %
General and administrative	18,115	5,888	12,227	207.7 %
Research and development	4,191	2,151	2,040	94.8 %
Total operating expenses	45,189	24,244	20,945	86.4 %
Loss from operations	(22,491)	(13,309)	(9,182)	69.0 %
Interest income	—	80	(80)	(100.0 %)
Interest expense	(10,663)	(8,714)	(1,949)	22.4 %
Change in fair value of derivative liabilities	15,243	9,201	6,042	65.7 %
Bargain purchase gain	—	643	(643)	(100.0 %)
Loss on extinguishment of convertible notes	(16,853)	—	(16,853)	100.0 %
Gain on extinguishment of PPP loan	3,036	—	3,036	100.0 %
Other income (expense), net	(544)	75	(619)	(825.3 %)
Net loss before income taxes	(32,272)	(12,024)	(20,248)	168.4 %
Income tax benefit	—	132	(132)	(100.0 %)
Net Loss	$ (32,272)	$ (11,892)	$ (20,380)	171.4 %
Net loss margin	(83.9 %)	(49.1 %)		

Revenue

Revenue increased by $14.2 million, or 58.8%, to $38.5 million during the nine months ended September 30, 2021,compared to $24.2 million during the nine months ended September 30, 2020. The increase was primarily due to the acquisition of BSC's intrauterine health assets in May 2020.

For the nine months ended September 30, 2021 and 2020, sales of Minerva ES contributed 46.8% and 59.5% of revenue, respectively; sales of the Genesys HTA contributed 32.0% and 26.2% of revenue, respectively; sales of Symphion contributed 20.2% and 13.6% and of revenue, respectively; and sales of other products and warranties contributed 1.0% and approximately 0.7% of revenue, respectively. Revenue was negatively impacted in the nine months ended September 30, 2020 because elective procedures were restricted at ASCs across the country as a result of the COVID-19 pandemic. These restrictions were lifted in most ASCs across the country towards the end of the third quarter of 2020. Revenue growth was slower than expected in the nine months ended September 30, 2021 when certain state governments responded to a second wave of COVID infection rates and reinstated hospital and ASC closures for elective procedures.

Cost of goods sold

Cost of goods sold increased by $2.5 million, or 18.6%, to $15.8 million during the nine months ended September 30, 2021, compared to $13.3 million during the nine months ended September 30, 2020. The increase was primarily due to growth in the sales volume of our newly acquired Genesys HTA and Symphion products.

Gross margin

Our gross margin increased from 45.2% for the nine months ended September 30, 2020 to 59.0% for the nine months ended September 30, 2021. The increase in gross margin was primarily due to the sales volume of our newly acquired Genesys HTA and Symphion products and resulting sales mix of our product portfolio.

Sales and marketing expenses

Sales and marketing expenses increased by $6.7 million, or 41.2%, to $22.9 million during the nine months ended September 30, 2021, compared to $16.2 million during the nine months ended September 30, 2020. The increase was primarily due to a $1.7 million increase in intangible amortization expense recorded for customer relationships as a result of the acquisition of BSC's intrauterine health assets in May 2020, a $2.6 million increase in compensation and personnel related expenses due to growth in salesforce, a $1.1 million increase in commission expenses due to an increase in sales volume, a $0.8 million increase in case coverage and travel and

entertainment expenses due to increase of in-person sales activities, a $0.4 million increase in marketing costs and website expenses, a $0.2 million increase in recruiting expenses due to increased efforts in expanding the salesforce, a $0.1 million increase in consulting and other services and a $0.2 million increase in use tax expenses related to field assets and insurance expenses, offset by $0.4 million decrease in distribution, customer training, seminar and other sales related expenses.

General and administrative expenses

General and administrative expenses increased by $12.2 million, or 207.7%, to $18.1 million during the nine months ended September 30, 2021, compared to $5.9 million during the nine months ended September 30, 2020. The increase was primarily due to a $5.0 million increase in compensation and personnel related expenses due to increases in headcount and stock-based compensation expenses, a $3.5 million increase in legal expenses in connection with our patent infringement lawsuit with Hologic, a $2.0 million increase in consulting, accounting, tax, and other services, a $0.8 million increase in expenses due to the change in value of the contingent consideration liability due to BSC for the milestones, a $0.5 million decrease in common cost allocation, a $0.9 million increase in business insurance, property taxes, merchant fees and other administrative expenses, offset by a $0.5 million decrease in rent expenses due to the new corporate office in Santa Clara.

Research and development expenses

Research and development expenses increased by $2.0 million, or 94.8%, to $4.2 million during the nine months ended September 30, 2021, compared to $2.2 million during the nine months ended September 30, 2020. The increase was primarily due to a $1.4 million increase in intangible amortization expense recorded for trademarks and developed technology as a result of the acquisition of BSC's intrauterine health assets in May 2020, a $0.4 million in product development expenses for Genesys HTA and Symphion products and a $0.2 million increase in compensation and personnel related expenses due to an increase in headcount, and stock-based compensation expenses.

Interest expense and income

Interest expense increased by $1.9 million, or 22.4%, to $10.7 million during the nine months ended September 30, 2021, compared to $8.7 million during the nine months ended September 30, 2020, primarily due to higher average outstanding balances of our convertible notes and term loans during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Interest income decreased by $0.1 million for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020, which was primarily due to a decrease of average balances of our money market funds during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Other income and expenses

	Nine months ended September 30,			
(in thousands, except percentage figures)	**2021**	**2020**	**Change**	**% Change**
Change in fair value of derivative liabilities	$ 15,243	$ 9,201	$ 6,042	65.7 %
Change in fair value of redeemable convertible preferred stock warrant liability	(535)	34	(569)	(1673.5 %)
Bargain purchase gain	—	643	(643)	(100.0 %)
Loss on extinguishment of convertible notes	(16,853)	—	(16,853)	100.0 %
Gain on extinguishment of PPP loan	3,036	—	3,036	100.0 %
Other income (expense), net	(9)	41	(50)	(122.0 %)
Total	$ 882	$ 9,919	$ (9,037)	(91.1 %)

Changes in fair value of derivative liabilities increased by $6 million, or 65.7%, to $15.2 million other income during the nine months ended September 30, 2021, compared to $9.2 million of other income during the nine months ended September 30, 2020, primarily due to management's view on the key assumptions that changed the probabilities of a qualified financing, change of control, non-qualified financing, and all other events that do not trigger put rights resulting in a gain on the change in fair value of $6.0 million.
The PPP loan principal and interest amount was forgiven in June 2021, which contributed $3.0 million gain on extinguishment of the PPP loan that we recorded in the nine months ended September 30, 2021.

The amendment of the 2018 Note Agreements and the 2019 Note Agreements (the Amendment) was accounted for as a debt extinguishment, which resulted in a $16.9 million loss on extinguishment in other expenses for the nine months ended September 30, 2021.
Additionally, other expense decreased by $0.6 million to $0.5 million during the nine months ended September 30, 2021, compared to less than $0.1 million during the nine months ended September 30, 2020, primarily due to changes in the fair value of our redeemable convertible preferred stock warrant liability that increased other expenses by $0.6 million. The bargain purchase gain of $0.6 million

was recorded in the nine months ended September 30, 2021 as a result of the acquisition of BSC's intrauterine health assets in May 2020.

Liquidity and capital resources

Prior to the Company's IPO in October 2021, we financed our operations primarily through private placements of equity securities, debt financing arrangements, and sales of our products. As of September 30, 2021, we had an accumulated deficit of $260.4 million, cash and cash equivalents of $6.1 million, $32.8 million outstanding under the Ares Agreement before debt discount and issuance cost, and $78.8 million of convertible notes, including interest and before debt premium, exit fees and issuance costs.

In February, May and November 2019, we raised a total of $21.0 million through the sale and issuance of additional convertible notes. In May 2020, we raised $15.0 million through the sale and issuance of additional convertible promissory notes. In December 2019, we entered into the Ares Agreement providing for an aggregate of up to $40.0 million in term loans, including an initial $30.0 million term loan. We used part of the proceeds from the Ares Loan to repay the principal, interest, and fees due under the previously existing term loan facility with SVB described below. In October 2021, we entered into the CIBC Agreement with CIBC which provides for a senior secured term loan in an aggregate principal amount of $40.0 million. Most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of $35.5 million.

SVB term loan

In May 2017, we entered into a Loan and Security Agreement (the 2017 SVB Agreement) with Silicon Valley Bank (SVB) for up to $10.0 million in term loans (the Initial SVB Loan). In May 2017, we borrowed $3.0 million at an interest rate of 5.0% per annum. In June 2017, we borrowed $2.0 million at an interest rate of 5.25%. In December 2017, we borrowed $3.0 million at an interest rate of 5.5% per annum. Interest rates were equal to the greater of one percent above the Prime Rate or 4.75% per annum. The remaining $2.0 million was not advanced. Interest payments began upon loan advance and principal payments began in April 2018. The loans all had maturity dates in December 2020. The SVB Loan had an effective interest rate of 8.2% per annum.

The borrowing arrangement also included a revolving line of credit for up to $5.0 million. The amount available for draw was limited by the lesser of the revolving line or the amount available under a borrowing base determined by the lender less the outstanding balance of any advances. The line of credit bore interest at a rate equal to the greater of one percent above the Prime Rate or 4.75% per annum and had a maturity date of May 2020.

In connection with the SVB Agreement and upon each loan advance, we issued a 10-year warrant to purchase shares of our Series D redeemable convertible preferred stock equal to 4.8% of the total term loan principal amount divided by (i) $11.31 or (ii) if exercised in connection with a subsequent equity financing, the lowest price per share sold in such financing, in each case subject to adjustment.

The debt discount was comprised of the end of term fee of $0.4 million, anniversary fees of $0.1 million, fair value of warrants issued of $0.2 million, and issuance costs of less than $0.1 million. The debt discount amortized to interest expense over the life of the loan using the effective interest method.

In July 2019, we amended and restated the 2017 SVB Agreement with SVB and WestRiver Innovation Lending Fund VIII, L.P. (WestRiver) to, among other things, receive a term loan advance of $5.0 million (the New SVB Loan) to repay the Initial SVB Loan in full. In connection with the entrance into the amendment of the SVB Agreement, we issued SVB and WestRiver warrants to purchase 43,878 shares of our Series D redeemable convertible preferred stock (Series D Warrants) at an exercise price of $11.31 per share. Series D Warrants had a fair value of $0.1 million as of the issuance date, which was accounted for as debt discount. We paid $0.2 million in fees to the lenders in connection with the amendment of SVB Agreement which were reflected as a discount on the loan and were accreted over the life of the loan using the effective interest method.

In July 2019, we used the proceeds of the New SVB Loan to repay all of our outstanding obligations under the 2017 SVB Agreement, amounting to $4.5 million, including principal of $4.1 million, and fees of $0.4 million. This repayment of the outstanding obligations under the 2017 SVB Agreement was accounted for as debt modification.

The New SVB Loan bore interest at an annual rate equal to the greater of (i) 7.5% and (ii) 2.0% above the Prime Rate. The New SVB Loan had a maturity date in June 2023. As of December 30, 2019, the New SVB Loan had an annual effective interest rate of 12.7% per year.

On December 30, 2019, we used the proceeds of the Ares Loan to repay all of our outstanding obligations under the New SVB Loan amounting to $5.4 million, including principal of $5.0 million and fees of $0.4 million. This repayment of the outstanding obligations under the New SVB Loan was accounted as extinguishment and we recorded a loss on extinguishment of $0.5 million.

Ares credit agreement

On December 30, 2019, we entered into the Ares Agreement that provided for an aggregate of up to $40.0 million in term loans, including an initial $30.0 million term loan. We used a portion of the proceeds from the Ares Loan to repay principal of $5.0 million and fees of $0.4 million due under the outstanding New SVB Loan. The Ares Agreement included a two-year interest-only period ending on December 31, 2021, and during such interest-only period, quarterly interest payments were due on the Ares Loan. Quarterly payments of principal of, and interest on, the Ares Loan were payable beginning on December 31, 2021; provided, if we satisfied certain conditions related to an intended sale or merger transaction or received net cash proceeds of at least $10.0 million from certain specified events, in each case before December 31, 2021, then the principal payments would have been deferred until June 2022. In May 2020, we satisfied one of the amortization period extension conditions and the interest-only period was extended to ten quarters. The Ares Loan had a maturity date of December 30, 2022.

Borrowings under the Ares Agreement, including the Ares Loan, bore interest at either the ABR plus 8.5% per annum or the Eurodollar Rate plus 9.5% per annum, as applicable. The ABR equaled the greatest of (a) 3.0%, (b) the prime rate, (c) the federal funds rate plus 0.5% and (d) the three-month Eurodollar Rate plus 1.0%. The Eurodollar Rate equaled the greater of (a) 2.0% and (b) the rate per annum appearing on Bloomberg Professional Service Page BBAM1 offered rate for deposits in U.S. dollars at approximately two business days prior to the first day of such interest period for a three (3) month term; multiplied by the Statutory Reserve Rate. The Statutory Reserve Rate was based on a fraction, the numerator of which is the number one and the denominator of which is the number one minus the applicable reserve percentage for that day.

Payments of interest under the Ares Loan were payable quarterly commencing on March 31, 2020. Through December 30, 2021, we had the option to pay all accrued interest in cash or to pay up to 50.0% of such accrued interest in kind (PIK) by increasing the then-aggregate principal amount of the Ares Loan by the amount of the accrued and unpaid interest in kind. In the event we made such an election, the applicable interest rate would have increased by 0.5%. On each payment date through December 31, 2020, we elected the PIK option, issuing PIK notes totaling $1.9 million. As of September 30, 2021, the Ares Loan had an annual effective interest rate of 24.9% per year.

Additionally, the Ares Agreement included a prepayment premium on the Ares Loan in an amount equal to the difference, if any, between (x) the principal amount of the prepayment amount multiplied by 1.30 minus (y) the sum of (i) the principal amount of the Ares Loan being prepaid as of the date of such prepayment plus (ii) all interest payments and fees paid on such Ares Loan in cash on or prior to the date of such prepayment (including the exit fee, if applicable).

Furthermore, we were required to pay an exit fee upon the maturity date or the earlier payment (or prepayment) of all remaining balances under the Ares Agreement in an amount ranging from 4.0% to 10.0% of the principal amount of the loans funded under the agreement based on exit fee equity value (as further described in the Ares Agreement). The Ares Agreement also included customary affirmative covenants, restrictive covenants, financial covenants, events of default, and other customary terms and conditions. The financial covenants in the Ares Agreement required us to have revenue for the four consecutive fiscal quarters ending on March 31, 2020, and the last day of each June, September, December, and March thereafter, of not less than the minimum revenue amount specified in the Ares Agreement and maintain a minimum cash and cash equivalents balance of $5.0 million at any time.

In January 2021, we entered into a waiver and amendment to the Ares Agreement providing for, among other things, a waiver of default in connection with our failure to satisfy a covenant relating to delivery of financial statements and a modification of that financial reporting covenant. Additionally, the amendment extended the availability date of the second tranche of funding to June 30, 2021. The amendment was accounted for as a debt modification and no gain or loss was recognized. In March 2021, we entered into a second amendment to the credit agreement, which, among other things, further amended that financial reporting covenant.

In July 2021, we entered into a waiver and amendment to the Ares Agreement providing for, among other things, a waiver of default in connection with our failure to satisfy a covenant relating to delivery of financial statements and a modification of that financial reporting covenant. The timing for delivery of our annual audited financial statements was amended to 210 days from the end of the fiscal year for the year ended December 31, 2020. The amendment also modified the fee due to Ares upon repayment of the loan from a variable amount based on our equity value to a fixed fee of 6.25% of the principal amount of the Loans funded under the Ares Agreement. The amendment was accounted for as a debt modification and no gain or loss was recognized

We were required to make mandatory prepayments of the Ares Loan upon the occurrence of specified prepayment trigger events, including the occurrence of any event of default or the occurrence of a change in control event. Upon the prepayment of all or any of the outstanding principal balance, we were required to pay, in addition to such prepayment, the prepayment premium noted above. As Ares could have exercised the option to require prepayment by us, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The mandatory prepayment derivative liability had a fair value of $4.3 million upon entering into the Ares Agreement, which was accounted for as a debt discount.

On October 8, 2021, most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of $35.5 million.

Paycheck Protection Program

In April 2020, we received $3.0 million in connection with our PPP Loan. The PPP Loan bore interest at 1.0% per year on the outstanding principal amount and was scheduled to mature 24 months from the date of the note. No payments were due for the six-month period beginning on the date of the note. Payments of principal and interest are due over the following 18 months. We applied for full forgiveness of the PPP Loan and in June 2021, we received formal notification from the Small Business Administration (SBA) that the Company's PPP loan and interest had been formally forgiven in the principal amount of $3,000,684 plus interest of $35,091.

Convertible notes

In March and December 2018, we entered into Note Purchase Agreements (the 2018 Note Agreements) with certain investors, for up to $20.0 million and $10.0 million in subordinated secured convertible promissory notes, respectively (collectively, the 2018 Notes). The loans under the 2018 Note Agreements were subordinated to the SVB Loan and collateralized by our assets, including cash and cash equivalents, accounts receivable, and property and equipment. All loans under the 2018 Note Agreements accrue interest at an annual compound interest rate of 8.0%.

In May and November 2019, we entered into additional Note Purchase Agreements (the 2019 Note Agreements) with certain investors, each for up to $10.5 million in subordinated secured convertible promissory notes, respectively (collectively, the 2019 Notes). With the exception of the date of offering and maturity date, all contractual terms of the 2019 Note Agreements and 2019 Notes are substantially similar to the 2018 Note Agreements and 2018 Notes.

In December 2019, we entered into an amendment to the 2018 Note Agreements and the 2019 Note Agreements (the Amendment), which extended the maturity of the 2018 Notes and 2019 Notes to June 2023. Moreover, the 2018 Notes and 2019 Notes were subordinated to the Ares Loan, and collateralized by assets, including cash and cash equivalents, accounts receivable, and property and equipment. The Amendment was accounted for as a debt extinguishment, and we recognized a $1.8 million extinguishment gain to additional paid-in capital (APIC), as the transaction was with our stockholders, as well as a $7.7 million loss on extinguishment in the statement of operations.

In May 2020, we entered into another Note Purchase Agreement (the 2020 Note Agreement) with certain investors, for up to $30.0 million in subordinated secured convertible promissory notes, (collectively, the 2020 Notes). The loans under the 2020 Note Agreement were also subordinated to the Ares Loan and collateralized by our assets, including cash and cash equivalents, accounts receivable, and property and equipment. All loans under the 2020 Note Agreement accrue interest at an annual compound interest rate of 8.0%.

We borrowed $29.2 million in 2018, $21.0 million in 2019, and $15.0 million in 2020 under the 2018 Note Purchase Agreements, 2019 Note Purchase Agreements and 2020 Note Purchase Agreement, respectively. On September 30, 2021 we retained the ability to draw up to an additional $15.0 million under the 2020 Note Agreement for the purpose of paying the Company's deferred payment obligation to BSC.

The Notes contain embedded features—a Qualified Financing put, Non-Qualified Financing put, and change of control put—that were bifurcated and accounted as a single derivative liability and recorded as a debt discount. Debt discount is reported as a direct deduction to the carrying amount of the Notes and amortized using the effective interest rate over the life of the Notes as interest expense. The derivative liability is recognized at fair value initially and subsequently measured at fair value with the change in fair value recorded in the statements of operations at each reporting period, and classified as either short-term, or long-term, consistent with their respective host contract.

The outstanding principal amount and all accrued and unpaid interest on the Notes automatically converted into shares of Series D redeemable convertible preferred stock, at a price per share equal to $11.31 per share, immediately prior to our IPO.

CIBC

On October 8, 2021, we entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce (CIBC), which provides for a senior secured term loan in an aggregate principal amount of $40.0 million (the CIBC Loan), the full amount of which was funded at the closing of the CIBC Agreement. Most of the proceeds of the CIBC Loan were used to repay our entire obligation under our existing loan agreement with Ares Capital Corporation, including the principal, interest, prepayment premium and fees, in a total amount of $35.5 million. The remaining proceeds will be used for working capital and general corporate purposes.

The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the final obligations due and payable in full on October 8, 2026. The CIBC Loan accrues interest at a floating rate equal to 2.50% above the prime rate, and the interest is payable monthly in arrears. We are obligated to pay CIBC a success fee of $0.4 million upon certain change of control events, including upon the closing of the IPO.

Future funding requirements

We expect to incur continued expenditures in the future in support of our commercialization efforts in the United States. In addition, we intend to continue to make investments in clinical studies, development of new products, and other ongoing research and development programs. We expect to incur additional ongoing costs associated with operating as a public company. We may incur additional expenses to expand our commercial organization and efforts, further enhance our research and development efforts, and pursue commercial opportunities outside of the United States.

As of September 30, 2021, we had cash and cash equivalents of $6.1 million. Based on our current planned operations, we expect to incur significant operating expenses as we continue to expand product sales and develop and commercialize new products. Our management believes that our operating losses and negative cash flows will continue into the foreseeable future.

We expect our existing capital resources including the proceeds from our IPO provide sufficient funding to finance our operations for at least 12 months from the issuance date of this Quarterly Report.
We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with product sales and develop and commercialize new products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the timing, receipt and amount of sales from our current and potential products;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the degree of success we experience in commercializing future products;
- the emergence of competing or complementary technologies; and
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and

Summary Statements of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

	Nine months ended September 30,	
	2021	**2020**
Net cash (used in) provided by:		
Operating activities	$ (11,306)	$ (10,570)
Investing activities	(888)	(15,726)
Financing activities	963	18,050
Net (decrease) increase in cash and cash equivalents	$ (11,231)	$ (8,246)

Cash flows used in operating activities

Net cash used in operating activities was $11.3 million for the nine months ended September 30, 2021, primarily attributable to a net loss of $32.3 million and a net change in our net operating assets and liabilities of $1.3 million, partially offset by non-cash charges of $22.3 million. Non-cash charges primarily consist of $15.2 million in change in fair value of derivatives liabilities, $16.9 million loss on long-term debt extinguishment, $7.9 million in depreciation and amortization, $5.7 million in stock-based compensation expense, $5.4 million in interest expense from long-term debt and convertible notes, $3.0 million gain on extinguishment of PPP loan, $3.4 million in amortization of debt discount and debt issuance costs, $0.8 million in change in fair value of contingent consideration liability, and $0.5 million in change in fair value of redeemable convertible preferred stock warrant liability. The change in our net operating assets and liabilities was primarily due to a $6.7 million increase in inventory, and a $2.5 million increase in prepaid expenses and other current assets. These changes were partially offset by a $6.2 million increase in accounts payable and accrued

liabilities resulting primarily from increases in our operating activities and accrued consulting expenses, and a $1.6 million decrease in accounts receivable.

Net cash used in operating activities was $10.6 million for the nine months ended September 30, 2020, primarily attributable to a net loss of $11.9 million and a net change in our net operating assets and liabilities of $1.2 million, partially offset by non-cash charges of $2.5 million. Non-cash charges primarily consist of $9.2 million in change in fair value of derivatives liabilities, $5.1 million in interest expense from long-term debt and convertible notes, $4.4 million in depreciation and amortization, $2.2 million in amortization of debt discount and debt issuance costs, $0.8 million in stock-based compensation expense, $0.6 million bargain purchase gain and $0.2 million deferred taxes and change in fair value of redeemable convertible preferred stock warrant liability. The change in our net operating assets and liabilities was primarily due to a $4.8 million increase in accounts receivable, a $1.9 million increase in prepaid expenses and other current assets. These changes were partially offset by a $5.3 million decrease in inventory and a $0.3 million increase in accounts payable and accrued liabilities resulting from an increase in our operating activities.

Cash flows used in investing activities

Net cash used in investing activities was $0.9 million for the nine months ended September 30, 2021, which consisted of $0.9 million used to purchase property and equipment.

Net cash used in investing activities was $15.7 million for the nine months ended September 30, 2020, which consisted of $15 million cash paid for the purchase of assets from BSC and $0.7 million used to purchase property and equipment.

Cash flows provided by financing activities

Net cash provided by financing activities was $0.9 million for the nine months ended September 30, 2021, which primarily relates to $0.9 million proceeds from issuance of common stock.

Net cash provided by financing activities was $18 million for the nine months ended September 30, 2020, which primarily relates to proceeds of $18 million from borrowing under term loans and convertible notes, net of payment of lender fees and costs.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of September 30, 2021 (in thousands):

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations[1]	$ 218	$ 1,204	$ —	$ —	$ 1,422
Debt obligations[2]	493	157,015	—	—	157,508
Total contractual obligations	$ 711	$ 158,219	$ —	$ —	$ 158,930

(1) We lease our office in Santa Clara, California under a non-cancellable operating lease which expires in May 2023. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

(2) In December 2019, we entered into the Ares Loan and borrowed $30.0 million and paid off in full all amounts outstanding under the New SVB Loan. As of September 30, 2021, we had $78.8 million of outstanding principal and accrued interest before debt discount under our Notes, $32.8 million in principal before debt discount, issuance costs and exit fees under the Ares Loan. In June 2021, we received formal notification from the SBA that the Company's PPP loan and interest had been formally forgiven in the principal amount of $3,000,684 plus interest of $35,091. In September 2021, we amended the 2018 Note Agreements, 2019 Note Agreements and 2020 Note Agreement to modify the maturity dates to December 31, 2026 and to automatically convert all principal and interest owing on our outstanding convertible promissory notes into shares of common stock if either (i) the offering price per share of the IPO is greater than $5.61(as adjusted for recapitalization) and the aggregate gross proceeds to us from the IPO are greater than $50.0 million or (ii) we receive a written request from the holders of at least 66 2/3% of the redeemable convertible preferred stock to convert all outstanding redeemable convertible preferred stock to common stock. As of September 30, 2021, we had 157.5 million of aggregate future payments under our Notes, including interest payments.

We enter into contracts in the normal course of business with third-party contract organizations for pre-clinical studies and testing, manufacture and supply of our pre-clinical materials, and providing other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancellable obligations under these agreements are not material.

Critical accounting policies, significant judgments and use of estimates

There have been no material changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2021 as compared to those disclosed in the Prospectus.

Recent accounting pronouncements

See “Recent Accounting Pronouncements” in Note 3 to our audited financial statements for the year ended December 31, 2020, included in the Prospectus.

Emerging growth company status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company,” (EGC) can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our IPO.

JOBS Act accounting election

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest rate sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2021, we had cash and cash equivalents of $6.1 million, consisting of cash and money market funds. However, due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10.0% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income. As of September 30, 2021, we had $30.8 million of borrowings outstanding under our debt facility with Ares Capital, which bore interest at a rate of ABR plus 8.5% per annum or the Eurodollar Rate plus 9.5% per annum, as applicable. The ABR equaled the greatest of (a) 3.0%, (b) the prime rate, (c) the federal funds rate plus 0.5% and (d) the three-month Eurodollar Rate plus 1.0%. The Eurodollar Rate equaled the greater of (a) 2.0% and (b) the rate per annum appearing on Bloomberg Professional Service Page BBAM1 offered rate for deposits in U.S. dollars at approximately two business days prior to the first day of such interest period for a three month term; multiplied by the Statutory Reserve Rate. The Statutory Reserve Rate was based on a fraction, the numerator of which is the number one and the denominator of which is the number one minus the applicable reserve percentage for that day.
Additionally, the interest rate for our borrowings under the term loan is variable.

Foreign Currency Rate Risk

Because we do not have any material operations outside of the United States, we are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency rates in the future. We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein. Our operations may be subject to inflation in the future.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act prior to the filing of this Quarterly Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of

the period covered by this Quarterly Report, our disclosure controls and procedures were not effective as described below. However, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Material Weakness in Internal Control Over Financial Reporting

In connection with the preparation of our financial statements for the year ended December 31, 2020, we concluded there was a material weakness in our internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that was identified primarily related to having an insufficient number of qualified personnel within the accounting function, lack of segregation of duties and a lack of timely review over the financial statement close process.

Management's Plan to Remediate the Material Weakness

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in early 2021 and these measures were ongoing during 2021. These efforts focus on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe these measures will remediate the material weakness identified on or before the filing date of our Quarterly Report on Form 10-Q the quarterly period ended March 31, 2022 and strengthen our internal control over financial reporting. We are committed to continuing to improve our internal control processes and we will continue to diligently and vigorously review our financial reporting controls and procedures.

Changes in Internal Control Over Financial Reporting

There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q (Quarterly Report), there have been no material changes from the legal proceedings disclosed in our Prospectus, relating to our registration statement on Form S-1 (File No. 333- 259832)

Item 1A. Risk factors

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes thereto, before making a decision to invest in our common stock. The realization of any of the following risks could materially and adversely affect our business, financial condition, operating results and prospects. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Summary Risk Factors

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock speculative or risky include, among others:

- We have a limited history operating as a commercial company. We have a history of net losses, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability;
- We expect to derive substantially all of our future revenue from sales of our existing products, and these products could fail to generate significant revenue or achieve market adoption;
- Our business is dependent upon increasing awareness of treatment options for AUB and the broad adoption of our products by hospitals, physicians, and patients;
- If we fail to maintain and grow our direct sales force, differentiate our products from others, or develop broad brand awareness in a cost-effective manner, our growth will be impeded and our business will suffer;
- Our ability to increase our customer base and achieve broader market acceptance of our products with OB/GYNs and their patients depends on our ability to expand our marketing efforts;
- The market for our products is highly competitive;
- We rely heavily on third-party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers;
- We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies, and materials, and may not be able to find replacements or immediately transition to alternative suppliers, which makes us vulnerable to supply shortages and price fluctuations;
- COVID-19 and its variants and efforts to reduce its spread have negatively impacted, and may continue to negatively impact, our business, and operations;
- If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed;
- We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business;
- The failure of our products to meet patient's expectations, or the occurrence of adverse events related to our products, could impair our financial performance;
- The estimates of market opportunity and forecasts of market and revenue growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all;

- Our ability to compete depends on our ability to innovate successfully and deliver any product improvements and new products in a timely manner;
- Endometrial ablation and tissue resection involves surgical risks, and these procedures are contraindicated in certain patients, which may limit adoption;
- If we are unable to transition the manufacturing and operations for newly acquired product lines, or if we fail to comply with our obligations in our agreement with BSC related to such products, our business and operations could be harmed;
- Litigation against us could be costly and time-consuming to defend, and could result in additional liabilities;
- If our facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations;
- Our business is subject to quarterly, annual, and seasonal fluctuations;
- Adoption of our products depends upon appropriate physician education, and inadequate education may lead to negative patient outcomes, adversely affecting adoption of our products and our business;
- Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory;
- We may not be able to maintain satisfactory pricing and margins for our products;
- Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability;
- Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity;
- Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities;
- We may need additional funding and may not be able to raise capital when needed, which could force us to delay or reduce our product development programs and commercialization efforts;
- We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future;
- We may continue to acquire technologies and products from other companies, which acquisitions could fail to result in a commercial product or generate additional sales, divert management's attention, result in additional dilution to our stockholders, and otherwise disrupt our operations and harm our operating results;
- Our ability to utilize our net operating loss carryforwards may be limited;
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers' patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- If we decide to pursue an international expansion of our business, it will expose us to market, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States;
- We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business;
- We are currently a party to intellectual property litigation with Hologic, Inc. and may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products;
- We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own;

- Our success will depend on our ability to obtain, maintain, and protect our intellectual property rights. If we are unable to obtain and maintain patent or other intellectual property protection for any products we develop or for our technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be harmed;
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements;
- If we fail to comply with our obligations in our intellectual property licenses, including from Hermes Innovations, we could lose license rights that are important to our business;
- Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time;
- Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products;
- Our patent rights and other intellectual property may be subject to priority or inventorship disputes, interferences, and similar proceedings;
- If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed;
- We may not be able to protect our intellectual property rights throughout the world;
- If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected;
- We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition, and results of operations;
- Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition, and results of operations;
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business;
- Disruptions at the FDA, the SEC and other government agencies or foreign bodies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business;
- Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals, or certifications for our products or to manufacture, market, or distribute our products after clearance, approval, or certification is obtained;
- Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition, and results of operations;
- If coverage and reimbursement from third-party payors for procedures using our products significantly decline, physicians, hospitals, and other healthcare providers may be reluctant to use our products and our sales may decline;
- If we fail to comply with healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected;
- If we fail to obtain and maintain necessary regulatory clearances, approvals, or certifications for our products, or if clearances, approvals or certifications for future products and indications are delayed or not issued, our commercial operations would be harmed;
- The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines, or 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;

- Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA or another governmental authority, and if we fail to do so, we would be subject to sanctions that could negatively affect our reputation, business, financial condition, and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us;
- We may not receive, or may be delayed in receiving, the necessary clearances, approvals, or certifications for our future products or modifications to our current products, and failure to timely obtain necessary clearances, approvals, or certifications for our future products or modifications to our current products would adversely affect our ability to grow our business;
- Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market;
- Our products must be manufactured in accordance with federal, state, and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations. If we, or our suppliers, fail to comply with the FDA's QSR or similar foreign regulatory requirements, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer;
- Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements;
- Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability;
- An active trading market for our common stock may not be sustained;
- The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock;
- We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock;
- If securities or industry analysts do not continue to publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline;
- A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline;
- Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders;
- We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors;
- Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management;
- Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees;
- We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices;
- We have identified a material weakness in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce accurate financial statements on a timely basis;
- We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock;

- Our actual operating results may differ significantly from any guidance that we provide;
- If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Risks related to our business and products

We have a limited history operating as a commercial company. We have a history of net losses, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.

We have incurred significant operating losses since inception. Our net loss was $18.3 million for the year ended December 31, 2020 and $32.3 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $260.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. private placements of equity securities and debt. On October 21, 2021, the Company completed an IPO in which the Company issued and sold 6,2500,000 shares of its common stock at a public offering price of $12.00 per share, for aggregate gross proceeds of $75 million. The Company received approximately $69.8 million in net proceeds after deducting underwriting discounts and commissions.

The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products and acquire new products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure and product improvements.

We received United States Food and Drug Administration (FDA) premarket approval for our Minerva Endometrial Ablation System (Minerva ES) in July 2015, and acquired the Genesys HTA Endometrial Ablation System (Genesys HTA), Symphion Tissue Removal System (Symphion), and Resectr Tissue Resection Device (Resectr) from Boston Scientific Corporation (BSC) in May 2020, and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue devoting a substantial amount of our resources to expand commercialization efforts and increase adoption of our products to treat AUB and to develop additional products. These efforts may prove more costly than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses or at all. In addition, as a newly public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Accordingly, we expect to continue incurring operating losses for the foreseeable future and we cannot provide assurance that we will achieve profitability in the future or that, if we become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition, and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition, and results of operations.

We expect to derive substantially all of our future revenue from sales of our existing products, and these products could fail to generate significant revenue or achieve market adoption.

Currently, we market four products: Minerva ES, Genesys HTA, Symphion, and Resectr, which became commercially available in 2015, 2001, 2014, and 2016, respectively. We expect that sales of these products will account for substantially all of our revenue for at least the next several years. To date, a substantial majority of our product sales and revenue have been derived from a limited number of physicians who have adopted our products to treat AUB.

We recently acquired three of our four products, Genesys HTA, Symphion, and Resectr, from BSC in May 2020. We have limited experience marketing and selling these newly acquired products and the experience we do have has been limited by the impact of COVID-19 and its variants (COVID-19). If physicians and patients do not adopt our products as a preferred treatment for AUB, our operating results and our business will be harmed. It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

In addition, because we devote substantially all of our resources to these four products and rely on these products as our sole source of revenue, any factors that negatively impact these products, or result in a decrease in sales of our products, could have a material adverse effect on our business, financial condition, and results of operations.

Our business is dependent upon increasing awareness of treatment options for AUB and the broad adoption of our products by hospitals, physicians, and patients.

Our future growth and profitability largely depend on our ability to increase physician and patient awareness of treatment for AUB using our products and on the willingness of physicians to adopt our products and recommend them to their patients. Physicians may not adopt our products unless they are confident, based on experience, clinical data, medical society recommendations, and other analyses, that our products provide safe and effective treatment alternatives for AUB. We may have difficulty gaining widespread awareness of our products among physicians and patients. Even if we are able to raise awareness among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to patients for a variety of reasons, including:

- physician and hospital demand for our products, including the rate at which physicians recommend our products to their patients;
- long-standing relationships with competing companies with longer operating histories, more recognizable names, such as Hologic, Inc. and Medtronic plc, and more established distribution networks that sell competing products;
- lack of experience with our products and concerns that we are relatively new to market;
- the introduction of competing products or technologies that may be more effective, cheaper, safer, or easier to use than our products for treating AUB;
- negative selling efforts from providers of alternative products for treating AUB;
- reluctance to change to or use new products and procedures, including perceptions that our products are unproven, create new liabilities, or that they do not provide a substantial benefit over those offered by our competitors;
- time commitment and skill development that may be required to gain familiarity and proficiency with our products;
- positive or negative press or social media coverage of our products or competing products or procedures;
- physician and patient perceptions of our products as compared to other treatments for AUB, including with respect to safety or effectiveness;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- the continued availability of satisfactory reimbursement from healthcare payors for endometrial ablation or tissue resection procedures;
- our ability to maintain our current, or obtain further, regulatory clearances or approvals; and
- delays in, or failure by, our third-party suppliers to deliver products and components.

Physicians play a significant role in determining the course of a patient's treatment for AUB and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing, and education efforts primarily on obstetrician-gynecologists (OB/GYNs). Although we maintain a website with information that is useful to patients, we do not currently focus our marketing efforts directly on patients. If we are not able to effectively demonstrate to OB/GYNs that our products are safe and effective and confer benefits over other available treatment methods in a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that our products will achieve broad market acceptance among hospitals and physicians. Any failure of our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

As physicians are influenced by guidelines issued by physician organizations, such as the American College of Obstetricians and Gynecologists (ACOG), the rate of adoption and sales of our products to treat AUB may be heavily influenced by medical society recommendations. We believe the ACOG guidelines regarding treatment of AUB are of particular importance to the broader market acceptance of our products. The current ACOG guidelines on the management of AUB, contained in ACOG Practice Bulletin No. 81, cover endometrial ablation, and discuss technologies available for performing an endometrial ablation although they do not specifically mention our products. If ACOG issues a negative statement regarding endometrial ablation procedures in the future, physicians may not adopt or continue to use our products, which would have a material adverse effect on our business, financial condition, and results of operations. Additionally, if key opinion leaders who currently support endometrial ablation procedures cease to recommend endometrial ablation procedures or our products, our business, financial condition, and results of operations will be adversely affected.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or by the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products. If we are not successful, it could have a material adverse effect on our business, financial condition, and results of operations.

In addition, the rate of adoption of our products and sales of our products are heavily influenced by clinical data. Although in our Single-Arm Study the success rate of the Minerva endometrial ablation system was demonstrated to be statistically significantly greater when compared to an FDA-developed objective performance criteria (OPC), which utilized data from the pivotal clinical trials of the five previously FDA-approved endometrial ablation devices, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors, or third parties, or the interpretation of our clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to maintain and grow our direct sales force, differentiate our products from others, or develop broad brand awareness in a cost-effective manner, our growth will be impeded and our business will suffer.

We currently rely on our direct sales force to sell our products in targeted geographic regions, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in driving adoption of our products. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

In order to generate future growth, we plan on continuing to expand and leverage our sales infrastructure to increase our hospital, ASC, and physician office customer base and generate awareness of the benefits of using our products with OB/GYNs and their patients. Identifying and recruiting qualified sales personnel and educating them on our products, on applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense, and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition, and results of operations.

Our ability to increase our customer base and achieve broader market acceptance of our products with OB/GYNs and their patients depends on our ability to expand our marketing efforts.

We believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new accounts. We plan to dedicate significant resources to our marketing programs to explain the benefits of using our products and differentiate them from those of our competitors. Our business may be harmed if our marketing efforts and planned additional expenditures do not generate a corresponding increase in revenue. Brand promotion activities may not generate physician or patient awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain, and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

The market for our products is highly competitive. If our competitors are able to develop or market AUB treatments that are safer or more effective, or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.

Our industry is highly competitive, subject to change, and significantly affected by new product introductions and other activities of industry participants. We currently face direct competition for the treatment of AUB primarily from Hologic, Inc., Medtronic plc, and CooperSurgical, Inc., each of which currently markets an FDA-approved second-generation endometrial ablation or tissue resection device. Products commercialized by our competitors, other products that are currently in clinical trials or investigations, new drugs, or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs, or greater physician and patient acceptance, thereby reducing the demand for our endometrial and tissue resection products.

Additionally, because drug therapy is an alternative to endometrial ablation and tissue resection, our competitors also include many major pharmaceutical companies that manufacture hormonal drugs for women, either as a standalone therapy or in conjunction with a drug eluting intrauterine device (IUD). Some of our competitors that sell hormonal drugs, including Johnson & Johnson, Bayer AG, AbbVie, Inc., and Endo International plc, are large, well-established companies. Many of our competitors enjoy several competitive advantages, including:

- greater financial and human capital resources;
- longer operating histories with significantly greater name recognition;
- established relationships with physicians, customers, and third-party payors for their existing products;
- 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.

Because of the size of the market opportunity for the treatment of AUB, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. Given the high incidence of AUB and extensive ongoing research and technological progress, new AUB treatment options may be developed that could compete more effectively with our products.

We rely heavily on third-party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on our business, financial condition, and results of operations.

We rely heavily on third-party suppliers and contract manufacturers in the United States, China, Germany, and Costa Rica for raw materials, components, manufacturing, assembly, and sterilization of our products. We rely on third-party contractors to manufacture components of our Minerva ES disposable handpiece, while we conduct the final assembly of the handpiece at our Santa Clara facility. We are in the process of establishing a contract manufacturer in China to act as a second source for the final assembly of the disposable handpiece. We anticipate the new contract manufacturer will be operational in 2022. However, we cannot assure you that we will receive FDA approval for use of this contract manufacturing facility in a timely manner or at all. Until such time as we receive FDA approval for another contract manufacturer, our Santa Clara facility will remain the sole source for assembly of the disposable handpieces. We purchase the Minerva RF controller from another third-party manufacturer in the United States, and we then test and package the controller at our Santa Clara facility before placing the product in finished goods inventory. In most cases these manufacturers are single source suppliers. Any of our suppliers or our third-party contract manufacturers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate are required by the market and we may be required to locate and qualify additional suppliers.

Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain materials, components and products in accordance with regulatory requirements and in sufficient quantities for development, testing, and commercialization. While our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will be able to meet our demand for their products in the future. One or more of our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us and we may be required to contract with alternative manufacturers. If we are required to change contract manufacturers due to a change in or termination of our relationships with these third parties, or if our manufacturers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs, or experience other impairments to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

If required, establishing additional or replacement suppliers for any of these materials, components, products, or services could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our products, or could require that we modify product designs. Even if we are able to find replacement suppliers or third-party contract manufacturers, we will be required to verify that the new supplier or third-party manufacturer maintains facilities, procedures, and operations that comply with our quality expectations and applicable regulatory requirements.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products could be delayed, limited, or prevented, which could have a material adverse effect on our business, financial condition, and results of operations.

We cannot guarantee that the political, labor, and economic climate where our contract manufacturers are located will remain sufficiently stable for our manufacturing purposes. Our operations could be adversely affected by political unrest and value fluctuations in the local currencies in Germany, China, or Costa Rica. We could also be harmed by strikes and other labor disruptions. Any of these events could result in increased costs or in disruptions of supply of our products, which would harm our business and operating results.

We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies, and materials, and may not be able to find replacements or immediately transition to alternative suppliers, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition, and results of operations.

These single source suppliers provide us with dual pressure sensor monitors, plasma array balloons, custom injection molded and ceramic parts, plastic connectors, hollow fiber filters, and complex programmable logic devices, among others. These components, sub-assemblies, and materials are critical and there are relatively few alternative sources of supply. For example, in our Symphion product line, we rely on ceramic rings and plastic connectors which are in short supply given COVID-19 and its variants (COVID-19). In the event we are unable to obtain a sufficient supply of these components, we may have to switch to alternative components which may negatively affect the performance of our Symphion product line and increase our costs, or delay or temporarily discontinue production of our Symphion product line, which would adversely affect our revenue.

We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies, and materials. These sole suppliers, and any of our other suppliers, may be unwilling or unable to supply components of these systems to us reliably and at the levels we anticipate or that are required by the market. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs, and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute.

While we believe that alternative sources of supply are available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that our manufacturing partners would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Any such interruption or alternation could harm our reputation, business, financial condition, and results of operations. We cannot assure you that we will be able to secure alternative equipment and materials and utilize such equipment and materials without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and components we require for our products, our reputation, business, financial condition, and results of operations could be negatively impacted.

Furthermore, if we are required to change the manufacturer of a critical component of our products, we will be required to verify that the new manufacturer maintains facilities, procedures, and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products, or could require that we modify the design of those systems. If the change in manufacturer results in a significant change to any 510(k) cleared product, a new 510(k) clearance from the FDA or similar international regulatory authorization or certification may be necessary before we implement the change, which could cause substantial delays. Similarly, changes to our PMA-approved products, including a change in manufacturer, could require a new PMA approval prior to making such change. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely of cost-effective manner.

Our dependence on third-party suppliers subjects us to a number of risks that could negatively impact our ability to manufacture products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier’s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier’s failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;

- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the FDA's Quality System Regulation (QSR) or other applicable laws or regulations enforced by the FDA or California and other state regulatory authorities and foreign regulatory authorities;
- inability to ensure the quality of products and components manufactured by third parties;
- production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or their other customers, or our suppliers prioritizing their other customers over us; and
- an outbreak of disease or similar public health threat, such as the existing threat of COVID-19, particularly as it may impact our supply chain.

Although we require that our third-party suppliers provide our manufacturing partners with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, there is a risk that our suppliers will not always act with our best interests in mind, and they may not always supply components that meet our requirements or supply components in a timely manner. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. These events could harm our business and our operating results.

The spread of COVID-19 and efforts to reduce its spread have negatively impacted, and may continue to negatively impact, our business, and operations.

The spread of COVID-19 in the United States has resulted in travel restrictions impacting our sales professionals. In addition, some treatment facilities have reduced staffing and postponed certain procedures in response to COVID-19 or diverted resources to treat those patients with COVID-19. Some treatment facilities have also restricted or limited access for non-patients, including our sales professionals, which has negatively impacted our access to physicians and their patients. Our business and operations may be further impacted by new treatment facility sanitization and social distancing protocols. Our field-based team continues to be available, in-person or virtually, to support procedures using our products. However, members of our field team may choose not to enter hospitals, ASCs, or physicians' offices due to preexisting conditions, personal choice, or on doctors' orders, or may be unable to enter such facilities due to their policies. Additionally, we anticipate that an increase in the unemployment rate due to the impact of COVID-19 may decrease the number of potential patients with health insurance, which may result in fewer diagnoses, a lower number of procedures, or a shift to procedures which are reimbursed by government payors. As treatment facilities cancel and defer elective procedures, it reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as healthcare providers seek cost savings. Prolonged restrictions relating to COVID-19 have adversely affected the number of endometrial ablation and tissue resection procedures and our revenue as a result. Additionally, some treatment facilities have had cash flow problems or have ceased doing business due to the impact of COVID-19 on their operations, which has reduced the number of treatment facilities where endometrial ablations or tissue resections can be performed, and has adversely affected our ability to collect amounts due to us and our revenue as a result.

We expect these challenges to continue to impact the number of endometrial ablation and tissue resection procedures through the remainder of 2021, particularly given the increased prevalence of the Delta variant of COVID-19 in the United States during the second and third quarter of 2021, but the extent cannot be quantified at this time. Our customers' patients are also experiencing the economic impact of the COVID-19 pandemic. Procedures like an endometrial ablation or tissue resection may be less of a priority than other priorities for those patients who have lost their jobs, are furloughed, have reduced work hours, or are worried about the continuation of their medical insurance. Patients may also be reluctant to visit their physicians at their offices, in ASCs or in hospitals due to fear of contracting COVID-19. The reduction in physician visits, the increase in deferred treatments, and patient behaviors are translating into fewer than expected endometrial ablation and tissue resection procedures being performed in the current environment.

COVID-19 has impacted, and we expect will continue to impact, our personnel and the personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and reduce our margins. Restrictions related to us and our suppliers are country-specific. The spread of an infectious disease, including COVID-19, could result in the inability of our suppliers to deliver components or raw materials to our contract manufacturers on a timely basis due to these impacts or restrictions. If there were a shortage of supply, the cost of these materials or components could increase and harm our contract manufacturers' ability to provide our products on a cost-effective basis. In connection with any supply shortages in the future, reliable and cost-effective replacement sources may not be available on short notice or at all. This may force us to increase prices and face a corresponding decrease in demand for our products. In the event that any of our suppliers were to discontinue production of our key product components, developing alternate sources of supply for these components would be time

consuming, difficult, and costly. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including the duration and severity of the COVID-19 pandemic, the actions taken to reduce the transmission of COVID-19, and the speed with which normal economic and operating conditions resume, among others.

COVID-19 has had a material adverse impact on our liquidity, capital resources, operations, and business and those of the third parties on which we rely. However, the ultimate impact of COVID-19 is still unknown. The extent to which COVID-19 further impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. We do not yet know the full extent of potential delays or impacts on our business, financial condition, and results of operations. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of COVID-19 on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to operate.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

Our sales force headcount and our total company headcount have increased significantly since our full commercial launch in August 2015. In addition, we acquired three new products from BSC in May 2020 which require additional selling and marketing support. Any growth that we experience in the future may require us to expand our sales and marketing personnel, manufacturing operations, and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that less experienced employees market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue improving our operational, financial and management controls, reporting systems, and procedures. If we are unable to manage our growth effectively, it may be difficult for us to deliver our products in a timely manner.

As the demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes, and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes, or hire the necessary personnel could result in higher costs of processing data or our inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards, or physician expectations, our reputation could be harmed and our business could suffer.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of our executive officers are essential to driving adoption of our products, executing on our corporate strategy, and ensuring the continued operations and integrity of financial reporting within our company and development, manufacturing, and commercialization of our products. Any of our employees may terminate their employment with us at any time. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies, and implementing our business strategy.

In addition, our research and development programs, clinical operations, and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. Competition for skilled engineers is especially high in the San Francisco Bay Area, where our headquarters is located. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. When we hire employees from competitors or other companies, their former employers may in the future attempt to assert that these employees or we have breached legal obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

The failure of our products to meet patient's expectations, or the occurrence of adverse events related to our products, could impair our financial performance.

Our future success depends upon increased physician demand for our products, resulting from positive patient word-of-mouth, and social media patient feedback that their experience with our products met their expectations. Patients may be dissatisfied if their expectations of the treatment results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as pain, hemorrhaging, infection, thermal injury to adjacent tissue and organs, or perforation of the uterus. If the results of endometrial ablation or tissue resection using our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from referring our products to others. Dissatisfied patients may express negative opinions to the press or through social media. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

The estimates of market opportunity and forecasts of market and revenue growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.

We cannot accurately predict the size of the market for endometrial ablation and tissue resection products, and our market opportunity estimates, along with long-term growth forecasts, are subject to significant uncertainty. Our estimates of the annual total addressable market for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the number of endometrial ablation and tissue resection procedures annually in the United States and worldwide, the growth in number of procedures, and the growth in awareness of AUB and the treatments for AUB.

For example, our long-term growth will be dependent upon our ability to convince a significant number of physicians and women that our solutions are preferable to currently available treatments for excessive menstrual bleeding and other treatments that may be developed and commercialized in the future. Existing treatments for AUB include drug therapy, endometrial ablation, hysteroscopic tissue removal, or a hysterectomy. Drug therapy has traditionally been the initial treatment for women experiencing AUB. First-generation endometrial ablation procedures which use a resectoscopic electrosurgical instrument, such as a rollerball or wire loop, or a laser are less frequently performed today. Second-generation procedures, which include those performed with the Minerva ES and Genesys HTA, are non-resectoscopic treatments that are faster, require less general anesthesia or pre-treatment and, in most cases, are associated with lower complication rates when compared to first-generation procedures. We cannot assure you that the market for endometrial ablation products will develop further in the future or that the new endometrial ablation and tissue resection procedures will continue to experience similar or greater rates of use. Additionally, our growth may depend in part upon our ability to attract those women who are not currently seeking treatment for AUB by communicating to them the benefits of our products. We cannot assure you that we will be successful in continuing to attract physicians and women to use our products, or whether or not evolving trends in the treatment of excessive menstrual bleeding will favor new endometrial ablation and tissue resection procedures as compared to traditional approaches.

While we believe our assumptions and the data underlying our estimates for population growth among women with AUB and the growth in our addressable market are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time and be affected by the COVID-19 pandemic, thereby reducing their predictive accuracy. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of procedures or the annual total addressable market for our products is smaller than we have estimated or does not grow as quickly as we would expect, it may impair our sales growth and have an adverse impact on our business.

Our ability to compete depends on our ability to innovate successfully and deliver any product improvements and new products in a timely manner.

The market for our products is competitive, dynamic, and marked by substantial technological development and product innovation. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We plan to devote additional resources to research and development of product improvements and new products in the future. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of product enhancements or any new product offerings will depend on several factors, including our ability to:

- develop and introduce new products and product enhancements in a timely manner;
- for any new product, receive adequate coverage and reimbursement, if necessary;
- continue to properly identify and anticipate physician and patient needs;
- avoid infringing upon the intellectual property rights of third-parties;

- demonstrate, if required, the safety and efficacy of new products with clinical data;
- obtain the necessary regulatory clearances, approvals or certifications for expanded indications, new products, or product modifications;
- be fully FDA-compliant with any new or modified products; and
- provide adequate education to potential users of our products.

If we are unable to develop new products, applications, or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote considerably greater funding to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product's development, including during research and development, clinical trials or investigations, regulatory review, manufacturing, and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition, and results of operations.

Endometrial ablation and tissue resection involves surgical risks, and these procedures are contraindicated in certain patients, which may limit adoption.

Risks of using our products include the risks that are common to endometrial ablation and tissue resection procedures, including pain, hemorrhaging, infection, or thermal injury to adjacent tissue and organs, or perforation of the uterus. Treatments for AUB are contraindicated in certain patients, and therefore should not be used. For example, second-generation endometrial ablation products, including Minerva ES and Genesys HTA, are contraindicated in certain patients, including, but not limited to, those who are pregnant or who want to become pregnant in the future; have known or suspected malignant or pre-malignant conditions of the endometrium; have any anatomic condition or pathologic condition that could lead to weakening of the myometrium; have active pelvic inflammatory disease; or have an IUD in place. Uterine tissue resection products, including Symphion and Resectr, are contraindicated in certain patients, including, but not limited to, patients who have acute pelvic inflammatory disease; a uterus that cannot be adequately distended or visualized; cervical or vaginal infection; are pregnant; have cervical malignancies or invasive carcinoma of the cervix; have had a recent uterine perforation; are receiving anti-coagulant therapy or have bleeding disorders; have a medical contraindication or intolerance to anesthesia; have severe anemia; or have a myoma so large that it cannot be circumnavigated during hysteroscopic myomectomy surgery. The FDA authorized labeling for our products, which is publicly available on the FDA website, contains a complete list of these contraindications. To the extent this patient population comprises a significant portion of women with AUB, our products may not become widely adopted and our operating results may suffer as a result.

If we are unable to transition the manufacturing and operations for newly acquired product lines, or if we fail to comply with our obligations in our agreement with BSC related to such products, our business and operations could be harmed.

In May 2020, we acquired our Genesys HTA, Symphion, and Resectr products from BSC. BSC manufactures the Genesys HTA System Operational Unit (controller) and its Genesys HTA ProCerva disposable procedure set at their facilities. In connection with that acquisition, we entered into a supply agreement with BSC relating to the Genesys HTA system and certain of its components. Pursuant to the supply agreement, BSC will supply us with controllers and procedure sets until the earlier of February 2022, or such time as we have successfully transferred manufacturing to third-party manufacturers. We have identified, and are in the process of transferring the manufacturing of the Genesys HTA controller and Genesys HTA ProCerva procedure set to, third-party contract manufacturers. We anticipate this process will be complete prior to the termination of BSC's obligations under the supply agreement. If we are unable to complete the transfer to an FDA-approved contract manufacturer prior to February 2022, we would need to negotiate additional supply terms with BSC. We cannot assure you that BSC would be willing to supply additional products on commercially reasonable terms or at all, and we could be without supply until our contract manufacturers are operational. Any delay in the supply of the Genesys HTA controller and the Genesys HTA ProCerva procedure set could have material adverse effect on our business and operations.

The Symphion and Resectr products were previously manufactured for BSC by various third-party manufacturers. We intend to rely on those same manufacturers to supply us with these products and we are in the process of assuming those relationships. Pursuant to the transition services agreement with BSC, BSC agreed to provide us resources and inventory during the time period until the products and the manufacturing agreements with various third-party manufacturers were transferred to us. If we experience a delay in the transfer of the Symphion operations, or if we are unable to obtain the necessary supply of Resectr or Symphion products from these third parties, are business and operations would be adversely affected.

Our agreement with BSC imposes additional obligations on our business, including relating to payment and milestone obligations related to Genesys HTA, Symphion, and Resectr. If we fail to make payments under the contracts we have with BSC, it may be determined that we are in breach of contract and we may have to pay damages or renegotiate those contracts. We can provide no assurance that we will be able to renegotiate the contracts we have with BSC or that any renegotiated terms will be favorable to us. The occurrence of such events could materially harm our business and financial condition.

Moreover, we acquired the BSC products during the COVID-19 pandemic and have never had to produce those products during a commercial period that was not impacted by the pandemic. Our suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements.

Litigation against us could be costly and time-consuming to defend, and could result in additional liabilities.

We have, from time to time, been subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes, employment claims made by our current or former employees, alleged patient injuries, or claims by competitors concerning intellectual property disputes. Claims may also be asserted by, or on behalf of, a variety of other parties, including government agencies, patients, vendors, and stockholders. Further, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and this risk is especially relevant to industries that experience significant stock price volatility. Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may negatively affect our business, financial condition, and results of operations. For more information on risks related to intellectual property litigation, see "Risk factors—Risks related to our intellectual property."

If our facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

Our corporate headquarters in Santa Clara, California supports in-house production and distribution operations, including manufacturing, quality control, raw material, and finished goods storage. The facility is situated on or near earthquake fault lines, and we do not have redundant facilities. We are also dependent on suppliers located in the United States, China, Germany, and Costa Rica. Should our building, or that of one of our suppliers, be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires, or other events, it could take months to relocate or rebuild, and during that time our employees may seek other positions, our research, development, and manufacturing would cease or be delayed, and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems would require FDA review and approval of a PMA supplement for a product previously approved under a PMA, and may require a new 510(k) for a previously 510(k) cleared device. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California, and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding, relocating and lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development, and manufacturing activities, combined with our limited inventory of materials, components, and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition, and results of operations.

Furthermore, the current lease for our manufacturing facility expires in May 2023, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

Our business is subject to quarterly, annual, and seasonal fluctuations.

Our quarterly and annual results of operations, including our revenue, profitability, and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or

period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors including:

- the level of demand for our products, which may vary significantly from period to period;
- the rate at which we grow our sales force and the speed at which newly hired territory managers become effective, and the cost and level of investment therein;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- the timing and cost of obtaining regulatory approval, clearances, or certifications for future products;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials or investigations for our current or future products or any future products we develop or competing products;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold, and the geographic mix of where products are sold;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- timing and adequacy of supply chain to meet demand;
- natural disasters, outbreaks of disease or public health crises, such as COVID-19;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. Additionally, our business is subject to seasonal fluctuations in that our revenue is typically higher in the fourth quarter, primarily because patients tend to schedule expensive, more complex elective procedures closer to the end of the year after they have largely or fully paid their annual insurance deductibles and in connection with the holiday season when patients may have time off from work for recovery. As a result of these and other factors, our financial results for any single quarter or period of less than one year are not necessarily indicative of the results that may be achieved for a full fiscal year.

Additionally, any quarterly, annual, or seasonal fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. Further, if our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially.

Adoption of our products depends upon appropriate physician education, and inadequate education may lead to negative patient outcomes, adversely affecting adoption of our products and our business.

The success of our products depends in part on the skill of the physicians performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques. We believe that the intuitive design of our products allows physicians to become comfortable with our products using the surgical skills they already possess. However, before using our products, physicians must:

- have sufficient and adequate experience in performing procedures in the uterine cavity, such as IUD insertion, dilation and curettage, and hysteroscopy;
- review and be familiar with the product Instructions for Use (IFU);

- be aware of the appropriate sequence of actions detailed in the operator's manual, along with the troubleshooting section in the event the system detects a high CO_2 flow rate during the uterine integrity test, which may be indicative of a uterine perforation; and
- review the patient selection criteria for the clinical trials or investigations to determine which patients are appropriate for the procedures associated with our products.

We cannot guarantee that all physicians will have the necessary skill set to perform procedures using our products, or that they will review the IFUs for our products. We do not control which physicians perform the procedures or control the level and adequacy of their medical training. If physicians perform an endometrial ablation or tissue resection procedure using our products in a manner that is inconsistent with the IFUs or without adhering to or reviewing our IFUs, their patient outcomes may not be consistent with the outcomes achieved in our clinical trials or investigations. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products that are utilized for endometrial ablation or tissue resection, which would have a material adverse effect on our business, financial condition, and results of operations.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to avoid supply interruptions, but keep limited amounts of finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast materials requirements and demand for our products in order to predict future inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and the weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete, as well as inventory write-downs or write-offs, which would impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies, and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies, and materials to meet our standards or legal requirements, which could result in inadequate inventory levels or interruptions, delays, or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships, and business. In addition, several components, sub-assemblies, and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We may not be able to maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. For example, we believe our competitors have historically undercut the price of our products by offering theirs at a lower price to incentivize leading hospitals, ASCs, and physician offices to order more of their products. Additionally, any decline in the amount that insurance payors reimburse our customers for our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations (GPOs) and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers of products with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups reduces market prices for our products or requires the payment of administrative fees, thereby reducing our revenue and/or margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts can typically be terminated without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are used by OB/GYN's for surgical procedures, including the risk that patients may be severely injured by, or even die from, the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a product recall or market withdrawal, or issuance of a safety alert relating to our products, and could result in significant costs, negative publicity, and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry has historically been subject to extensive litigation over product liability claims. We currently are party to four litigation matters involving patient harm, where either the performance of our Minerva ES product or physician use of it is at issue. We may be subject to product liability claims in the future if our products cause, or merely appear to have caused, patient harm, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, may be the basis for a claim against us by patients, hospitals, ASCs, physicians, or others purchasing or using our products, even if our products were not the actual cause of such patient harm. We may choose to settle any claims to avoid fault and complication not due to failure of our products. If our products are found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. In addition, claims of this nature may adversely affect our reputation, which could damage our position in the market.

We maintain product liability insurance. However, we cannot assure you that any future product liability claims, will not result in court judgments or settlements that are in excess of the liability limits of our product liability insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court that exceed our coverage limitations or that are not covered by our insurance.

An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications, applications, or certifications for marketing. Finally, even a meritless or unsuccessful product liability claim would be time consuming and expensive to defend and could result in a diversion of management's attention from our core business, which would cause our business to suffer. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition, and results of operations.

We are required to file a MedWatch Medical Device Report (MDR) with the FDA, whenever we become aware that our products have, or may have, caused or contributed to a serious injury or death, or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR report associated with a significant adverse event could result in FDA enforcement action or negative publicity, which could harm our reputation, physician adoption, and future sales.

We provide a limited warranty that our disposable products are free of material defects at the time of delivery and conform to specifications, and offer to repair, replace, or refund the purchase price of defective products. For our controllers, we offer a one-year warranty against manufacturer's defects. As a result, we bear the risk of potential warranty claims on our products. The limited warranty on our products does not protect us from product liability claims. In the event that we attempt to recover some or all of the expenses associated with a warranty or product liability claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Although we have product 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, or otherwise

protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities, or for amounts in excess of insured liabilities, could negatively affect our business, financial condition, and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or investigations or regulatory approvals could be suspended. Additionally, we carry a limited amount of cyber liability and third-party crime insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition, and results of operations.

We may need additional funding and may not be able to raise capital when needed, which could force us to delay or reduce our product development programs and commercialization efforts.

We believe that our cash and cash equivalents, together with our expected revenue and the net proceeds from the IPO, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- the degree and rate of market acceptance of our products;
- the achievement of certain milestones related to our agreement with BSC;
- the extent to which we acquire third-party companies, products, or technologies;
- restructuring, refinancing, or repayment of debt;
- the scope and timing of investment in our sales force;
- the timing, receipt, and amount of sales from our current products and any future products we develop;
- the costs of attaining, defending, and enforcing our intellectual property rights, including our litigation matters with Hologic, Inc.;
- the cost of our research and development activities, regulatory clearances, approvals, or certifications;
- the continued impact of COVID-19 on our business and operations;
- expenses associated with any product recall that may occur;
- the emergence of competing technologies or other adverse market developments;
- the cost of any additional clinical studies or investigations we initiate; and
- the rate at which we expand into international markets.

We may seek to raise additional capital through equity offerings or debt financings, and such additional financings may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

In addition, the terms of debt securities issued, or borrowings, could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might

otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay sales and marketing efforts or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition, and results of operations.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

On October 8, 2021, we entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce, which provides for a senior secured term loan in an aggregate principal amount of $40.0 million, the full amount of which was funded at the closing of the CIBC Agreement. The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the total obligations due and payable in full on October 8, 2026. The payments under the CIBC Agreement, will divert resources from other activities. Our obligations under the CIBC Agreement are collateralized by substantially all of our assets, including our material intellectual property, which includes our patents filed at the U.S. Patent and Trademark Office (USPTO), and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, repurchase stock, and make investments, in each case subject to certain exceptions. The covenants related to the CIBC Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand, or otherwise pursue our business activities and strategies. While we are not currently in breach of any covenants contained in our CIBC Agreement, we have breached our reporting covenants in the past under our term loan agreements, and there can be no guarantee that we will not breach these or other covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the CIBC Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the CIBC Agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have, or are unable to generate, sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

We may continue to acquire technologies and products from other companies, which acquisitions could fail to result in a commercial product or generate additional sales, divert management's attention, result in additional dilution to our stockholders, and otherwise disrupt our operations and harm our operating results.

As part of our business strategy, we have acquired, and may make future acquisitions of, complimentary companies, technologies, and products. For example, in May 2020, we acquired Genesys HTA, Symphion, and Resectr from BSC to complete our portfolio of products. We may in the future seek to acquire, license, or invest in other businesses, products, or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We could also seek to enter into distribution arrangements or strategic partnerships with third parties that we believe could increase our revenue or offer other commercial benefits. However, we cannot assure you that we would be able to successfully complete any acquisition, license agreement or distribution agreement we choose to pursue, or that we would be able to successfully integrate any acquired business, or product or technology in a cost-effective and non-disruptive manner. Similarly, we cannot guarantee that we would derive benefits from any distribution arrangement or other strategic partnership. The pursuit of potential acquisition, license or distribution opportunities may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating, and pursuing suitable transactions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or strategic partners, or be successful in entering into an agreement with any particular target or partner, or obtain the expected benefits of any acquisition, license, investment, or other strategic partnership arrangement.

We may not be able to successfully integrate any acquired personnel, operations, and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business, product, or technology fails to meet our expectations, our operating results, business, and financial condition may suffer.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards (NOLs) of $168.8 million and $116.3 million, respectively. NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2028 (U.S. federal NOLs arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended (the Code), may limit the NOLs we may use in

any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5.0% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We performed the analysis and determined that we have experienced an ownership change in February 2010 as a result of stock transfers and the issuance of preferred stock. In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future “ownership changes.” “Ownership changes” that have occurred in the past or that may occur in the future, including in connection with the IPO, could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income or income tax liability, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results. Furthermore, under the Tax Cuts and Jobs Act of 2017, although the treatment of U.S. federal NOLs arising in tax years beginning on or before December 31, 2017 has generally not changed, U.S. federal NOLs arising in tax years beginning after December 31, 2017 may only be used to offset 80.0% of our taxable income in tax years beginning after December 31, 2020. This change may require us to pay U.S. federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. See Note 10 to our audited financial statements and notes thereto for the year ended December 31, 2020, included in our Prospectus.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers’ patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally-protected health information, credit card and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology (IT) and infrastructure, and that of our technology partners, may be vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. We rely extensively on IT systems, networks, and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software, and technical applications, and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction, or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers’ systems, portable media, or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware, or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. In addition, adoption of work-from-home requirements in connection with COVID-19 could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature, such as phishing attacks, and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers’ databases or systems that could adversely affect our business.

If we decide to pursue an international expansion of our business, it will expose us to market, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

Any international expansion that we pursue will involve a number of risks, including:

- difficulties in staffing and managing our international operations;
- working with in-country distributors with whom we are not familiar and over whom we have limited control;
- multiple, conflicting, and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- reduced or varied protection for intellectual property rights in some countries;

- obtaining regulatory clearance or certification where required for our products in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers, and payors;
- natural disasters and political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977 (FCPA), U.K. Bribery Act of 2010, and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition, and results of operations.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business.

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of further enhancing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition, and results of operations.

Risks related to our intellectual property

We are currently a party to intellectual property litigation with Hologic, Inc. and may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents, along with pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell, and/or export our products or to use product names. For example, in November 2015, Hologic and Cytyc Surgical (collectively, Hologic), filed suit against us in the U.S. District Court for the District of Delaware alleging infringement of four patents and asserting various other claims including unfair competition, deceptive trade practices, and tortious interference with business relationships. Hologic dropped two of the patents before trial. Pre-trial, the district court determined that we infringed two of Hologic's asserted patents and that these two patents were valid. At trial, the district court ruled against Hologic's non-patent claims as a matter of law, and the jury found no willfulness and awarded Hologic damages in the amount of about $4.8 million, which the court increased post-trial to include supplemental damages and interest, bringing the total amount of damages to approximately $7.2 million. Subsequently, one of the two patents was determined to be invalid by the U.S. Court of Appeals for the Federal Circuit, and the district court denied Hologic's request for an injunction. As to the remaining patent, it expired shortly after trial on November 19, 2018, thereby capping the damages (other than interest that continues to accrue pending appeal). On June 29, 2021, the U.S. Supreme Court vacated and remanded the Federal Circuit's decision

that Minerva cannot challenge the validity of the remaining patent due to assignor estoppel. A decision from the Federal Circuit on remand as to the invalidity of the remaining patent is expected to take several months. We have posted a bond of approximately $7.2 million pending appeal. In July 2020, Hologic filed a related case against us in the U.S. District Court for the District of Delaware asserting that our redesigned endometrial ablation system infringed the one remaining patent currently on appeal for a period of about five months until that patent expired on November 19, 2018. This related case has been stayed pending appeal. We have spent a substantial sum of money and other resources in defending against these two litigation matters and we expect to continue to incur significant litigation expenses going forward. We cannot provide any guarantee that the Hologic claims, or any other intellectual property claims, will be resolved in our favor. For more information on the litigation matters with Hologic, Inc., see “Item 1-Legal proceedings.”

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use, or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology, or methods do not exist, have not been filed, or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management’s attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party’s patent or trademark or of misappropriating a third-party’s trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents in court, before an administrative agency, or at the patent office, if issued, by proving that the invention was not original, was not novel, was obvious, or was obtained without disclosing all pertinent material prior art information to the patent office, among other reasons. For example, in litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons or are unenforceable due to inequitable conduct. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information, or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if third-party claims of patent or trademark infringement or trade secret misappropriation are successfully asserted against us, such claims may harm our business, result in injunctions preventing us from selling our products, and require payment of license fees, damages, attorney fees, and court costs, which may be substantial and have a material adverse impact on our business. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties that may substantially erode our margins. Further, we may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and as such may need to stop selling the infringing products, which would have a significant adverse impact on our business, financial condition, and results of operations.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine priority with respect to our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents, trademarks, or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents, trademarks, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. For example, in April 2017, we initiated an action in the U.S. District Court for the Northern District of California alleging that one of Hologic's products infringes one of our patents. This action was subsequently transferred to the U.S. District Court for the District of Delaware. On July 23, 2021, the district court found on summary judgment that our '208 patent is invalid, dismissed the case, and entered judgment. On August 24, 2021, we filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. We have incurred substantial expenses litigating against Hologic. We cannot provide any guarantee that our claim against Hologic will be resolved in our favor. For more information on the litigation matters with Hologic, Inc., see "Item 1–Legal proceedings." In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market, and an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition, and results of operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at, or engaged by, other medical device, biotechnology, or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and contractors may have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how, or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition, and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition, and results of operations.

Our success will depend on our ability to obtain, maintain, and protect our intellectual property rights. If we are unable to obtain and maintain patent or other intellectual property protection for any products we develop or for our technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be harmed.

In order to remain competitive, we must develop, maintain, and protect the proprietary aspects of our brands, technologies, and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret, and other intellectual property laws to protect the proprietary aspects of our brands, technologies, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data, and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients, and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic, or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition, and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our trademarks, data, technology, and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated.

As with other medical device companies, our success depends, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Additionally, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our products or any future products we may develop. The acquisition or licensing of third-party intellectual property

rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources, and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product, which could harm our business, financial condition, and results of operations.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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, 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.

If we fail to comply with our obligations in our intellectual property licenses, including from Hermes Innovations, we could lose license rights that are important to our business.

We are a party to a license agreement with Hermes Innovations, LLC (Hermes), under which Hermes has granted us a worldwide, exclusive, royalty-free license to certain of its intellectual property related to the endometrial ablation procedure. This license agreement imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Hermes, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into a new license for a different endometrial ablation product. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors, including Hermes, to obtain, maintain, defend, and enforce these rights could have a material adverse effect on our business. In some cases, we do not have control over the prosecution, maintenance, or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance, and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend, and enforce the licensed patents, any of which could have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent

applications are prosecuted, and also may affect patent litigation. The Leahy-Smith Act also includes provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution, and set forth additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. A third party that files a patent application in the USPTO after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts, and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Our patent rights and other intellectual property may be subject to priority or inventorship disputes, interferences, and similar proceedings.

We may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned patent applications or in-licensed patents or patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent applications, such co-owners rights may be subject, or in the future subject, to assignment or license to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any patents that issue from such patent applications against third parties, and such cooperation may not be provided to us.

If we or our licensors are unsuccessful in any priority, validity (including any patent oppositions), or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through the loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we are successful in priority, inventorship, or ownership disputes, it could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, suppliers, contract manufacturers, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in research and development or acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our IT systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any such breach.

We may not be able to protect our intellectual property rights throughout the world.

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks, or tradenames in foreign countries where we do not have sufficient patents or patent protection and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks

may compete with our products or trademarks, and our patents, trademarks, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We rely on trademarks, service marks, tradenames, and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. 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 towards advertising and marketing new brands and managing through regulatory implications such as relabeling. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic, and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition, and results of operations.

As is common in the medical device industry, our employees, consultants, and advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. Also, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could harm our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition, and results of operations.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- claims of our patents or patent applications, if and when issued, may not cover our products or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition, and results of operations.

Risks related to government regulation

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and by the FDA's foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development, manufacturing, and release; laboratory, preclinical, and clinical testing; labeling, packaging, content, and language of instructions for use and storage; product safety and efficacy claims; establishment, registration, and device listing; marketing, sales, and distribution; pre-market clearances, approvals, and certifications; service operations; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign counterparts enforce these regulatory requirements through, among other means, periodic unannounced inspections and periodic reviews of public marketing and promotion materials. We do not know whether we will be found compliant in connection with any future FDA or foreign counterparts' inspections or reviews. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, approvals, or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

Disruptions at the FDA, the SEC and other government agencies or foreign bodies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (SEC), and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or foreign bodies may also slow the time necessary for new medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to COVID-19, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to COVID-19. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals, or certifications for our products or to manufacture, market, or distribute our products after clearance, approval, or certification is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has

proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the Food, Drug, and Cosmetic Act (FDCA). Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market, or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation, or policies, when and if promulgated, enacted, or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

On May 25, 2017, the Medical Devices Regulation entered into force in the European Union (EU), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and eliminate current differences in the regulation of medical devices among EU member states. The EU Medical Devices Regulation, among other things, establishes a uniform, transparent, predictable, and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation.

The EU Medical Devices Regulation was originally intended to become effective three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year, until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021, may generally continue to be made available on the market or put into service until May 26, 2025. Complying with this new regulation may result in Europe being less attractive as a "first market" destination.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition, and results of operations.

In the United States, there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (ACA) was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models and expanded the eligibility criteria for Medicaid programs.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2.0% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market, or distribute our products after clearance or approval is obtained. Any such reforms could have a material adverse effect on our industry generally and on our customers. In addition, any healthcare reforms that expand the government's role in the U.S. healthcare industry may result in decreased sale of our products and lower reimbursement by payors for procedures using our products, any of which could affect demand for our products and/or result in additional pricing pressure, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition, and results of operations. Changes and reforms in the EU and other countries where we may decide to commercialize could have similar effects.

If coverage and reimbursement from third-party payors for procedures using our products significantly decline, physicians, hospitals, and other healthcare providers may be reluctant to use our products and our sales may decline.

In the United States, healthcare providers who purchase our products generally rely on third-party payors, including Medicare, Medicaid, and private health insurance plans, to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for products used in surgical procedures, the additional cost associated with the use of our products can impact the profit margin of the hospital or surgery center where the surgery is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for the procedures using our products may make it difficult for existing customers to continue using, or to adopt, our products and could create additional pricing pressure for us. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Physicians, hospitals, and other healthcare providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. If third-party payors issue non-coverage policies or if our customers are not reimbursed at adequate levels, this could adversely affect sales of our products.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement rates and policies. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals, and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products. For example, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations, or cash flows. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor.

Moreover, some healthcare providers in the United States have adopted, or are considering, a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs

by authorizing fewer surgical procedures or by requiring the use of the least expensive clinically appropriate products available. Additionally, as a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for surgical procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline. The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we fail to comply with healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.

We are subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws regarding payments and other transfers of value made to physicians and other healthcare professionals that could subject us to substantial penalties. Additionally, any challenge to, or investigation into, our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse laws and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell, and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to endometrial ablation and tissue resection and regulatory agencies enforcing those laws and regulations;
- FDA, Department of Justice, and other government authority prohibitions against the advertisement, promotion, and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- the federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws have been interpreted to apply to arrangements between medical device manufacturers, on the one hand, and prescribers, purchasers, and other healthcare-related professionals on the other. They can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. In addition, medical device companies have been prosecuted or faced civil and criminal liability under these laws for a variety of alleged promotional and marketing activities, including violations of the federal Anti-Kickback Statute and engaging in off-label promotion that caused claims to be submitted for non-covered off-label uses. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;
- HIPAA, which among other things, also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;

- the federal Physician Payment Sunshine Act (Open Payments), created under the ACA, and its implementing regulations, which requires applicable group purchasing organizations and manufacturers of covered drugs, medical devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to certain payments or other transfers of value made to covered recipients, including licensed physicians, certain other healthcare professionals, and teaching hospitals, including ownership and investment interests held by physicians and their immediate family members. Additionally, beginning with data reported to CMS in 2022, such reporting obligations with respect to payments or other transfers of value made in the previous year to covered recipients have been extended to include new provider types: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives;

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the EU General Data Protection Regulation (GDPR), governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

The scope and enforcement of each of the laws applicable to our business and products are uncertain and subject to rapid change in the current environment of healthcare reform. The U.S. Department of Justice has increased its scrutiny of interactions between manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to a government investigation is time and resource intensive, and may cause harm to our business and reputation even if we are able to successfully defend against it. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians or our practice of loaning equipment to customers at no additional cost, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, 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. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we fail to obtain and maintain necessary regulatory clearances, approvals, or certifications for our products, or if clearances, approvals or certifications for future products and indications are delayed or not issued, our commercial operations would be harmed.

Our endometrial ablation and tissue resection products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries outside of the United States. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, and manufacture;

- laboratory, preclinical and clinical testing, labeling, packaging, storage, and distribution;

- premarketing clearance, approval, or certification;

- record keeping;

- product marketing, promotion and advertising, sales, and distribution; and

- post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act (FDCA), approval of a PMA by the FDA, or grant of a *de novo* classification request from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for Minerva ES and Genesys HTA, is much more rigorous, costly, lengthy, and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life sustaining, life supporting, or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) submission may require a new 510(k) clearance, or such modification may put the device into Class III and require PMA approval or the grant of a *de novo* classification request.

The PMA approval, 510(k) clearance, and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals, clearances or certifications would have a material adverse effect on our business, financial condition, and results of operations.

The FDA and foreign bodies can delay, limit, or deny clearance, approval, or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses or substantially equivalent to a predicate device;
- the disagreement of the FDA or the applicable foreign body with the design, conduct or implementation of our clinical trials or investigations or the analyses or interpretation of data from pre-clinical studies or clinical trials or investigations;
- serious and unexpected adverse device effects experienced by participants in our clinical trials or investigations;
- the data from our pre-clinical studies and clinical trials or investigations may be insufficient to support clearance, *de novo* classification, approval, or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies, clinical trials or investigations, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority or notified body may still not approve or certify the product;
- the applicable regulatory authority or notified body may identify significant deficiencies in our manufacturing processes, facilities, or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory submissions insufficient for clearance, *de novo* classification, approval, or certification; and
- the FDA or foreign regulatory authorities or bodies may audit our clinical trial or investigation data and conclude that the data is not sufficiently reliable to support approval, clearance, or certification.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial or investigation site, or the utility of the clinical trial or investigation itself. Even if we are granted regulatory clearances, approvals, or

certifications, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.

Moreover, the FDA and other foreign counterparts strictly regulate the labeling, promotion, and advertising of our products, including comparative and superiority claims vis-a-vis competitors' products.

As a condition of approving a PMA application or granting a *de novo* request, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals, and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites, and facilities as part of its review process. Similar requirements may apply in foreign countries.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny from the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel orders, which could harm our reputation.

The FDA and the Federal Trade Commission (FTC) also regulate the advertising, promotion, and labeling of our products to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable scientific data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated, or not permissible, we may be subject to enforcement actions, including adverse publicity and/or warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

- adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention, or seizure of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- denial of our requests for marketing authorizations or certifications for new products, new intended uses, or modifications to existing products;
- withdrawal of marketing authorizations or certifications that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or certification that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition, and results of operations.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines, or 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.

Our currently marketed products have been cleared, classified, or approved by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA authorized indications for use, known as "off-label" uses. We cannot, however, prevent a physician from using our devices 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 devices off-label. Furthermore, the use of our devices for indications other than those that are cleared, approved, or certified 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.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate 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 under other regulatory authority, such as false claims laws, 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.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA or another governmental authority, and if we fail to do so, we would be subject to sanctions that could negatively affect our reputation, business, financial condition, and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA and similar foreign regulators when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event, as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA and similar foreign regulators could take action, including, but not limited to, warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, approval or certification, seizure of our products or delay in clearance, approval, or certification of future products.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in certain circumstances, such as where the FDA or similar governmental authority finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, or design or labeling defects, or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls of our products would divert managerial attention, be expensive, harm our reputation with customers, and harm our financial condition and results of operations. A recall announcement would also negatively affect our stock price.

To date, we have not conducted or initiated a formal recall for one of our products. If we initiate a correction or removal for our products to reduce a risk to health posed by them or to remedy a violation of law that may present a risk to health, we would be required to submit a report to the FDA and may be required to submit similar notifications to other regulatory authorities. This report could lead to increased scrutiny by the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports, to the extent made publicly available in accordance with FDA or similar governmental authority regulations, could be used by competitors against us and cause physicians to delay or cancel product orders, which will harm our reputation.

If we assess a potential quality issue or complaint as not requiring either field action or regulatory notification, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation, regulatory agencies may impose sanctions and we may be subject to regulatory

enforcement actions, including warning letters, all of which will negatively affect our business, financial condition, and results of operations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Similar requirements may apply in foreign countries.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or similar governmental authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or similar governmental authorities. If the FDA or a similar governmental authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us, and negatively affect our sales. 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 will negatively affect our reputation, business, financial condition, and results of operations.

We may not receive, or may be delayed in receiving, the necessary clearances, approvals, or certifications for our future products or modifications to our current products, and failure to timely obtain necessary clearances, approvals, or certifications for our future products or modifications to our current products would adversely affect our ability to grow our business.

Material modifications to the intended use or technological characteristics of our products may require new 510(k) clearances, premarket approvals, CE Marks, or comparable foreign marketing authorization prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances, approvals or certifications are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement, or with respect to a 510(k) cleared product, may require a new 510(k) clearance.

In the United States, our Resectr product is 510(k) cleared and components of our Symphion product were authorized through the 510(k) clearance or received *de novo* classification from the FDA. Any material modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification to a 510(k) cleared product requires a new clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or even approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or PMA approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications that we believe do not require a new 510(k) clearance or PMA approval in the future. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA or an EU Notified Body disagrees and requires new clearances, approvals, or certifications for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions including significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA and foreign bodies can delay, limit, or deny clearance, approval, or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses, or substantially equivalent to their predicate devices in the case of a device subject to the 510(k) pathway;
- the disagreement of the FDA or the applicable foreign regulatory authority or notified body with the design or implementation of our clinical trials or investigations or the interpretation of data from pre-clinical studies or clinical trials or investigations;
- serious and unexpected adverse device effects experienced by participants in our clinical trials or investigations;
- the data from our pre-clinical studies and clinical trials or investigations may be insufficient to support clearance, approval, or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;

- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval or certification.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Even though we have obtained FDA clearance and approval for our current products in the United States, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of 510(k) clearance. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state, and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- adverse publicity;
- fines, injunctions, consent decrees, and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations or certifications of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of our current 510(k) clearances or PMAs, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

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

In addition, the FDA and foreign counterparts may change their clearance or premarket approval or certification policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance, approval, or certification of our future products under development or impact our ability to modify our currently cleared or certified products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances, approvals, or certifications, increase the costs of compliance or restrict our ability to maintain our clearance, approval, or certification of our current products, any of which could have an adverse impact on our results of operations. For example, the FDA recently announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. For more information, see “Risk factors—Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals, or certifications for our products or to manufacture, market or distribute our products after clearance or approval is obtained.”

Our products must be manufactured in accordance with federal, state, and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations. If we, or our suppliers, fail to comply with the FDA's QSR or similar foreign regulatory requirements, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes, and those of our third-party component suppliers, are required to comply with the FDA's QSR and similar foreign requirements. These rules cover procedures and documentation of the design, testing, production, process, controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service.

In addition, we must engage in extensive recordkeeping and reporting and must make available our records and facilities, and the facilities certain of our contract manufacturers, for periodic unannounced or planned inspections or audits by governmental agencies or bodies, including the FDA, state authorities, and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our third-party manufacturers and key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers and suppliers, including subcontractors, are subject to unannounced or planned inspections or audits by the FDA and the Food and Drug Branch of the California Department of Public Health (CDPH) and foreign bodies to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. We can provide no assurance that we or our third-party manufacturers or suppliers will continue to remain in material compliance with the QSR or similar foreign requirements. If the FDA, CDPH, or other foreign body inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming, and a distraction for management, and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business.

In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products and similar decisions from a notified body; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims, and we could lose customers and experience reduced sales and increased costs.

Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other regulators (both domestic and foreign), including those laws requiring the reporting of true, complete, and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws, and regulations in the United States and internationally or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible

exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our business, financial condition and results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of some hazardous substances and are subject to a variety of federal, state, local, and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks related to Ownership of Our Common Stocks

An active trading market for our common stock may not develop or be sustained.

Prior to our initial public offering in October 2021, there had been no public market for shares of our common stock. The lack of an active market may impair investor's ability to sell shares at the time the investors wish to sell them or at a price that they consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other products, technologies, or businesses using our shares as consideration. There can be no guarantee that we will continue to satisfy the continued listing standards of the Nasdaq Global Stock Market. If we fail to satisfy the continued listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, these factors including:

- changes in analysts’ estimates, investors’ perceptions, recommendations by securities analysts, or our failure to achieve analysts’ estimates;
- quarterly variations in our or our competitors’ results of operations;
- periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- the financial projections we may provide to the public, any changes in these projections, or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in reimbursement by current or potential payor;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- actual or anticipated changes in regulatory oversight of our products;
- the loss of key personnel, including changes in our board of directors and management;
- product recalls or other problems associated with our products;
- legislation or regulation of our market;

- lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower, or other claims;
- the announcement of new products, product enhancements, or new product trials by us or our competitors;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- announcements related to patents issued to us or our competitors and related litigation, including with Hologic, Inc.; and
- developments in our industry.

In recent years, the stock markets generally, and the market for life sciences technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business, and harm our business, results of operations, financial condition, and reputation. These factors may materially and adversely affect the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings, and other factors our board of directors may deem relevant. In addition, our loan agreement with Canadian Imperial Bank of Commerce (CIBC) limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market, and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up and other legal restrictions on resale, the trading price of our common stock could decline. Each of our directors and officers and substantially all of our other stockholders and option holders have entered into a lock-up agreement with the underwriters that restricts their ability to sell or transfer their shares. The lock-up agreements pertaining to the IPO will expire 180 days from the date of our Prospectus, underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. 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. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

As of September 30, 2021, the holders of an aggregate of 3,149,777 shares of our outstanding common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. Registration of these shares under the Securities Act of 1933, as amended (the Securities Act) would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our executive officers, directors and current beneficial owners of 5.0% or more of our common stock beneficially own a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of

directors and approval of significant corporate transactions. Actions taken by these stockholders may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.

We currently qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual revenue of more than $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock that is held by non-affiliates exceeds $250 million as of the prior June 30th or (2) our annual revenue exceeded $100 million during such completed fiscal year and the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum to Delaware for certain litigation against us; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer, or the president, in the absence of a chief executive officer.

These provisions might discourage, delay, or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors

might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. See "Description of capital stock."

Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our amended and restated bylaws specify that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, stockholders, officers, or other employees to us or our stockholders, (c) any action or proceeding asserting a claim arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws, or (d) any action or proceeding asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or, if no state court in Delaware has jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom, in all cases subject to the court having jurisdiction over the claims at issue and the indispensable parties; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the Exchange Act).

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. 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 also provide that 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.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing, or increase the cost of bringing a claim, which may discourage lawsuits with respect to claims against us and our current and former directors, officers, stockholders, or other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our amended and restated bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies. As a result, our management and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

We have identified a material weakness in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce accurate financial statements on a timely basis.

During the preparation of our financial statements for the years ended December 31, 2019 and 2020, we identified a material weakness in internal control over financial reporting primarily related to a lack of timely, effective review over the financial statement close process. During the periods under audit, we did not have a sufficient complement of qualified personnel within the accounting function and had a lack of segregation of duties to adequately conduct review and analysis of certain routine transactions.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a

timely basis. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. We have initiated the process to remediate the material weakness through hiring additional accounting personnel, formalizing documentation of policies and procedures, and implementing additional accounting processes and controls. Remediation costs consist primarily of additional personnel expenses and upgrading our accounting systems which we do not anticipate will have a material impact to our financial statements.

Since October 21, 2021, the time the registration statement of which our final Prospectus forms a part was declared effective, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

The measures we have taken to date, and actions we may take in the future, may not be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or to prevent or avoid potential future material weaknesses. We may not have identified all material weaknesses. Moreover, our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods, which could cause the price of our common stock to decline. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we are required to furnish a report by management on the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report is required to be filed with the SEC, following the date we are no longer an "emerging growth company," as defined in the JOBS Act. If at such time as we are required to obtain auditor attestation, we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing, and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we are unable to remediate our existing material weaknesses, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be additional weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

Our actual operating results may differ significantly from any guidance that we provide.

From time to time, we may provide guidance in our quarterly earnings conference calls, quarterly earnings releases, or otherwise, regarding our future performance that represents our management's estimates as of the date of release. This guidance, which would include forward-looking statements, would be based on projections prepared by our management. Neither our registered public accountants nor any other independent expert or outside party would compile or examine the projections. Accordingly, no such person would express any opinion or any other form of assurance with respect to the projections. Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic, and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. The principal reason that we would release guidance is to provide a basis for our management to discuss our business outlook with analysts and investors. We do not accept any responsibility for any projections or reports published by any such third parties. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions underlying any guidance furnished by us will not materialize or will vary significantly from actual results. Accordingly, our guidance would be only an estimate of what management believes is realizable as of the date of release. Actual results may vary from our guidance and the variations may be material.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard related to product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates, or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

During the three months ended September 30, 2021, we issued to certain directors, officers, employees and consultants an aggregate of 62,477 shares of our common stock upon the exercise of options under our 2008 Stock Plan, as amended at an exercise price of $0.61 per share.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 39b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds

On October 21, 2021, the Company's registration statement on Form S-1 (File No. 333- 259832) relating to its initial public offering ("IPO") of common stock became effective. The Company issued and sold 6,250,000 shares of its common stock, at a public offering price of $12.00 per share, for aggregate gross proceeds of $75.0 million. The Company received $69.8 million in net proceeds after deducting underwriting discounts and commissions of $5.3 million. The total IPO offering costs other than underwriting discounts and commissions were $3.3 million. At September 30, 2021, $1.9 million of expenses incurred in connection with our IPO had not yet been paid and are included in Accounts payable and accrued liabilities on the interim condensed balance sheet as of September 30, 2021.

All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333- 259832), which was declared effective by the SEC on October 21, 2021. J.P. Morgan Securities LLC, Piper Sandler & Co., UBS Securities LLC and SVB Leerink LLC acted as joint book-running managers for the offering. Shares of our common stock began trading on the Nasdaq Global Select Market on October 22, 2021 and, following the sale of all the shares upon the closing of the initial public offering, the offer terminated.

There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in the final Prospectus.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated October 26, 2021.				X
3.2	Amended and Restated Bylaws of the Registrant, dated October 26, 2021.				X
4.1	Form of common stock certificate of the Registrant.	S-1/A	10/15/21	4.1	
4.2	Amended and Restated Investors' Rights Agreement, by and among the registrant and certain holders of its capital stock dated as of December 19, 2012, as amended.	S-1	9/27/21	4.2	
4.3	Warrant to Purchase Stock issued to SVB Financial Group, dated as of May 9, 2017.	S-1/A	10/15/21	4.3	
4.4	Warrant to Purchase Stock issued to SVB Financial Group, dated as of July 19, 2019.	S-1/A	10/15/21	4.4	
4.5	Warrant to Purchase Stock issued to SVB Innovation Credit Fund VIII L.P., dated as of July 19, 2019.	S-1/A	10/15/21	4.5	
31.1	Certification of the Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Chief Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of the Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of the Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following financial information from Minerva Surgical, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 formatted in Inline XBRL (Extensible Business Reporting Language) includes: (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of redeemable Convertible Preferred Stock and Stockholders' Equity deficit, (v) the Condensed Statements of Cash Flows, and (vi) Notes to the Condensed Consolidated Financial Statements.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

* The certifications filed as Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MINERVA SURGICAL INC

Date: December 2, 2021

By: /s/ David M. Clapper

Chief Financial Officer

(Principal Executive Officer)

Date: December 2, 2021

By: /s/ Joel R. Jung

Chief Financial Officer

(*Principal Financial Officer, and Accounting Officer*)

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF

MINERVA SURGICAL, INC.

a Delaware corporation

Minerva Surgical, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Company**"), does hereby certify as follows:

A. The original Certificate of Incorporation of the Company was filed with the Secretary of State of the State of Delaware on November 3, 2008.

B. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware (the "**DGCL**") by the Board of Directors of the Company (the "**Board of Directors**") and has been duly approved by the written consent of the stockholders of the Company in accordance with Section 228 of the DGCL.

C. The text of the Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

ARTICLE I

The name of the Company is Minerva Surgical, Inc.

ARTICLE II

The address of the Company's registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted by the Company is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

Section 1. This Company is authorized to issue two classes of stock, to be designated, respectively, Common Stock and Preferred Stock. The total number of shares of stock that the Company shall have authority to issue is 105,000,000 shares, of which 100,000,000 shares are Common Stock, $0.001 par value per share, and 5,000,000 shares are Preferred Stock, $0.001 par value per share.

Section 2. Each share of Common Stock outstanding as of the applicable record date shall entitle the holder thereof to one (1) vote on any matter submitted to a vote at a meeting of stockholders.

Section 3. The Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers,

preferences and rights, and the qualifications, limitations or restrictions thereof, of any series of Preferred Stock, including, without limitation, authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Amended and Restated Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. Except as may be otherwise specified by the terms of any series of Preferred Stock, if the number of shares of any series of Preferred Stock is so decreased, then the Company shall take all such steps as are necessary to cause the shares constituting such decrease to resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

Section 4. Except as otherwise required by law or provided in this Amended and Restated Certificate of Incorporation, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

Section 5. The number of authorized shares of Preferred Stock or Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all the then-outstanding shares of capital stock of the Company entitled to vote thereon, without a separate vote of the holders of the class or classes the number of authorized shares of which are being increased or decreased, unless a vote of any holders of one or more series of Preferred Stock is required pursuant to the terms of any certificate of designation relating to any series of Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V

Section 1. Subject to the rights of holders of Preferred Stock, the number of directors that constitutes the entire Board of Directors of the Company shall be fixed only by resolution of the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board. For the purposes of this Amended and Restated Certificate of Incorporation, the term "**Whole Board**" shall mean the total number of authorized directorships whether or not there exist any vacancies or other unfilled seats in previously authorized directorships. At each annual meeting of stockholders, directors of the Company shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been duly elected and qualified or until their earlier resignation or removal; except that if any such meeting shall not be so held, such election shall take place at a stockholders' meeting called and held in accordance with the DGCL.

Section 2. From and after the effectiveness of this Amended and Restated Certificate of Incorporation, the directors of the Company (other than any who may be elected by holders of Preferred Stock under specified circumstances) shall be divided into three classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. Directors already in office shall be assigned to each class at the time such classification becomes effective in accordance with a resolution or resolutions adopted by the Board of Directors. At the first annual meeting of stockholders following the date hereof,

the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following the date hereof, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following the date hereof, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. If the number of directors is changed, any newly created directorships or decrease in directorships shall be so apportioned hereafter among the classes as to make all classes as nearly equal in number as is practicable, *provided that* no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

ARTICLE VI

Section 1. From and after the effectiveness of this Amended and Restated Certificate of Incorporation, only for so long as the Board of Directors is classified and subject to the rights of holders of Preferred Stock, any director or the entire Board of Directors may be removed from office at any time, but only for cause, and only by the affirmative vote of the holders of at least a majority of the voting power of the issued and outstanding capital stock of the Company entitled to vote in the election of directors.

Section 2. Except as otherwise provided for or fixed by or pursuant to the provisions of ARTICLE IV hereof in relation to the rights of the holders of Preferred Stock to elect directors under specified circumstances or except as otherwise provided by resolution of a majority of the Whole Board, newly created directorships resulting from any increase in the number of directors, created in accordance with the Bylaws of the Company, and any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other cause shall be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders. A person so elected by the Board of Directors to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen until his or her successor shall have been duly elected and qualified, or until such director's earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

ARTICLE VII

Section 1. The Company is to have perpetual existence.

Section 2. The business and affairs of the Company shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred upon them by statute or by this Amended and Restated Certificate of Incorporation or the Bylaws of the Company, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Company.

Section 3. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, alter, amend or repeal the Bylaws of the Company. The affirmative vote of at least a majority of the Whole Board shall be required in order for the Board of Directors to adopt, amend, alter or repeal the Company's Bylaws. The Company's Bylaws may also be adopted, amended, altered or repealed by the stockholders of the Company. Notwithstanding the above or any other provision of this Amended and Restated Certificate of Incorporation, the Bylaws of the Company may not be amended, altered or repealed except in accordance with the provisions of the Bylaws relating to amendments to the Bylaws. No Bylaw hereafter legally adopted, amended, altered or repealed shall

invalidate any prior act of the directors or officers of the Company that would have been valid if such Bylaw had not been adopted, amended, altered or repealed.

Section 4. The election of directors need not be by written ballot unless the Bylaws of the Company shall so provide.

Section 5. No stockholder will be permitted to cumulate votes at any election of directors.

ARTICLE VIII

Section 1. From and after the closing of a firm commitment underwritten initial public offering of securities of the Company pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, and subject to the rights of holders of Preferred Stock, any action required or permitted to be taken by the stockholders of the Company must be effected at a duly called annual or special meeting of stockholders of the Company and may not be effected by any consent in writing by such stockholders.

Section 2. Subject to the terms of any series of Preferred Stock, special meetings of stockholders of the Company may be called only by the Chairperson of the Board of Directors, the Chief Executive Officer, the President or the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board, but a special meeting may not be called by any other person or persons and any power of stockholders to call a special meeting of stockholders is specifically denied. Only such business shall be considered at a special meeting of stockholders as shall have been stated in the notice for such meeting.

Section 3. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Company shall be given in the manner and to the extent provided in the Bylaws of the Company.

ARTICLE IX

Section 1. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended from time to time, a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Section 2. Subject to any provisions in the Bylaws of the Company related to indemnification of directors of the Company, the Company shall indemnify, to the fullest extent permitted by applicable law, any director of the Company who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**") by reason of the fact that he or she is or was a director of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding. The Company shall be required to indemnify a person in connection with a Proceeding (or part thereof) initiated by such person only if the Proceeding (or part thereof) was authorized by the Board of Directors.

Section 3. The Company shall have the power to indemnify, to the extent permitted by applicable law, any officer, employee or agent of the Company who was or is a party or is threatened to be made a party to any Proceeding by reason of the fact that he or she is or was a director, officer, employee

or agent of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

Section 4. Neither any amendment nor repeal of any Section of this ARTICLE IX, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation or the Bylaws of the Company inconsistent with this ARTICLE IX, shall eliminate or reduce the effect of this ARTICLE IX in respect of any matter occurring, or any Proceeding accruing or arising or that, but for this ARTICLE IX, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE X

Meetings of stockholders may be held within or outside of the State of Delaware, as the Bylaws may provide. The books of the Company may be kept (subject to any provision of applicable law) outside of the State of Delaware at such place or places or in such manner or manners as may be designated from time to time by the Board of Directors or in the Bylaws of the Company.

ARTICLE XI

The Company reserves the right to amend or repeal any provision contained in this Amended and Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; *provided*, *however*, that notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote, the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board and the affirmative vote of 66 2/3% of the voting power of the then outstanding voting securities of the Company, voting together as a single class, shall be required for the amendment, repeal or modification of the provisions of Section 3 of ARTICLE IV, Section 2 of ARTICLE V, Section 1 of ARTICLE VI, Section 2 of ARTICLE VI, Section 5 of ARTICLE VII, Section 1 of ARTICLE VIII, Section 2 of ARTICLE VIII, Section 3 of ARTICLE VIII, or this ARTICLE XI of this Amended and Restated Certificate of Incorporation.

IN WITNESS WHEREOF, Minerva Surgical, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by the President and Chief Executive Officer of the Company on this 26th day of October 2021.

By: /s/ David Clapper
David Clapper
President and Chief Executive Officer

Exhibit 3.2

AMENDED AND RESTATED BYLAWS OF

MINERVA SURGICAL, INC.

(effective as of the
closing of the Company's initial public offering, on October 26, 2021)

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BYLAWS OF MINERVA SURGICAL, INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of Minerva Surgical, Inc. (the "**Company**") shall be fixed in the Company's certificate of incorporation, as the same may be amended from time to time.

1.2 OTHER OFFICES

The Company may at any time establish other offices.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at a place, if any, within or outside the State of Delaware, determined by the board of directors of the Company (the "**Board of Directors**"). The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the Delaware General Corporation Law (the "**DGCL**"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Company's principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held each year. The Board of Directors shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted. The Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board may cancel, postpone or reschedule any previously scheduled annual meeting at any time, before or after the notice for such meeting has been sent to the stockholders. For the purposes of these bylaws, the term "**Whole Board**" shall mean the total number of authorized directorships whether or not there exist any vacancies or other unfilled seats in previously authorized directorships.

2.3 SPECIAL MEETING

(a) A special meeting of the stockholders, other than as required by statute, may be called at any time by (i) the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board, (ii) the chairperson of the Board of Directors, (iii) the chief executive officer or (iv) the president, but a special meeting may not be called by any other person or persons and any power of stockholders to call a special meeting of stockholders is specifically denied. The Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders.

(b) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the

meeting by or at the direction of a majority of the Whole Board, the chairperson of the Board of Directors, the chief executive officer or the president. Nothing contained in this Section 2.3(b) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the Board of Directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(a) *Annual Meetings of Stockholders.*

(i) Nominations of persons for election to the Board of Directors or the proposal of other business to be transacted by the stockholders at an annual meeting of stockholders may be made only (1) pursuant to the Company's notice of meeting (or any supplement thereto); (2) by or at the direction of the Board of Directors; (3) as may be provided in the certificate of designations for any class or series of preferred stock; or (4) by any stockholder of the Company who (A) is a stockholder of record at the time of giving of the notice contemplated by Section 2.4(a)(ii); (B) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the annual meeting; (C) is a stockholder of record on the record date for the determination of stockholders entitled to vote at the annual meeting; (D) is a stockholder of record at the time of the annual meeting; and (E) complies with the procedures set forth in this Section 2.4(a).

(ii) For nominations or other business to be properly brought before an annual meeting of stockholders by a stockholder pursuant to clause (4) of Section 2.4(a)(i), the stockholder must have given timely notice in writing to the secretary and any such nomination or proposed business must constitute a proper matter for stockholder action. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day and no later than 5:00 p.m., local time, on the 90th day prior to the day of the first anniversary of the preceding year's annual meeting of stockholders. However, if no annual meeting of stockholders was held in the preceding year, or if the date of the applicable annual meeting has been changed by more than 25 days from the first anniversary of the preceding year's annual meeting, then to be timely such notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day prior to the day of the annual meeting and no later than 5:00 p.m., local time, on the 10th day following the day on which public announcement of the date of the annual meeting was first made by the Company. In no event will the adjournment, rescheduling or postponement of any annual meeting, or any announcement thereof, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. If the number of directors to be elected to the Board of Directors is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors at least 10 days before the last day that a stockholder may deliver a notice of nomination pursuant to the foregoing provisions, then a stockholder's notice required by this Section 2.4(a)(ii) will also be considered timely, but only with respect to nominees for any new positions created by such increase, if it is received by the secretary at the principal executive offices of the Company no later than 5:00 p.m., local time, on the 10th day following the day on which such public announcement is first made. "**Public announcement**" means disclosure in a press release reported by a national news service or in a document publicly filed by the Company with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934 (as amended and inclusive of rules and regulations thereunder, the "**1934 Act**").

(iii) A stockholder's notice to the secretary must set forth:

(1) as to each person whom the stockholder proposes to nominate for election as a director:

(A) such person's name, age, business address, residence address and principal occupation or employment; the class and number of shares of the Company that are held of record or are beneficially owned by such person and a description of any Derivative Instruments (defined below) held or beneficially owned thereby or of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of such person; and all information relating to such person that is required to be disclosed in solicitations of proxies for the contested election of directors, or is otherwise required, in each case pursuant to the Section 14 of the 1934 Act;

(B) such person's written consent to being named in such stockholder's proxy statement as a nominee of such stockholder and to serving as a director of the Company if elected;

(C) a reasonably detailed description of any direct or indirect compensatory, payment, indemnification or other financial agreement, arrangement or understanding that such person has, or has had within the past three years, with any person or entity other than the Company (including the amount of any payment or payments received or receivable thereunder), in each case in connection with candidacy or service as a director of the Company (a "**Third-Party Compensation Arrangement**"); and

(D) a description of any other material relationships between such person and such person's respective affiliates and associates, or others acting in concert with them, on the one hand, and such stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made, and their respective affiliates and associates, or others acting in concert with them, on the other hand;

(2) as to any other business that the stockholder proposes to bring before the annual meeting:

(A) a brief description of the business desired to be brought before the annual meeting;

(B) the text of the proposal or business (including the text of any resolutions proposed for consideration and, if applicable, the text of any proposed amendment to these bylaws or the Company's certificate of incorporation);

(C) the reasons for conducting such business at the annual meeting;

(D) any material interest in such business of such stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates and associates, or others acting in concert with them; and

(E) a description of all agreements, arrangements and understandings between such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates or associates or others acting in concert with them, and any other person or persons (including their names) in connection with the proposal of such business by such stockholder; and

(3) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made:

(A) the name and address of such stockholder (as they appear on the Company's books), of such beneficial owner and of their respective affiliates or associates or others acting in concert with them;

(B) for each class or series, the number of shares of stock of the Company that are, directly or indirectly, held of record or are beneficially owned by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(C) a description of any agreement, arrangement or understanding between such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, and any other person or persons (including, in each case, their names) in connection with the proposal of such nomination or other business;

(D) a description of any agreement, arrangement or understanding (including, regardless of the form of settlement, any derivative, long or short positions, profit interests, forwards, futures, swaps, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions and borrowed or loaned shares) that has been entered into by or on behalf of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Company's securities (any of the foregoing, a "**Derivative Instrument**"), or any other agreement, arrangement or understanding that has been made the effect or intent of which is to create or mitigate loss to, manage risk or benefit of share price changes for or increase or decrease the voting power of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Company's securities;

(E) any rights to dividends on the Company's securities owned beneficially by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, that are separated or separable from the underlying security;

(F) any proportionate interest in the Company's securities or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(G) any performance-related fees (other than an asset-based fee) that such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with, them is entitled to based on any increase or decrease in the value of the Company's securities or Derivative Instruments, including, without limitation, any such interests held by members of the immediate family of such persons sharing the same household;

(H) any significant equity interests or any Derivative Instruments in any principal competitor of the Company that are held by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(I) any direct or indirect interest of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, in any contract with the Company, any affiliate of the Company or any principal competitor of the Company (in

each case, including any employment agreement, collective bargaining agreement or consulting agreement);

(J) a representation and undertaking that the stockholder is a holder of record of stock of the Company as of the date of submission of the stockholder's notice and intends to appear in person or by proxy at the meeting to bring such nomination or other business before the meeting;

(K) a representation and undertaking that such stockholder or any such beneficial owner intends, or is part of a group that intends, to (x) deliver a proxy statement or form of proxy to holders of at least the percentage of the voting power of the Company's then-outstanding stock required to approve or adopt the proposal or to elect each such nominee; or (y) otherwise solicit proxies from stockholders in support of such proposal or nomination;

(L) any other information relating to such stockholder, such beneficial owner, or their respective affiliates or associates or others acting in concert with them, or director nominee or proposed business that, in each case, would be required to be disclosed in a proxy statement or other filing required to be made in connection with the solicitation of proxies in support of such nominee (in a contested election of directors) or proposal pursuant to Section 14 of the 1934 Act; and

(M) such other information relating to any proposed item of business as the Company may reasonably require to determine whether such proposed item of business is a proper matter for stockholder action.

(iv) In addition to the requirements of this Section 2.4, to be timely, a stockholder's notice (and any additional information submitted to the Company in connection therewith) must further be updated and supplemented (1) if necessary, so that the information provided or required to be provided in such notice is true and correct as of the record date(s) for determining the stockholders entitled to notice of, and to vote at, the meeting and as of the date that is 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof and (2) to provide any additional information that the Company may reasonably request. Such update and supplement or additional information, if applicable, must be received by the secretary at the principal executive offices of the Company, in the case of a request for additional information, promptly following a request therefor, which response must be delivered not later than such reasonable time as is specified in any such request from the Company or, in the case of any other update or supplement of any information, not later than five business days after the record date(s) for the meeting (in the case of any update and supplement required to be made as of the record date(s)), and not later than eight business days prior to the date for the meeting or any adjournment, rescheduling or postponement thereof (in the case of the update and supplement required to be made as of 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof). The failure to timely provide such update, supplement or additional information shall result in the nomination or proposal no longer being eligible for consideration at the meeting.

(b) *Special Meetings of Stockholders*. Except to the extent required by the DGCL, and subject to Section 2.3(a), special meetings of stockholders may be called only in accordance with the Company's certificate of incorporation and these bylaws. Only such business will be conducted at a special meeting of stockholders as has been brought before the special meeting pursuant to the Company's notice of meeting. If the election of directors is included as business to be brought before a special meeting in the Company's notice of meeting, then nominations of persons for election to the Board of Directors at such special meeting may be made by any stockholder who (i) is a stockholder of record at the time of giving of the notice contemplated by this Section 2.4(b); (ii) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the special meeting; (iii) is a stockholder of record on the record date

for the determination of stockholders entitled to vote at the special meeting; (iv) is a stockholder of record at the time of the special meeting; and (v) complies with the procedures set forth in this Section 2.4(b). For nominations to be properly brought by a stockholder before a special meeting pursuant to this Section 2.4(b), the stockholder's notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day prior to the day of the special meeting and no later than 5:00 p.m., local time, on the 10th day following the day on which public announcement of the date of the special meeting was first made. In no event will any adjournment, rescheduling or postponement of a special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice. A stockholder's notice to the Secretary must comply with the applicable notice requirements of Section 2.4(a)(iii).

(c) *Other Requirements.*

(i) To be eligible to be a nominee by any stockholder for election as a director of the Company, the proposed nominee must provide to the secretary, in accordance with the applicable time periods prescribed for delivery of notice under Section 2.4(a)(ii) or Section 2.4(b):

(1) a signed and completed written questionnaire (in the form provided by the secretary at the written request of the nominating stockholder, which form will be provided by the secretary within 10 days of receiving such request) containing information regarding such nominee's background and qualifications and such other information as may reasonably be required by the Company to determine the eligibility of such nominee to serve as a director of the Company or to serve as an independent director of the Company;

(2) a written representation and undertaking that, unless previously disclosed to the Company, such nominee is not, and will not become, a party to any voting agreement, arrangement, commitment, assurance or understanding with any person or entity as to how such nominee, if elected as a director, will vote on any issue;

(3) a written representation and undertaking that, unless previously disclosed to the Company, such nominee is not, and will not become, a party to any Third-Party Compensation Arrangement;

(4) a written representation and undertaking that, if elected as a director, such nominee would be in compliance, and will continue to comply, with the Company's corporate governance guidelines as disclosed on the Company's website, as amended from time to time; and

(5) a written representation and undertaking that such nominee, if elected, intends to serve a full term on the Board of Directors.

(ii) At the request of the Board of Directors, any person nominated by the Board of Directors for election as a director must furnish to the secretary the information that is required to be set forth in a stockholder's notice of nomination that pertains to such nominee.

(iii) No person will be eligible to be nominated by a stockholder for election as a director of the Company unless nominated in accordance with the procedures set forth in this Section 2.4. No business proposed by a stockholder will be conducted at a stockholder meeting except in accordance with this Section 2.4.

(iv) The chairperson of the applicable meeting of stockholders will, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the

procedures prescribed by these bylaws or that business was not properly brought before the meeting. If the chairperson of the meeting should so determine, then the chairperson of the meeting will so declare to the meeting and the defective nomination will be disregarded or such business will not be transacted, as the case may be.

(v) Notwithstanding anything to the contrary in this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear in person at the meeting to present a nomination or other proposed business, such nomination will be disregarded or such proposed business will not be transacted, as the case may be, notwithstanding that proxies in respect of such nomination or business may have been received by the Company and counted for purposes of determining a quorum. For purposes of this Section 2.4, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting, and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

(vi) Without limiting this Section 2.4, a stockholder must also comply with all applicable requirements of the 1934 Act with respect to the matters set forth in this Section 2.4, it being understood that (1) any references in these bylaws to the 1934 Act are not intended to, and will not, limit any requirements applicable to nominations or proposals as to any other business to be considered pursuant to this Section 2.4; and (2) compliance with clause (4) of Section 2.4(a)(i) and with Section 2.4(b) are the exclusive means for a stockholder to make nominations or submit other business (other than as provided in Section 2.4(c)(vii)).

(vii) Notwithstanding anything to the contrary in this Section 2.4, the notice requirements set forth in these bylaws with respect to the proposal of any business pursuant to this Section 2.4 will be deemed to be satisfied by a stockholder if (1) such stockholder has submitted a proposal to the Company in compliance with Rule 14a-8 under the 1934 Act; and (2) such stockholder's proposal has been included in a proxy statement that has been prepared by the Company to solicit proxies for the meeting of stockholders. Subject to Rule 14a-8 and other applicable rules and regulations under the 1934 Act, nothing in these bylaws will be construed to permit any stockholder, or give any stockholder the right, to include or have disseminated or described in the Company's proxy statement any nomination of a director or any other business proposal.

2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 QUORUM

The holders of a majority of the voting power of the capital stock of the Company issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. Where a separate vote by a class or series or classes or series is required, a majority of the voting power of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (a) the chairperson of the meeting, or (b) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the original meeting.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Company may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business and discussion as seem to the chairperson in order. The chairperson of any meeting of stockholders shall be designated by the Board of Directors; in the absence of such designation, the chairperson of the Board of Directors, if any, or the chief executive officer (in the absence of the chairperson of the Board of Directors) or the president (in the absence of the chairperson of the Board of Directors and the chief executive officer), or in their absence any other executive officer of the Company, shall serve as chairperson of the stockholder meeting. The chairperson of any meeting of stockholders shall have the power to adjourn the meeting to another place, if any, date or time, whether or not a quorum is present.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of the stock exchange on which the Company's securities are listed, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders and broker non-votes and abstentions will be considered for purposes of establishing a quorum, but will not be considered as votes cast for or against a proposal. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the voting power of the outstanding shares of such class or series or classes or series present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of such class or series or classes or series (and broker non-votes and abstentions will not be considered as votes cast for or against a proposal), except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of the stock exchange on which the securities of the Company are listed.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Subject to the rights of holders of preferred stock of the Company, any action required or permitted to be taken by the stockholders of the Company must be effected at a duly called annual or special meeting of stockholders of the Company and may not be effected by any consent in writing by such stockholders.

2.11 RECORD DATES

In order that the Company may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided*, *however*, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the Company may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action,

the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders, or such stockholder's authorized officer, director, employee or agent, may authorize another person or persons to act for such stockholder by proxy authorized by a document or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL.

2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The Company shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided, however,* if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Company shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Company's principal place of business. In the event that the Company determines to make the list available on an electronic network, the Company may take reasonable steps to ensure that such information is available only to stockholders of the Company. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then such list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the Company shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The Company may designate one or more persons as alternate inspectors to replace any inspector who fails to act.

Such inspectors shall:

(a) ascertain the number of shares outstanding and the voting power of each;

(b) determine the shares represented at the meeting and the validity of proxies and ballots;

(c) count all votes and ballots;

(d) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors; and

(e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots.

The inspectors of election shall perform their duties impartially, in good faith, to the best of their ability and as expeditiously as is practical. If there are multiple inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is *prima facie* evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS

The business and affairs of the Company shall be managed by or under the direction of the Board of Directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 NUMBER OF DIRECTORS

The Board of Directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution of a majority of the Whole Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

If so provided in the certificate of incorporation, the directors of the Company shall be divided into three classes.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the Company. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws or permitted in the specific case by resolution of the Board of Directors, and subject to the rights of holders of Preferred Stock,

vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and not by stockholders. If the directors are divided into classes, a person so chosen to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The Board of Directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board of Directors may participate in a meeting of the Board of Directors by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the Board of Directors may be held without notice at such time and at such place as shall from time to time be determined by the Board of Directors.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the chairperson of the Board of Directors, the chief executive officer, the president, the secretary or a majority of the Whole Board.

Notice of the time and place of special meetings shall be:

(a) delivered personally by hand, by courier or by telephone;

(b) sent by United States first-class mail, postage prepaid;

(c) sent by facsimile;

(d) sent by electronic mail; or

(e) otherwise given by electronic transmission (as defined in Section 232 of the DGCL),

directed to each director at that director’s address, telephone number, facsimile number, electronic mail address or other contact for notice by electronic transmission, as the case may be, as shown on the Company’s records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile, (iii) sent by electronic mail or (iv) otherwise given by electronic transmission, it shall be delivered, sent or otherwise directed to each director, as applicable, at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Company’s principal executive office) nor the purpose of the meeting, unless required by statute.

3.8 QUORUM; VOTING

At all meetings of the Board of Directors, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the Board of Directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

The affirmative vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, except as may otherwise be expressly provided herein or therein and denoted with the phrase “notwithstanding the final paragraph of Section 3.8 of the bylaws” or language to similar effect, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or of any committee thereof, may be taken without a meeting if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this Section 3.9 at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board of Directors shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS

Any director or the entire Board of Directors may be removed from office by stockholders of the Company in the manner specified in the certificate of incorporation and applicable law. No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director’s term of office.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The Board of Directors may, by resolution passed by a majority of the Whole Board, designate one or more committees, each committee to consist of one or more of the directors of the Company. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from

voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors or in these bylaws, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Company, and may authorize the seal of the Company to be affixed to all papers that may require it; but no such committee shall have the power or authority to (a) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (b) adopt, amend or repeal any bylaw of the Company.

4.2 COMMITTEE MINUTES

Each committee and subcommittee shall keep regular minutes of its meetings.

4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees and subcommittees shall be governed by, and held and taken in accordance with, the provisions of:

(a) Section 3.5 (place of meetings and meetings by telephone);

(b) Section 3.6 (regular meetings);

(c) Section 3.7 (special meetings and notice);

(d) Section 3.8 (quorum; voting);

(e) Section 3.9 (action without a meeting); and

(f) Section 7.4 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee or subcommittee and its members for the Board of Directors and its members. *However*, (i) the time and place of regular meetings of committees or subcommittees may be determined either by resolution of the Board of Directors or by resolution of the committee or subcommittee; (ii) special meetings of committees or subcommittees may also be called by resolution of the Board of Directors or the committee or the subcommittee; and (iii) notice of special meetings of committees and subcommittees shall also be given to all alternate members who shall have the right to attend all meetings of the committee or subcommittee. The Board of Directors may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V - OFFICERS

5.1 OFFICERS

The officers of the Company shall be a president and a secretary. The Company may also have, at the discretion of the Board of Directors, a chairperson of the Board of Directors, a vice chairperson of the Board of Directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The Board of Directors shall appoint the officers of the Company, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS

The Board of Directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers as the business of the Company may require. Each of such officers shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board of Directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board of Directors or, for the avoidance of doubt, any duly authorized committee or subcommittee thereof or by any officer who has been conferred such power of removal.

Any officer may resign at any time by giving notice, in writing or by electronic transmission, to the Company. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Company under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the Company shall be filled by the Board of Directors or as provided in Section 5.3.

5.6 REPRESENTATION OF SECURITIES OF OTHER ENTITIES

The chairperson of the Board of Directors, the chief executive officer, the president, any vice president, the treasurer, the secretary or assistant secretary of this Company or any other person authorized by the Board of Directors or the chief executive officer, the president or a vice president, is authorized to vote, represent and exercise on behalf of this Company all rights incident to any and all shares or other securities of any other entity or entities, and all rights incident to any management authority conferred on the Company in accordance with the governing documents of any entity or entities, standing in the name of this Company, including the right to act by written consent. The authority granted herein may be

exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the Company shall respectively have such authority and perform such duties in the management of the business of the Company as may be designated from time to time by the Board of Directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board of Directors.

ARTICLE VI - STOCK

6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the Company shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Company. Unless otherwise provided by resolution of the Board of Directors, every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of, the Company by any two officers of the Company representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Company with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The Company shall not have power to issue a certificate in bearer form.

The Company may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the Company in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the Company shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the Company is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Company shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Company shall issue to represent such class or series of stock, a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 156, 202(a), 218(a) or 364 of the DGCL or with respect to this Section 6.2 a statement that the Company will furnish without charge to each

stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

6.3 LOST CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Company and cancelled at the same time. The Company may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Company may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Company a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 DIVIDENDS

The Board of Directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the Company's capital stock. Dividends may be paid in cash, in property, or in shares of the Company's capital stock, subject to the provisions of the certificate of incorporation. The Board of Directors may set apart out of any of the funds of the Company available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the Company shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer.

6.6 STOCK TRANSFER AGREEMENTS

The Company shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Company to restrict the transfer of shares of stock of the Company of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.7 REGISTERED STOCKHOLDERS

The Company:

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and notices and to vote as such owner; and

(b) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII - MANNER OF GIVING NOTICE AND WAIVER

7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders shall be given in the manner set forth in the DGCL.

7.2 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Company under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the Company. Any stockholder who fails to object in writing to the Company, within 60 days of having been given written notice by the Company of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice. This Section 7.2 shall not apply to Sections 164, 296, 311, 312 or 324 of the DGCL.

7.3 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Company is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.4 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - INDEMNIFICATION

8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether

civil, criminal, administrative or investigative (a "**Proceeding**") (other than an action by or in the right of the Company) by reason of the fact that such person is or was a director or officer of the Company, or is or was a director or officer of the Company serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE COMPANY

Subject to the other provisions of this Article VIII, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the Company, or is or was a director or officer of the Company serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Company unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer (for purposes of this Section 8.3 only, as such term is defined in Section 145(c)(1) of the DGCL) of the Company has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. The Company may indemnify any other person who is not a present or former director or officer of the Company against expenses (including attorneys' fees) actually and reasonably incurred by such person to the extent he or she has been successful on the merits or otherwise in defense of any suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein.

8.4 INDEMNIFICATION OF OTHERS

Subject to the other provisions of this Article VIII, the Company shall have power to indemnify its employees and agents, or any other persons, to the extent not prohibited by the DGCL or other applicable law. The Board of Directors shall have the power to delegate to any person or persons identified in

subsections (1) through (4) of Section 145(d) of the DGCL the determination of whether employees or agents shall be indemnified.

8.5 ADVANCED PAYMENT OF EXPENSES

Expenses (including attorneys' fees) actually and reasonably incurred by an officer or director of the Company in defending any Proceeding shall be paid by the Company in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) actually and reasonably incurred by former directors and officers or other employees and agents of the Company or by persons serving at the request of the Company as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the Company deems appropriate. The right to advancement of expenses shall not apply to any Proceeding (or any part of any Proceeding) for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding (or any part of any Proceeding) referenced in Section 8.6(b) or 8.6(c) prior to a determination that the person is not entitled to be indemnified by the Company.

Notwithstanding the foregoing, unless otherwise determined pursuant to Section 8.8, no advance shall be made by the Company to an officer of the Company (except by reason of the fact that such officer is or was a director of the Company, in which event this paragraph shall not apply) in any Proceeding if a determination is reasonably and promptly made (a) by a vote of the directors who are not parties to such Proceeding, even though less than a quorum, or (b) by a committee of such directors designated by the vote of the majority of such directors, even though less than a quorum, or (c) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, that facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Company.

8.6 LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 and the DGCL, the Company shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

(a) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(b) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(c) for any reimbursement of the Company by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the Company, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the Company of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(d) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the Company or its directors, officers, employees, agents or other indemnitees, unless (i) the Board of Directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (iii) otherwise required to be made under Section 8.7 or (iv) otherwise required by applicable law; or

(e) if prohibited by applicable law.

8.7 DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the Company of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The Company shall indemnify such person against any and all expenses that are actually and reasonably incurred by such person in connection with any action for indemnification or advancement of expenses from the Company under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the Company shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8 NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The Company is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9 INSURANCE

The Company may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Company would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 EFFECT OF REPEAL OR MODIFICATION

A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to or repeal or elimination

of the certificate of incorporation or these bylaws after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "**Company**" shall include, in addition to the resulting company, any constituent company (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent company, or is or was serving at the request of such constituent company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving company as such person would have with respect to such constituent company if its separate existence had continued. For purposes of this Article VIII, references to "**other enterprises**" shall include employee benefit plans; references to "**fines**" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "**serving at the request of the Company**" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the Company**" as referred to in this Article VIII.

ARTICLE IX - GENERAL MATTERS

9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the Board of Directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the Company; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Company by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 FISCAL YEAR

The fiscal year of the Company shall be fixed by resolution of the Board of Directors and may be changed by the Board of Directors.

9.3 SEAL

The Company may adopt a corporate seal, which shall be adopted and which may be altered by the Board of Directors. The Company may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "**person**" includes a corporation, partnership, limited liability company, joint venture, trust or other enterprise, and a natural person. Any reference in these bylaws to a section of the DGCL shall be deemed to refer to such section as amended from time to time and any successor provisions thereto.

9.5 FORUM SELECTION

Unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, stockholder, officer or other employee of the Company to the Company or the Company's stockholders, (c) any action arising pursuant to any provision of the DGCL or the certificate of incorporation or these bylaws (as either may be amended from time to time) or (d) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (a) through (d) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction.

Unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Any person or entity purchasing or otherwise acquiring any interest in any security of the Company shall be deemed to have notice of and consented to the provisions of this Section 9.5. For the avoidance of doubt, nothing contained in this Section 9.5 shall apply to any action brought to enforce a duty or liability created by the 1934 Act or any successor thereto.

ARTICLE X - AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; provided, however, that the affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the Company to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII, Section 9.5 of Article IX or this Article X (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). The Board of Directors shall also have the power to adopt, amend or repeal bylaws; provided, however, that a bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the Board of Directors.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David M. Clapper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 of Minerva Surgical, Inc. ("the Company");

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

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

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

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

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

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

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

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

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

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

Date: December 2, 2021

By: /s/ David M. Clapper
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joel R. Jung, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ending September 30, 2021 of Minerva Surgical, Inc.(" the Company");

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

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

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

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

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

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

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

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

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

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

Date: December 2, 2021

By: /s/ Joel R. Jung
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Minerva Surgical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David M. Clapper certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: December 2, 2021

By: /s/ David M. Clapper
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Minerva Surgical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joel R. Jung certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: December 2, 2021

By: /s/ Joel R. Jung
Chief Financial Officer
(Principal Financial and Accounting Officer)