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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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 001-40797

**PROCEPT BioRobotics Corporation**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**26-0199180**

(I.R.S. Employer Identification No.)

**900 Island Drive**

(Address of Principal Executive Offices)

**Redwood City CA**

**94065**

(Zip Code)

**(650) 232-7200**

Registrant's telephone number, including area code

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, \$0.00001 par value per share	PRCT	Nasdaq Global 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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Act). Yes  No

The registrant had outstanding 43,496,831 shares of common stock as of October 31, 2021.

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**PROCEPT BioRobotics Corporation**  
**Form 10-Q – QUARTERLY REPORT**  
**For the Quarter Ended September 30, 2021**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “can,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements regarding our business model and strategic plans for our products, technologies and business, including our implementation thereof, the impact on our business, financial condition and results of operations from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, the timing of and our ability to obtain and maintain regulatory approvals, our commercialization, marketing and manufacturing capabilities and strategy, our expectations about the commercial success and market acceptance of our products, the sufficiency of our cash, cash equivalents and short-term investments, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described under the sections in this Quarterly Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely upon these forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance, or achievements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

### SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II. Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We are an early-stage company with a history of significant net losses, we expect to continue to incur operating losses for the foreseeable future and we may not be able to achieve or sustain profitability.
- Our revenue is primarily generated from sales of our AquaBeam Robotic System and the accompanying single-use disposable handpieces, and we are therefore highly dependent on the success of those products.
- Our quarterly and annual operating results may fluctuate significantly and may not fully reflect the underlying performance of our business. This makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- The terms of our loan and security agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- We may need additional funding beyond the proceeds of this offering to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate one or more of our product development programs and future commercialization efforts.

- The commercial success of our AquaBeam Robotic System and Aquablation therapy will depend upon the degree of market acceptance of our products among hospitals, surgeons and patients.
- We have limited experience in training and marketing and selling our products and we may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop and maintain broad brand awareness in a cost-effective manner.
- We may not be able to obtain or maintain adequate levels of third-party coverage and reimbursement, and third parties may rescind or modify their coverage or delay payments related to our products.
- We face competition from many sources, including larger companies, and we may be unable to compete successfully.
- We have limited experience manufacturing our products in large-scale commercial quantities, and we face a number of manufacturing risks that may adversely affect our manufacturing abilities which could delay, prevent or impair our growth.
- We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations.
- Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.
- The sizes of the addressable markets for our AquaBeam Robotic System have not been established with precision and our potential market opportunity may be smaller than we estimate and may decline.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.
- Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.
- We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.
- Changes to the reimbursement rates for BPH treatments and measures to reduce healthcare costs may adversely impact our business.
- We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.
- Our AquaBeam Robotic System and our operations are subject to extensive government regulation and oversight in the United States. If we fail to maintain necessary marketing authorizations for our AquaBeam Robotic System, or if approvals or clearances for future products or modifications to existing products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.
- Even though we have obtained marketing authorization for our AquaBeam Robotic System, we are subject to ongoing regulatory review and scrutiny. 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.
- We have to obtain, maintain and protect our intellectual property and failure to do so may adversely impact our competitive position.
- We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time-consuming, unsuccessful, and could interfere with our ability to sell and market our products or services.
- The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, which could result in substantial losses for purchasers of our common stock in this offering, and we may not be able to meet investor or analyst expectations.
- Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.

**PROCEPT BioRobotics Corporation**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except per share data)  
(unaudited)

	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 320,484	\$ 100,130
Accounts receivable, net	6,353	1,549
Inventory	10,401	6,924
Prepaid expenses and other current assets	2,232	1,653
Total current assets	339,470	110,256
Restricted cash	777	777
Property and equipment, net	5,731	8,274
Operating lease right-of-use assets, net	3,667	4,641
Intangible assets, net	1,818	2,023
Total assets	\$ 351,463	\$ 125,971
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,590	\$ 1,240
Accrued compensation	4,875	4,640
Note payable – current portion	—	4,551
Operating lease – current portion	2,032	1,708
Deferred revenue	848	233
Convertible preferred stock warrant liability	—	177
Other current liabilities	2,834	1,977
Total current liabilities	14,179	14,526
Note payable – non-current portion	49,762	44,407
Operating lease – non-current portion	2,550	4,096
Loan facility derivative liability	1,460	1,782
Other non-current liabilities	200	200
Total liabilities	68,151	65,011
Commitments and contingencies (see Note 9)		
Redeemable convertible preferred stock issuable in series, \$0.00001 par value;		
Authorized shares: none and 26,984, at September 30, 2021 and December 31, 2020, respectively		
Issued and outstanding shares: none and 25,402 at September 30, 2021 and December 31, 2020, respectively		
Aggregate liquidation preference: none and \$245,768 at September 30, 2021 and December 31, 2020, respectively	—	243,854
Stockholders' equity (deficit):		
Preferred stock, \$0.00001 par value;		
Authorized shares: 10,000 and none at September 30, 2021 and December 31, 2020, respectively		
Issued and outstanding shares: none at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.00001 par value;		
Authorized shares: 300,000 and 40,000 at September 30, 2021 and December 31, 2020, respectively		
Issued and outstanding shares: 43,472 and 4,713 at September 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	526,526	18,788
Accumulated other comprehensive loss	(41)	(14)
Accumulated deficit	(243,173)	(201,668)
Total stockholders' equity (deficit)	283,312	(182,894)
Total liabilities, convertible redeemable preferred stock and stockholders' equity (deficit)	\$ 351,463	\$ 125,971

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

**PROCEPT BioRobotics Corporation**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(in thousands, except per share data)**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue .....	\$ 8,668	\$ 2,107	\$ 24,335	\$ 4,496
Cost of sales .....	4,428	2,138	12,986	6,221
Gross profit .....	4,240	(31)	11,349	(1,725)
Operating expenses:				
Research and development .....	4,919	3,893	13,917	11,732
Selling, general and administrative .....	12,118	7,054	34,765	21,138
Total operating expenses .....	17,037	10,947	48,682	32,870
Loss from operations .....	(12,797)	(10,978)	(37,333)	(34,595)
Interest expense .....	(1,469)	(1,387)	(4,370)	(3,490)
Interest and other income, net .....	163	357	198	344
Net loss .....	\$ (14,103)	\$ (12,008)	\$ (41,505)	\$ (37,741)
Net loss per share, basic and diluted .....	\$ (1.22)	\$ (2.77)	\$ (5.64)	\$ (11.34)
Weighted-average common shares used to compute net loss per share attributable to common shareholders, basic and diluted .....	11,580	4,329	7,361	3,327
Other comprehensive loss:				
Unrealized (loss) gain on cash equivalents ..	(2)	(16)	(27)	3
Comprehensive loss .....	\$ (14,105)	\$ (12,024)	\$ (41,532)	\$ (37,738)

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

**PROCEPT BioRobotics Corporation**  
**CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY**  
**(DEFICIT)**  
**(in thousands)**  
**(unaudited)**

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	25,402	\$243,854	4,713	\$ —	\$ 18,788	\$ (14)	\$ (201,668)	\$ (182,894)
Issuance upon exercise of options	—	—	504	—	1,225	—	—	1,225
Stock-based compensation expense	—	—	—	—	650	—	—	650
Unrealized loss on cash equivalents	—	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	—	(12,822)	(12,822)
Balance at March 31, 2021	25,402	243,854	5,217	—	20,663	(30)	(214,490)	(193,857)
Issuance of redeemable convertible preferred stock, net of issuance costs of \$290	4,448	84,710	—	—	—	—	—	—
Issuance upon exercise of options	—	—	575	—	1,415	—	—	1,415
Stock-based compensation expense	—	—	—	—	725	—	—	725
Unrealized loss on cash equivalents	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	(14,580)	(14,580)
Balance at June 30, 2021	29,850	328,564	5,792	—	22,803	(39)	(229,070)	(206,306)
Issuance upon exercise of warrants	62	970	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(29,912)	(329,534)	29,912	—	329,534	—	—	329,534
Issuance of common stock upon initial public offering, net of underwriting discounts, commissions and offering expenses of \$16,076	—	—	7,539	—	172,409	—	—	172,409
Issuance upon exercise of options	—	—	229	—	855	—	—	855
Stock-based compensation expense	—	—	—	—	925	—	—	925
Unrealized loss on cash equivalents	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	(14,103)	(14,103)
Balance at September 30, 2021	—	\$ —	43,472	\$ —	\$526,526	\$ (41)	\$ (243,173)	\$ 283,312

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	20,998	\$ 173,068	2,290	\$ —	\$ 4,808	\$ 4	\$ (148,649)	\$ (143,837)
Issuance upon exercise of warrants	75	379	—	—	—	—	—	—
Issuance upon exercise of options	—	—	602	—	1,024	—	—	1,024
Stock-based compensation expense	—	—	—	—	561	—	—	561
Unrealized loss on cash equivalents	—	—	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	—	—	(13,126)	(13,126)
Balance at March 31, 2020	21,073	173,447	2,892	—	6,393	(3)	(161,775)	(155,385)
Issuance upon exercise of warrants	45	230	—	—	—	—	—	—
Issuance upon exercise of options	—	—	218	—	979	—	—	979
Stock-based compensation expense	—	—	—	—	445	—	—	445
Unrealized loss on cash equivalents	—	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	—	(12,606)	(12,606)
Balance at June 30, 2020	21,118	173,677	3,110	—	7,817	23	(174,381)	(166,541)
Conversion of redeemable convertible preferred stock to common stock	(1,474)	(9,520)	1,474	—	9,520	—	—	9,520
Issuance upon exercise of warrants	531	3,209	—	—	—	—	—	—
Issuance of redeemable convertible preferred stock, net of issuance costs of \$496	5,227	76,486	—	—	—	—	—	—
Issuance upon exercise of options	—	—	36	—	51	—	—	51
Stock-based compensation expense	—	—	—	—	563	—	—	563
Unrealized loss on cash equivalents	—	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	—	(12,008)	(12,008)
Balance at September 30, 2020	25,402	\$ 243,852	4,620	\$ —	\$ 17,951	\$ 7	\$ (186,389)	\$ (168,431)

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



**PROCEPT BioRobotics Corporation**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (41,505)	\$ (37,741)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
Depreciation and amortization	2,561	2,145
Stock-based compensation expense	2,300	1,569
Change in fair value of redeemable convertible preferred stock warrants and derivative liability	(235)	(408)
Non-cash lease expense	(249)	(82)
Inventory write-down	537	22
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable, net	(4,804)	(729)
Inventory	(3,580)	(895)
Prepaid expenses and other current assets	(606)	(200)
Accounts payable	2,362	(262)
Accrued compensation	235	1,307
Accrued interest expense	804	866
Deferred revenue	615	182
Other liabilities	707	(672)
Net cash used in operating activities	<u>(40,858)</u>	<u>(34,898)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(260)	(224)
Net cash used in investing activities	<u>(260)</u>	<u>(224)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock from the exercise of stock options	3,495	2,051
Proceeds from issuance of note payable, net of issuance costs	—	24,685
Proceeds from the exercise of redeemable convertible preferred stock warrants	858	3,310
Proceeds from issuance of Series F redeemable convertible preferred stock, net of issuance costs	—	76,488
Proceeds from issuance of Series G redeemable convertible preferred stock, net of issuance costs	84,710	—
Proceeds from issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses	172,409	—
Net cash provided by financing activities	<u>261,472</u>	<u>106,534</u>
Net increase in cash, cash equivalents and restricted cash	220,354	71,412
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of the period	100,907	42,712
End of the period	<u>\$ 321,261</u>	<u>\$ 114,124</u>
<b>Reconciliation of cash, cash equivalents and restricted cash to balance sheets:</b>		
Cash and cash equivalents	\$ 320,484	\$ 113,347
Restricted cash	777	777
Cash, cash equivalents and restricted cash in balance sheets	<u>\$ 321,261</u>	<u>\$ 114,124</u>
<b>Supplemental cash flow information</b>		
Interest paid	<u>\$ 3,566</u>	<u>\$ 2,785</u>
<b>Non-cash investing and financing activities</b>		
Transfer of evaluation units from inventory to property and equipment, net	<u>\$ (1,227)</u>	<u>\$ 1,470</u>
Property and equipment included in accounts payable and accrued expenses	<u>\$ 200</u>	<u>\$ 200</u>
Deferred offering costs included in accounts payable and other current liabilities	<u>\$ 819</u>	<u>\$ —</u>

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

**PROCEPT BioRobotics Corporation**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Organization**

***Description of Business***

PROCEPT BioRobotics Corporation (the “Company”) was incorporated in the state of California in 2007 and its headquarters are located in Redwood City, California. In April 2021, the Company re-incorporated in the state of Delaware. The Company received U.S. Food and Drug Administration clearance in December 2017 to market its AquaBeam<sup>®</sup> Robotic System, an automated surgical robot providing tissue removal for the treatment of benign prostatic hyperplasia, a prostate gland enlargement condition.

***Liquidity***

As of September 30, 2021 and December 31, 2020, the Company had cash and cash equivalents of \$320.5 million and \$100.1 million, respectively, and an accumulated deficit of \$243.2 million and \$201.7 million, respectively. In September 2021, the Company completed its initial public offering (“IPO”) for net proceeds of approximately \$172.4 million, after deducting underwriting discounts and commissions, and offering expenses. Since its inception, the Company has financed its operations with a combination of debt and equity financing arrangements. The Company expects its cash and cash equivalents, revenue and available debt financing arrangements will be sufficient to fund its operations through at least the next twelve months from the issuance date of these financial statements. The Company has not achieved positive cashflow from operations to date and expects to continue incurring losses for the foreseeable future as it focuses on growing its business.

The COVID-19 pandemic and the resulting economic downturn are affecting business conditions in the industry in which the Company operates. In response to the pandemic, many state and local governments in the United States issued orders that temporarily precluded elective medical procedures in order to conserve scarce health system resources. 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.

**2. Summary of Significant Accounting Policies**

***Basis of Preparation***

The condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”). These consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the consolidated financial statements. Management uses significant judgment when making estimates related to its common stock valuation in periods before the Company’s IPO and related stock-based compensation, right-of-use lease asset, lease liability, the valuations of the redeemable convertible preferred stock warrant liability and loan facility derivative liability, as well as certain accrued liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

### ***Reverse Stock Split***

In September 2021, the Board of Directors and stockholders approved, and the Company filed, an amended and restated certificate of incorporation effecting a 1-for-4.75 reverse stock split of common stock and all redeemable convertible preferred stock. The par value of the common and redeemable convertible preferred stock was not adjusted as a result of the reverse stock split. All authorized, issued and outstanding common stock, redeemable convertible preferred stock, warrants for preferred stock, stock options and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

### ***Initial Public Offering***

In September 2021, the Company completed its IPO by issuing 6,556,000 shares of common stock, and the exercise of the underwriters option for 983,400 shares, at an offering price of \$25.00 per share, for total net proceeds of approximately \$172.4 million, after deducting underwriting discounts and commissions of \$13.2 million and offering expenses of \$2.9 million. Offering costs are capitalized, and consist of fees and expenses incurred in connection with the sale of common stock in its IPO, including legal, accounting, printing and other IPO-related costs. Upon completion of its IPO, these deferred offering costs were reclassified to stockholders' equity and recorded against the proceeds from the offering. In addition, all 29,912,264 shares of its then-outstanding redeemable convertible preferred stock automatically converted into 29,912,264 shares of common stock and it reclassified \$329.5 million of redeemable convertible preferred stock to additional paid-in capital on its condensed consolidated balance sheet.

### ***Unaudited Interim Financial Statements***

The accompanying balance sheet as of September 30, 2021, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, cash flows for the nine months ended September 30, 2021 and 2020, and the statements of redeemable convertible preferred stock and stockholders' equity (deficit) as of September 30, 2021 and 2020, are unaudited. The financial data and other information disclosed in these notes to the financial statements related to September 30, 2021, and the three and nine months ended September 30, 2021 and 2020, are also unaudited. The accompanying balance sheet as of December 31, 2020 has been derived from the audited consolidated financial statements included in the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission.

The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to a fair statement of the Company's financial position as of September 30, 2021, and the results of its operations for the three and nine months ended September 30, 2021 and 2020, and cash flows for the nine months ended September 30, 2021 and 2020. 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, or for any other interim period or for any future year and should be read in conjunction with the annual consolidated financial statements included in the Company's Registration Statement on Form S-1.

### ***Par Value and Shares Authorized Change***

In June 2021, the Board of Directors and stockholders approved, and the Company filed, an amended and restated certificate of incorporation effecting a change in par value from \$0.001 to \$0.00001 per share of common stock and all redeemable convertible preferred stock. All issued and outstanding common stock and redeemable convertible preferred stock contained in the financial statements have been retroactively corrected to reflect this immaterial change in par value for all periods presented.

In September 2021, 10.0 million shares of preferred stock was authorized and the shares of common stock authorized was increased to 300.0 million shares, both having a par value of \$0.00001 per share.

### ***Cash, Cash Equivalents and Restricted Cash***

Cash and cash equivalents consist of cash in banks and highly liquid securities, which are readily convertible to cash, that mature within 90 days or less from the original date of purchase, to be cash equivalents, which include money market funds.

Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. Unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit).

Restricted cash is related to the Company's letter of credit for the lease of its corporate headquarters.

### ***Fair Value of Financial Instruments***

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash and cash equivalents, and accounts receivable, accounts payable and accrued liabilities, which approximate fair value due to their relatively short maturities as well as the redeemable convertible preferred stock warrant liability and loan facility derivative liability. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1- Observable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2- Other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data.
- Level 3- Unobservable inputs that are supported by little or no market activities, which would require the Company to develop its own assumptions.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The following is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	September 30,				December 31,			
	2021				2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:								
Cash .....	\$ 179,797	\$ —	\$ —	\$ 179,797	\$ 1,502	\$ —	\$ —	\$ 1,502
Cash equivalents .....	140,687	—	—	140,687	98,628	—	—	98,628
Total cash and cash equivalents .....	<u>\$ 320,484</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 320,484</u>	<u>\$ 100,130</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 100,130</u>
Preferred stock warrant liability .....	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 177	\$ 177
Loan facility derivative liability .....	\$ —	\$ —	\$ 1,610	\$ 1,610	\$ —	\$ —	\$ 1,782	\$ 1,782

Cash equivalents consist primarily of money market funds.

There were no transfers in and out of Level 3 during the nine months ended September 30, 2021 and year ended December 31, 2020.

### ***Redeemable Convertible Preferred Stock Warrants***

The following table sets forth a summary of the changes in the estimated fair value of the Company's redeemable convertible preferred stock warrants, which represents financial instruments with valuations classified as

Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gain or loss in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology recognized in the statement of operations as a component of interest and other income or expense as appropriate (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Beginning of the period	\$ 129	\$ 749	\$ 177	\$ 870
Exercised	(112)	(532)	(113)	(653)
Cancelled	(16)	(22)	(16)	(22)
Change in fair value	(1)	(67)	(48)	(67)
End of the period	\$ —	\$ 128	\$ —	\$ 128

Upon the completion of the Company's IPO in September 2021, warrants exercised for redeemable convertible preferred stock were automatically converted into 62,454 shares of common stock and the remaining unexercised warrants expired, therefore no warrants outstanding at September 30, 2021.

The fair value of the redeemable convertible preferred stock warrant liability was determined using the Black-Scholes option pricing model using the following assumptions:

	December 31, 2020
Expected life (years)	1.4
Expected volatility	80 %
Risk-free interest rate	0.1 %
Expected dividend rate	— %

#### *Loan facility derivative liability*

In connection with the Company's loan facility, the Company is obligated to pay a fee upon the earlier occurrence of a defined liquidity event, including but not limited to, a merger or sale of our assets or voting stock, or achieving a \$200.0 million trailing twelve months revenue target, in each case, by September 2029. The fee is calculated at the time of the liquidity event occurrence to be \$1.0 million if only the first installment has been drawn, \$2.0 million if the first two installments have been drawn, \$2.4 million if the first three installments have been drawn, or \$3.0 million if all four installments have been drawn, in each case, upon the occurrence of the liquidity event. The Company has determined this fee is a freestanding derivative instrument. The \$1.4 million fair value of this loan facility derivative was recorded as a debt discount and liability on the date of issuance in connection with obtaining additional financing as applicable and will be revalued every reporting period until the earlier occurrence of a defined liquidity event or achieving a revenue target by September 2029 or termination of such fee arrangement.

The following table sets forth a summary of the changes in the estimated fair value of the Company's loan facility derivative liability, classified as Level 3 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Beginning of the period	\$ 1,787	\$ 1,698	\$ 1,782	\$ 1,482
Issued	—	—	—	—
Change in fair value	(177)	(175)	(172)	41
Payment of success fee	—	—	—	—
End of the period	\$ 1,610	\$ 1,523	\$ 1,610	\$ 1,523

The fair value of the loan facility derivative liability was determined using a discounted cash flow calculation discounted at 10%.

### ***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents and, to a lesser extent, accounts receivable. The Company believes that credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms and diversity of its customer base. The Company generally does not require collateral and losses on accounts receivable have historically been within management's expectations.

The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies, and institutions with investment-grade credit ratings, as well as corporate debt or commercial paper issued by the highest quality financial and non-financial companies, and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents and issuers of investments to the extent recorded on the balance sheets. The Company has limited its credit risk associated with cash and cash equivalents by placing its investments with banks it believes are highly creditworthy and with highly rated investments.

### ***Allowance for Doubtful Accounts***

The Company provides for uncollectible accounts receivable by recording an allowance for doubtful accounts for balances deemed uncollectible. The Company evaluates the collectability of its accounts receivable based on known collection risks and historical experience. In circumstances where the Company is aware of a specific customer's inability to meet its financial obligations to the Company (e.g., bankruptcy filings, substantial downgrading of credit ratings), the Company records a specific allowance for bad debts against amounts due to reduce the carrying amount of accounts receivable to the amount it reasonably believes will be collected. The Company has not experienced any significant collection issues.

### ***Inventory***

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility expense, freight, handling costs, and consumption are expensed as incurred, and not included in overhead. The Company maintains provisions for excess and obsolete inventory based on management's estimates of forecasted demand and, where applicable, product expiration. The Company has initiated voluntary recalls for a limited number of handpieces due to certain issues related to supply chain and manufacturing processes, of which the provision recognized was not material.

### ***Property and Equipment and Intangible Assets***

Property and equipment and Intangible Assets are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization for property and equipment are determined using the straight-line method over the estimated useful lives of the respective assets, generally 3 to 5 years. The Company reclassifies inventory used at customer sites for evaluation purposes to property and equipment due to a limited history of sales of evaluation units. Amortization of intangible assets are determined using the straight-line method over the estimated useful lives, generally through the patent expiration date. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Maintenance and repairs are charged to operating expenses as incurred.

### ***Impairment of Long-Lived Assets***

Long-lived assets consist primarily of property and equipment and intangible assets, net, and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated by the asset group to the carrying amount of the

asset group. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. The Company determines fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. The Company's cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. Since inception, the Company has not recorded impairment charges on its long-lived assets.

### ***Deferred Offering Costs***

The Company capitalizes, within other assets, certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including its recent initial public offering, until such financings are consummated. After consummation of the equity financing, these costs are recorded to additional paid in capital as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs are immediately written off to operating expenses. There were no deferred offering costs as of September 30, 2021 and December 31, 2020. Upon the completion of the Company's IPO in September 2021, all deferred offering costs were reclassified to cost of issuance in additional paid in capital.

### ***Deferred Revenue***

The timing of revenue recognition may differ from the timing of invoicing to customers. The Company records deferred revenue when revenue will be recognized subsequent to invoicing. Service agreements are generally invoiced annually at the beginning of each coverage period and recorded as deferred revenue and recognized as revenue ratably over the coverage period. Deferred revenue that will be recognized during the twelve months following the balance sheet date is recorded as the current portion of deferred revenue, and the remaining portion, if any, would be recorded as non-current.

### ***Redeemable Convertible Preferred Stock***

The Company records redeemable convertible preferred stock at fair value on the date of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because it contains liquidation features that are not solely within the Company's control. The Company determined that the carrying values of the redeemable convertible preferred stock should not be adjusted to the liquidation preferences because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values of the redeemable convertible preferred stock to the liquidation preferences will be made only when it is probable that the redeemable convertible preferred stock will become redeemable. Upon the completion of the Company's IPO in September 2021, all 29,912,264 shares of its then-outstanding redeemable convertible preferred stock automatically converted into 29,912,264 shares of common stock and it reclassified \$329.5 million of redeemable convertible preferred stock to additional paid-in capital on its condensed consolidated balance sheet.

### ***Redeemable Convertible Preferred Stock Warrant Liability***

The Company has issued freestanding warrants to purchase shares of redeemable convertible preferred stock to investors in connection with sales of certain of its redeemable convertible preferred stock. The Company classified these warrants as a derivative liability because they create a conditional obligation for the Company to repurchase its own shares for cash or other assets. The fair value of the warrants are recorded on the consolidated balance sheets at the issuance of the warrants and remeasured to fair value at each financial reporting date. The changes in the fair value of the warrants are recorded in the statement of operations as a component of interest and other income or expense as appropriate. The Company will continue to adjust the carrying value of the redeemable convertible preferred stock warrant liability for changes in the fair value of the warrants until the earlier of: the exercise of the warrants, at which time the liability will be reclassified to temporary equity or the expiration of the warrant, at which time the entire amount would be reversed and reflected in the consolidated statements of operations and comprehensive loss. Upon the completion of the Company's IPO in September 2021, warrants exercised for redeemable convertible preferred stock were automatically converted into 62,454 shares of common stock and the remaining unexercised warrants expired.

### ***Loan Facility Derivative Liability***

The Company has determined that its obligation to pay success fees to a lender upon a successful liquidation event or achieving a revenue target represents freestanding financial instruments. The instruments are classified as a non-current liability in the consolidated balance sheets and are subject to remeasurement at each financial reporting date. Any change in fair value was recognized through other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

### ***Leases***

For agreements with a term of more than twelve months, the Company determines if an agreement contains a lease at inception. Operating lease liabilities represent an obligation to make lease payments arising from the lease agreement. Operating lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the remaining lease term. In determining the present value of lease payments, the Company estimates its incremental borrowing rate as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, of an amount equal to the lease payments in a similar economic environment. Operating lease liabilities are included in the Company's consolidated balance sheet. Right-of-use assets represent our right to use an underlying asset for the lease term and are classified as non-current assets. Lease expense is recognized on a straight-line basis over the expected lease term in the Company's consolidated statements of operations and comprehensive loss.

Through December 31, 2019, the Company recorded the difference between rent paid and the straight-line rent as a deferred rent liability and leasehold improvements funded by landlord incentives or allowances are recorded as leasehold improvement assets and a corresponding deferred rent liability. Upon adoption of Accounting Standards Codification ("ASC 842") on January 1, 2020, the unamortized deferred rent liability has been reclassified to reduce the right-of-use asset.

The Company has not elected to separate lease and non-lease components for any leases within its existing classes of assets and, as a result, records a right-of-use asset and lease liability based on the present value of the future minimum lease payments over the term at commencement date. Variable lease payments are expensed as incurred. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less and does not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

The Company has lessor arrangements with customers for a fixed monthly fee with no non-lease components, typically for 3-12 months. These arrangements are accounted for as an operating lease in accordance with ASC 842. These arrangements and related revenue are immaterial to the periods presented.

### ***Revenue Recognition***

Revenue is derived primarily from the sales of the AquaBeam<sup>®</sup> Robotic Systems, and handpieces that are for one-time use during each surgery using the AquaBeam Robotic System. The AquaBeam Robotic System contains both software and non-software components that are delivered together as a single product and generally contain a one-year warranty.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies the performance obligations. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct based on the contract.



The contracts are typically in the form of an agreement and a purchase order from the customer. The Company's AquaBeam Robotic System sales generally contain multiple products and services and can include a combination of the following performance obligations: robotic system, handpieces and consumables, and service.

The Company determines the transaction price it expects to be entitled to in exchange for transferring the promised product to the customer, which is based on the invoiced price for the products. All prices are at fixed amounts per the sales agreement with the customer and there are generally no discounts, rebates or other price concessions or a right of return, once the agreement is signed.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, and type of customer. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

The Company recognizes revenue as the performance obligations are satisfied by transferring control of the product or service to a customer. The Company generally recognizes revenue for the performance obligations at the following points in time:

*AquaBeam Robotic Systems* - For systems (including system components and system accessories) sold directly to end customers, revenue is recognized when the Company transfers control to the customer, which is generally at the time of delivery. Systems rented for a fixed monthly fee during an evaluation period, typically 3-12 months, are recognized as revenue straight-line during the lease term, in accordance with ASC 842, and are not material. For systems sold following an evaluation period, revenue is recognized generally once sales terms are mutually agreed (as the system is already installed at the customer site). For systems sold through distributors, revenue is recognized generally at the time of delivery. The Company's system arrangements generally do not provide a right of return. The systems are generally covered by a one-year service agreement. The service agreements have a stand alone selling price and are typically recognized as deferred revenue and amortized over the one-year service period.

*Hand pieces and other consumables* - Revenue from sales of handpieces and other consumables is recognized when control is transferred to the customers, which generally occurs at the time of shipment but also occurs at the time of delivery.

*Service* - Service revenue, inclusive of the amounts associated with the AquaBeam Robotic System warranties, is recognized over the term of the service period, as the customer benefits from the services throughout the service period.

The Company has determined that certain promises in the multiple-element arrangements, such as installation, training and certain ancillary products, are immaterial, and/or do not represent separate performance obligations for which transaction price is allocated.

The timing of revenue recognition may differ from the timing of invoicing to customers. The Company records deferred revenue when revenue is recognized subsequent to invoicing, such as service contracts, which are recognized ratably as revenue over the performance period, which is not material.

The Company's typical payment terms are between approximately 30 to 90 days. The Company expenses shipping and handling costs as incurred and includes them in the cost of sales. In those cases where shipping and handling costs are billed to customers, the Company classifies the amounts billed as a component of revenue. Taxes collected from customers and remitted to governmental authorities are excluded from revenue. The Company expenses any incremental costs of obtaining a contract, including but not limited to, sales commissions, as and when

incurred as the expected amortization period of the incremental costs would have been less than one year and are reported in selling, general and administrative expense in the statements of operations and comprehensive loss.

The following table presents revenue disaggregated by type and geography (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
U.S.				
System sales and rentals	\$ 5,038	\$ 646	\$ 14,368	\$ 1,106
Handpieces and other consumables	2,184	451	5,458	930
Service	169	16	378	26
Total U.S. revenue	7,391	1,113	20,204	2,062
Outside of U.S.				
System sales and rentals	481	369	1,725	1,111
Handpieces and other consumables	666	596	2,159	1,278
Service	130	29	247	45
Total outside of U.S. revenue	1,277	994	4,131	2,434
Total revenue	\$ 8,668	\$ 2,107	\$ 24,335	\$ 4,496

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

Cost of sales consists primarily of manufacturing overhead costs, material costs and direct labor, including stock-based compensation. A significant portion of the Company's cost of sales currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of sales also includes depreciation expense for production equipment, warranty and field service costs, and purchased intangibles and certain direct costs such as shipping costs.

### ***Research and Development***

Research and development costs are expensed as incurred. Research and development costs consist primarily of engineering, product development, and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies being developed, including employee and non-employee compensation, stock-based compensation, supplies, quality assurance expenses, related travel expenses and facilities expenses.

### ***Stock-Based Compensation***

The Company maintains a payment equity incentive plan to provide long-term incentives for employees, consultants and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

The Company is required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards made to employees and directors, including employee stock options. Stock-based compensation expense is recognized over the requisite service period in the statements of operations and comprehensive loss. The Company uses the straight-line method for expense attribution.

The valuation model used for calculating the fair value of awards for stock-based compensation expense is the Black-Scholes option-pricing model (the "Black-Scholes model"). The Black-Scholes model requires the Company to make assumptions and judgments about the variables used in the calculation, including the fair value of the Company's common stock, the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of common stock, an assumed risk-free interest rate and an expected dividend rate.

The fair value of the Company's common stock underlying the stock options has historically been determined by the Company's board of directors ("Board"). Because there was no public market for the Company's common

stock prior to the IPO, the Board determined the fair value of the Company's common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of the Company's redeemable convertible preferred stock, operating and financial performance and the general and industry-specific economic outlook. The Company used the "simplified method" to determine the expected term of the stock option. Expected volatility is based on an average of the historical volatilities of the common stock of publicly-traded companies with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected term of the option. The Company has elected to account for forfeitures when they occur.

### ***Common Stock Valuation***

The Company's intent has been to grant all options with an exercise price not less than the fair value of its common stock underlying those options on the date of grant. Prior to its IPO, the Company has determined the estimated fair value of its common stock at each valuation date in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"). The Company's board of directors, with the assistance of management, developed these valuations using significant judgment and taking into account numerous factors, including:

- valuations of its common stock with the assistance of independent third-party valuation specialists;
- the stage of development and business strategy, including the status of research and development efforts, of its products and product candidates, and the material risks related to its business and industry;
- the results of operations and financial position, including its levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and medical device sectors, as well as recently completed mergers and acquisitions of peer companies;
- the prices of its redeemable convertible preferred stock sold to investors in arm's length transactions and the rights, preferences, and privileges of its redeemable convertible preferred stock relative to those of its common stock;
- the likelihood of achieving a liquidity event for the holders of its common stock, such as an initial public offering or a sale of the Company given prevailing market conditions;
- the inability of the Company's stockholders to freely trade its common stock in the public markets, resulting in a discount to reflect the lack of marketability of the Company's common stock based on the weighted-average expected time to liquidity.
- trends and developments in its industry; and
- external market conditions affecting the life sciences and medical device industry sectors.

The Company's board of directors determined the fair value of its common stock by first determining the enterprise value of the Company's business using the market approach, income approach or from the value implied by the latest round of equity financing, and then allocating the value among the various classes of its equity securities to derive a per share value of its common stock. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

For all option granted prior to the Company's IPO in September 2021, the Board allocated the enterprise value based on the option pricing method ("OPM"). OPM treats the rights of the holders of preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the common stock can be determined by estimating the value of its portion of each of these call option rights. When valuing options granted round the time of an equity financing that is considered arms-

length, OPM derived the Company's equity value of a company from the price of the securities issued by the Company in the equity financing. Following the completion of the Company's IPO in September 2021, the fair value of the Company's common stock is determined based on the closing price of its common stock on The Nasdaq Global Market.

### ***Advertising Expenses***

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were not significant.

### ***Defined Contribution Plan***

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax basis. The Company is authorized to make matching contributions but has not made such contributions for the three and nine months ended September 30, 2021 and 2020.

### ***Income Taxes***

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. Valuation allowances against deferred tax assets are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Currently, the Company has recorded a full valuation allowance against its deferred tax assets and there is no provision for income taxes, as the Company has incurred operating losses to-date. The Company's policy is to record interest and penalties expense related to uncertain tax positions as a component of income tax expense in the statement of operations. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

### ***Net Loss Per Share***

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalent shares from dilutive stock options and common stock warrants outstanding during the period. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods as all potentially dilutive securities were antidilutive in those periods.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company's redeemable convertible preferred stock participated in any dividends declared by the Company and were therefore considered to be participating securities.

Upon the completion of the Company's IPO in September 2021, all 29,912,264 shares of its then-outstanding redeemable convertible preferred stock automatically converted into 29,912,264 shares of common stock.

Net loss per share was determined as follows (in thousands, except per share amounts):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Net loss	\$ (14,103)	\$ (12,008)	\$ (41,505)	\$ (37,741)
Weighted-average common stock outstanding	11,580	4,329	7,361	3,327
Net loss per share, basic and diluted	\$ (1.22)	\$ (2.77)	\$ (5.64)	\$ (11.34)

The following potentially dilutive securities outstanding have been excluded from the computations of weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares, in thousands):

	September 30,	
	2021	2020
Redeemable convertible preferred stock outstanding	—	25,402
Redeemable convertible preferred stock warrants	—	72
Common stock warrants	—	12
Common stock options	6,607	6,143
Total	6,607	31,629

### ***Comprehensive Loss***

Comprehensive loss consists of net loss and changes in unrealized gains and losses on cash equivalents and available-for-sale marketable securities. Accumulated other comprehensive income (loss) is presented in the accompanying balance sheets, when applicable.

### ***Segment, Geographical and Customer Concentration***

The Company operates as a single operating segment. The Company’s chief operating decision maker, its Chief Executive Officer, reviews financial information on an aggregate basis for the purposes of allocating resources and evaluating financial performance. The Company’s assets are primarily based in the United States.

No customers accounted for more than 10% of revenue during the three and nine months ended September 30, 2021. Three customers accounted for 16%, 13% and 13% of revenue during the three months ended September 30, 2020. No customers accounted for more than 10% of revenue during the nine months ended September 30, 2020.

The following table presents revenue by significant geographical locations outside the United States for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Germany	*	41%	*	32%

\* Less than 10% of total net revenues for the period indicated.

No customers accounted for more than 10% of accounts receivable at September 30, 2021. Two customers each accounted for 22% and 13% of accounts receivable at December 31, 2020.

### ***JOBS Act Accounting Election***

The Company is an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to avail itself of this exemption and, therefore, for new or revised accounting standards applicable to public companies, the Company will be subject to an extended transition period until those standards would otherwise apply to private companies.

### ***Recent Accounting Pronouncements***

In August 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). The amendments on changes in unrealized gains and losses recognized in other comprehensive income categorized within Level 3, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively in the initial fiscal year of adoption. All other amendments

should be applied retrospectively to all periods presented upon their effective date. The Company adopted ASU 2018-13 as of January 1, 2020, which did not have a material impact on its consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements (“ASU 2018-11”). ASU 2018-11 provided an alternative implementation method in addition to the current modified retrospective transition method for ASU No. 2016-2, Leases: Amendments to the FASB Accounting Standards Codification (“ASU 2016-2”), issued in February 2016. Under ASU 2018-11, an entity may elect to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Under ASU 2016-2, a lessee is required to recognize assets and liabilities for leases with lease terms of more than twelve months. ASU 2016-2 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted ASC Topic 842, Leases, on January 1, 2020 using the modified retrospective transition method. In addition, the Company elected certain practical expedients permitted under the transition guidance, which allowed it to carryforward its historical long-term lease classification, its assessment on whether a contract is or contains a lease and the treatment of its initial direct costs for any leases that existed prior to the adoption of Topic 842. In determining the lease term at commencement date, any renewal or termination options are considered if they are reasonably assured of exercise. The Company has elected to exclude from its consolidated balance sheet any leases having a term of 12 months or less. The Company recorded a right-of-use leased asset of approximately \$6.0 million and a corresponding lease liability of \$7.4 million in its adoption of Topic 842. In addition, as of the adoption date, the Company derecognized a deferred rent obligation of \$1.4 million. There was no cumulative effect adjustment upon the adoption of Topic 842.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”), which requires an entity to utilize a new impairment model known as the current expected credit loss (“CECL”) model to estimate its lifetime “expected credit loss” and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 will be effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), which simplifies the accounting for income taxes, primarily by eliminating certain exceptions to ASC 740. This standard is effective for fiscal periods beginning after December 15, 2021, and for fiscal years beginning after December 15, 2020 for public business entities. The Company adopted ASU 2019-12, effective of January 1, 2021, and the adoption did not have a material impact on its consolidated financial statements.

### 3. Composition of Certain Consolidated Financial Statement Items

#### *Inventory (in thousands):*

	September 30, 2021	December 31, 2020
Raw materials	\$ 4,602	\$ 2,647
Work-in-process	612	51
Finished goods	5,187	4,226
Total inventory	<u>\$ 10,401</u>	<u>\$ 6,924</u>

***Prepaid Expenses and Other Current Assets (in thousands):***

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
Inventory .....	\$ 310	\$ 553
Software .....	580	375
Rent .....	252	245
Insurance .....	447	124
Other .....	643	356
Total prepaid expenses and other current assets .....	<u>\$ 2,232</u>	<u>\$ 1,653</u>

***Property and Equipment, Net (in thousands):***

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
Laboratory, manufacturing and computer equipment and furniture .....	\$ 2,911	\$ 2,645
Rental equipment .....	821	1,247
Leasehold improvements .....	4,941	4,941
Evaluation units .....	3,492	4,229
Total property and equipment .....	<u>12,165</u>	<u>13,062</u>
Less: accumulated depreciation and amortization .....	(6,434)	(4,788)
Total property and equipment, net .....	<u>\$ 5,731</u>	<u>\$ 8,274</u>

***Other Current Liabilities (in thousands):***

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
Accrued purchases .....	\$ 134	\$ 432
Interest .....	390	403
Professional services .....	579	339
Sales tax .....	482	302
Clinical trial expenses .....	117	47
Other .....	1,132	454
Total other current liabilities .....	<u>\$ 2,834</u>	<u>\$ 1,977</u>

As of September 30, 2021 and December 31, 2020, other non-current liabilities consisted of an asset retirement obligation for the facility lease.

***Interest and Other Income (Expense), net (in thousands):***

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Interest income .....	\$ 22	\$ 23	\$ 49	\$ 161
Decrease (increase) in fair value of preferred stock warrants .....	16	142	78	233
Decrease (increase) in fair value of loan facility derivative liability .....	177	174	158	(41)
Other .....	(52)	18	(87)	(9)
Total interest and other income (expense), net .....	\$ 163	\$ 357	\$ 198	\$ 344

**4. Intangible Assets**

In March 2019, the Company entered into a license agreement with HydroCision, Inc. This agreement grants the Company an exclusive, perpetual, irrevocable, worldwide, fully paid-up license to develop, manufacture and commercialize products in the field of urology using the patented technology and know-how controlled by HydroCision as of the effective date and as well as new patented technology developed by HydroCision that cover certain activities and improvements that relate to the use of fluid jet technology in connection with the licensed products during the period commencing on the effective date and ending on the earlier of the date that the Company ceases to use HydroCision's existing contract manufacturers and the third anniversary of the effective date. Also included is the right to utilize HydroCision's contract manufacturers, if desired. The consideration paid was a one-time upfront payment of \$2.5 million, as well as allowing HydroCision (a reciprocal license) to use any new patented technology and know-how developed by the Company relating to the HydroCision patented technology and know-how in the field of urology for HydroCision use outside the field of urology. HydroCision will pay for any patent maintenance fees on HydroCision's licensed patents. As of September 30, 2021 and December 31, 2020, accumulated amortization was \$0.7 million and \$0.5 million, respectively, and the net carrying amount is expected to be amortized at a rate of \$0.3 million per year until fully amortized.

Amortization expense for intangible assets was \$0.1 million for each of the three months ended September 30, 2021 and 2020, and \$0.2 million for each of the nine months ended September 30, 2021 and 2020.

**5. Loan Facility**

In September 2019, the Company entered into a loan facility for up to \$75 million available in four installments. The Company borrowed \$25 million in September 2019. An additional \$25 million was borrowed in March 2020. The third installment of \$10 million was originally available for draw through March 31, 2021 contingent upon achieving \$20 million in trailing six months revenue. In January 2021, the third installment was amended to be available for draw through June 30, 2021 contingent upon achieving \$6.4 million trailing six months revenue. The remaining \$15 million was originally available for draw through June 30, 2021 and is contingent upon achieving \$25 million in trailing six months revenue. In January 2021, this installment was amended to be available for draw through June 30, 2022. The facility bears an interest rate of 9.37%, which is 7.17% plus the greater of 2.2% or 30-day LIBOR. The initial term of the facility is 60 months with interest-only payments each month for 24 months followed by 36 months amortization of principal and interest. In January 2021, the interest-only period was amended to 36 months followed by 24 months amortization (principal and interest) beginning October 1, 2022 since the amended trailing six months target revenue of \$6.4 million was achieved, and accordingly, the current portion of the amount due was reclassified to non-current. Upon drawing the final \$15 million tranche, interest-only period is extended 12 months followed by 24 months amortization of principal and interest. Upon the completion of the Company raising over \$50 million in its IPO in September 2021, interest-only payments were extended an additional 12 months followed by 12 months amortization of principal and interest. Substantially all assets of the Company are pledged as collateral. Commencing with the earlier of June 30, 2021 and the month following the funding of either the third or final installment, the Company is required to achieve revenues for the previous six months ended equal to the greater of (1) 70% of the forecast for the commensurate period, (2) \$15 million if neither third or final



installments have been drawn, (3) \$20 million if the third but not final installment has been drawn and (4) \$25 million if both the third and final installments have been drawn.

The loan facility includes certain fees payable to the lender recorded as a loan discount that are accrued and amortized to interest expense during the loan term. A 6% final payment fee of each funded tranche is payable at the earlier of prepayment or loan maturity and a 0.25% facility fee paid at each funded tranche. A prepayment fee was originally payable if the loan is paid before maturity in the amount of 3% of loans outstanding if paid in full during first 12 months, 2% if loan is paid in full during second 12 months, or 1% if loan is paid in full thereafter before maturity. In January 2021, the prepayment fee was removed as part of the amendments. In addition, the Company should pay the lender's loan initiation fees and a fee upon the earlier occurrence of a defined liquidity event, including but not limited to, a merger or sale of the Company's assets or voting stock, or achieving a \$200 million trailing twelve months revenue target, in each case, by September 2029. The success fees are calculated at the time of the liquidity event occurrence to be \$1.0 million if only the first installment has been drawn, \$2.0 million if the first two installments have been drawn, \$2.4 million if the first three installments have been drawn, or \$3.0 million if all four installments have been drawn, in each case, upon the occurrence of the defined liquidity event. The Company determined that this obligation to pay success fees represents freestanding financial instruments.

The amendments in January 2021 were accounted for as a debt modification under ASC 470-50-40 as the changes in the debt terms are not considered substantial, and thus no gain or loss was recorded and a new effective interest rate was established based on the carrying value of the loan and the revised cash flows.

## 6. Redeemable Convertible Preferred Stock Warrant Liability

Warrants to purchase shares of redeemable convertible preferred stock outstanding and exercisable are as follows (in thousands, except per share data):

Dates		Series	Exercise Price	Shares Outstanding at		Initial Value	Fair Value at	
Issuance	Expiration			September 30, 2021	December 31, 2020		September 30, 2021	December 31, 2020
Jun 2017	Jun 2022	E	13.73	—	72	763	\$ —	\$ 177

In July 2015, in connection with the issuance of convertible notes, the Company issued 869,842 redeemable convertible preferred stock warrants that were exercisable into Series D redeemable convertible preferred stock immediately, with \$5.08 exercise price and expiration in five years. During the three and nine months ended September 30, 2020, warrants for 531,423 and 651,328 shares were exercised, respectively, and none were outstanding at December 31, 2020.

In June 2017, in connection with the issuance of convertible notes, the Company issued 108,145 redeemable convertible preferred stock warrants that were exercisable into Series E or the next round of redeemable convertible preferred stock. During the and three and nine months ended September 30, 2021, 62,454 warrants were exercised and the remaining unexercised warrants expired, none were outstanding at September 30, 2021. During the three and nine months ended September 30, 2020, no warrants were exercised.

## 7. Redeemable Convertible Preferred Stock

A summary of the Company's redeemable convertible preferred stock are as follows:

Series	December 31, 2020		
	Shares Authorized	Shares Issued and Outstanding	Carrying Value (in thousands)
A	1,243,223	1,104,728	\$ 2,781
B	1,841,805	1,543,804	5,404
C	1,564,851	1,564,851	7,073
D	8,245,295	7,547,542	36,879
E	8,825,653	8,414,496	115,229
F	5,263,157	5,226,981	76,488
Total	26,983,984	25,402,402	\$ 243,854

Upon the completion of the Company's IPO in September 2021, all 29,912,264 shares of its then-outstanding redeemable convertible preferred stock automatically converted into 29,912,264 shares of common stock and it reclassified \$329.5 million of redeemable convertible preferred stock to additional paid-in capital on our condensed consolidated balance sheet.

In July 2020, an aggregate of \$1.5 million shares of redeemable convertible preferred stock was converted to common stock as requested by the holder. The corresponding carrying value was reclassified from redeemable convertible preferred stock to common stock and additional paid in capital.

### *Series G Redeemable Convertible Preferred Stock*

In June 2021, the Company issued 4,447,530 shares of Series G redeemable convertible preferred stock for gross proceeds of \$85.0 million. Issuance costs totaled \$0.3 million and were recorded as an offset to gross proceeds.

### *Series F Redeemable Convertible Preferred Stock*

In July and August 2020, the Company issued 5,226,969 shares of Series F redeemable convertible preferred stock for gross proceeds of \$77.0 million. Issuance costs totaled \$0.5 million and were recorded as an offset to gross proceeds.

A summary of the Company's redeemable convertible preferred stock terms were as follows:

Series	Liquidation Preference Per Share	8% Dividend Per Share
A	\$ 2.5175	\$ 0.2014
B	3.2376	0.2590
C	4.5600	0.3648
D	5.0825	0.4066
E	13.7275	1.0982
F	14.7279	1.1782
G	19.1116	1.5289

The Company recorded its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. A redemption event would only occur upon the liquidation or winding up of the Company, a greater than 50% change in control, or sale of substantially all of the assets of the Company. As the redemption event was outside the control of the Company, all shares of redeemable convertible preferred stock were presented outside of permanent equity. Further, the Company had determined the carrying values of the redeemable convertible preferred stock should not be adjusted to the redemption value of such shares, since it was uncertain whether or when a

redemption event would occur. Subsequent adjustments to increase the carrying values of the redeemable convertible preferred stock to the redemption values would have been made when it became probable that such redemption would occur. As of September 30, 2021, no shares of redeemable convertible preferred stock were outstanding, and as of December 31, 2020, it was not probable that such redemption would occur.

### ***Dividends***

The holders of the Series D, E, F and G redeemable convertible preferred stock, in preference to the holders of Series A, B and C redeemable convertible preferred stock and common stock, were entitled to receive noncumulative dividends at the rate of 8% per share of the original issuance price, when and as declared by the board of directors. After the payment of any dividends to holders of Series D, E, F and G redeemable convertible preferred stock, and in preference to the holders of common stock, the holders of Series A, B, and C redeemable convertible preferred stock would have been entitled to receive noncumulative dividends at the rate of 8% per share of the original issuance price, when and as declared by the board of directors. No dividends were declared and payable for the nine months ended September 30, 2021 and year ended December 31, 2020.

### ***Liquidation***

In the event of any liquidation, dissolution, or winding-up of the Company, including a merger, acquisition, or sale of assets, as defined in the certificate of incorporation, each holder of Series G redeemable convertible preferred stock was entitled to receive a liquidation preference amount, plus any dividends declared but unpaid before any payments to holders of Series A, B, C, D, E or F redeemable convertible preferred stock and common stock. If the assets of the Company were insufficient to make payment in full to all Series G redeemable convertible preferred stockholders, then the assets or consideration would have been distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise have been entitled to.

After the full payment of the liquidation preference to the holders of Series G redeemable convertible preferred stock, each holder of Series F redeemable convertible preferred stock would have been entitled to be paid a liquidation preference amount, plus any dividends declared but unpaid before any payments to holders of Series A, B, C, D or E redeemable convertible preferred stock and common stock. If the assets of the Company were insufficient to make payment in full to all Series F redeemable convertible preferred stockholders, then the assets or consideration would have been distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise have been entitled to.

After the full payment of the liquidation preference to the holders of Series F redeemable convertible preferred stock, each holder of Series E redeemable convertible preferred stock would have been entitled to be paid a liquidation preference amount, plus any dividends declared but unpaid before any payments to holders of Series A, B, C or D redeemable convertible preferred stock and common stock. If the assets of the Company were insufficient to make payment in full to all Series E redeemable convertible preferred stockholders, then the assets or consideration would have been distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise have been entitled to.

After the full payment of the liquidation preference to the holders of Series E redeemable convertible preferred stock, each holder of Series D redeemable convertible preferred stock would have been entitled to be paid a liquidation preference amount, plus any dividends declared but unpaid before any payments to holders of Series A, B or C redeemable convertible preferred stock and common stock. If the assets of the Company were insufficient to make payment in full to all Series D redeemable convertible preferred stockholders, then the assets or consideration would have been distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise have been entitled to.

After the full payment of the liquidation preference to the holders of Series D redeemable convertible preferred stock, each holder of Series A, B and C redeemable convertible preferred stock would have been entitled to be paid a liquidation preference amount, plus any dividends declared but unpaid before any payments to holders of common stock. If the assets of the Company were insufficient to make payment in full to all holders of Series A, B or C redeemable convertible preferred stock, then the assets or consideration would have been distributed ratably among

such holders in proportion to the full liquidation preference amounts to which the holders would otherwise have been entitled to.

After the payment of the full liquidation preference to holders of redeemable convertible preferred stock, the remaining assets of the Company legally available for distribution would have been distributed ratably to the holders of the common stock.

### ***Voting***

Each holder had the right to one vote for each share of common stock into which such redeemable convertible preferred stock would have been converted. So long as any shares of redeemable convertible preferred stock were outstanding, the Company was prohibited, without first obtaining the approval of more than 50% of the holders of redeemable convertible preferred stock then outstanding, voting together as a separate class to (a) amend certificate of incorporation in any way that would materially and adversely alter or change the rights, preferences, or privileges of the series preferred stock or (b) increase the total number of authorized shares of any Series Preferred stock. Additionally, the vote of at least a majority of the holders of Series D, E, F and G redeemable convertible preferred stock was needed to materially and adversely affect the rights of such holders of each series, including increasing or decreasing the number of authorized shares of Series D, E, F and G redeemable convertible preferred stock, as applicable.

### ***Redemption***

The redeemable convertible preferred shares were not mandatorily redeemable.

### ***Conversion***

Upon the completion of the Company's IPO in September 2021, all 29,912,264 shares of its then-outstanding redeemable convertible preferred stock automatically converted into 29,912,264 shares of common stock and it reclassified \$329.5 million of redeemable convertible preferred stock to additional paid-in capital on our condensed consolidated balance sheet.

## **8. Stockholder's Equity**

### ***2021 Equity Incentive Award Plan***

In September 2021, the Company adopted the 2021 Equity Incentive Award Plan (the "2021 Plan"), which allows for the granting of stock options and stock purchase rights to the employees, members of the board of directors, and consultants of the Company. A total of 3,303,910 shares of common stock were initially reserved for issuance under the 2021 Plan. Options granted under the 2021 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to the Company's employees, including officers and directors who are also employees. NSOs may be granted to employees and consultants.

Options under the 2021 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an ISO and NSO granted to a 10% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant.

Granted options for newly hired employees usually vest over four years monthly with a one-year cliff vesting, and follow-on options vest monthly over four years with no cliff vesting. Options granted to consultants have various vesting schedules depending on the underlying consulting arrangement and anticipated period of service. As of September 30, 2021, 3.2 million shares are available for grant under the 2021 Plan.

### ***2008 Stock Plan***

The Company ceased making awards under the 2008 Stock Plan upon the effective date of the Company's IPO. In 2008, the Company adopted the 2008 Stock Plan (the "2008 Plan"), which allows for the granting of stock options and stock purchase rights to the employees, members of the board of directors, and consultants of the

Company. Options granted under the 2008 Plan may be either incentive stock options (“ISOs”) or nonqualified stock options (“NSOs”). ISOs may be granted only to the Company’s employees, including officers and directors who are also employees. NSOs may be granted to employees and consultants. Options granted under the 2008 Plan will start expiring in August 2021. Options outstanding under the 2008 Plan will expire upon forfeiture. As of September 30, 2021, 6.5 million options were outstanding under the 2008 Plan.

A summary of the Company’s stock option activity and related information are as follows (options in thousands):

	Nine Months Ended September 30, 2021	
	Options	Price
Outstanding, beginning of period	6,507	\$ 3.94
Granted	1,511	8.03
Exercised	(1,307)	2.70
Forfeited	(104)	6.01
Outstanding, end of period	<u>6,607</u>	5.08
Vested and expected to vest	<u>6,607</u>	5.08
Exercisable	<u>2,885</u>	3.95

As of September 30, 2021 and December 31, 2020, the aggregate pre-tax intrinsic value of options outstanding and exercisable was \$98.7 million and \$6.9 million, respectively, and options outstanding were \$218.5 million and \$9.9 million, respectively. The aggregate pre-tax intrinsic value of options exercised was \$5.1 million and \$1.8 million during the nine months ended September 30, 2021 and 2020, respectively. The aggregate pre-tax intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise. The total fair value of options vested was \$2.4 million and \$1.2 million during the nine months ended September 30, 2021 and 2020, respectively.

The Company estimates the fair value of stock-based compensation on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company’s common stock on the date of grant and is affected by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the fair market value of the Company’s common stock, volatility over the expected term of the awards and actual and projected employee stock option exercise behaviors. The Company has opted to use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Due to the Company’s limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the share-based payments. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company’s common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company’s stock options. The expected dividend assumption is based on the Company’s history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

Total stock-based compensation recognized, before taxes, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of sales	\$ 62	\$ 18	\$ 135	\$ 68
Research and development	174	134	482	397
Sales, general and administrative	689	411	1,683	1,104
Total stock-based compensation	\$ 925	\$ 563	\$ 2,300	\$ 1,569

The amount of unearned stock-based compensation related to unvested employee stock-based payment awards as of September 30, 2021 and December 31, 2020 is \$9.7 million and \$6.5 million, respectively. The weighted-average period over which the unearned stock-based compensation is expected to be recognized as of September 30, 2021 and December 31, 2020 is 2.9 years for both periods.

The fair value of the options granted to employees or directors was estimated as of the grant date using the Black-Scholes model assuming the weighted-average assumptions listed in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2020	2019
Expected life (years)	5.9	6.0	6.0	6.0
Expected volatility	53 %	50 %	50 %	40 %
Risk-free interest rate	0.9 %	0.3 %	1.0 %	1.1 %
Expected dividend rate	— %	— %	— %	— %
Weighted-average fair value	\$ 7.00	\$ 2.41	\$ 3.88	\$ 1.85

### ***2021 Employee Stock Purchase Plan***

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan (the “2021 ESPP”). The 2021 ESPP became effective on the effective date of the IPO. A total of 412,988 shares were initially reserved for issuance under the 2021 ESPP. Additionally, the number of shares of common stock reserved for issuance under the 2021 ESPP will increase automatically each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; or (2) such lesser number as determined by the Company’s board of directors. The number of shares that may be issued under the 2021 ESPP shall not exceed a total of 10,526,315 shares. As of September 30, 2021, the Company has not implemented the 2021 ESPP.

### ***Common Stock Warrants***

In May 2015, the Company issued warrants to purchase 12,308 shares of the Company’s common stock in exchange for recruiting services. These warrants are exercisable immediately and expire on April 30, 2025. These common stock warrants of \$15,000 were recorded as general and administrative expense and additional paid-in capital, as this warrant met the equity classification requirements. In November 2020, these warrants were fully exercised.

## **9. Commitments and Contingencies**

### ***Guarantees and Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2021 and December 31, 2020, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

### Facility Lease

In July 2013, the Company entered into a three-year lease agreement for its current facility located in Redwood City, California. In 2018, the Company expanded the lease space and extended the lease agreement through October 2023. The lease agreement provides for an escalation of rent payments each year and the Company records rent expense on a straight-line basis over the term of the lease. Rent is payable monthly. As of September 30, 2021 and December 31, 2020, the remaining future minimum lease payments under this lease is \$5.1 million and \$6.7 million, respectively.

In connection with the Company's adoption of ASC Topic 842, Leases, on January 1, 2020, the Company recorded a right-of-use leased asset of \$6.0 million and a corresponding lease liability of \$7.4 million and derecognized a deferred rent obligation of \$1.4 million. The Company used its borrowing rate of 10% as its discount rate and the remaining operating lease term was 3.8 years. The results for the year ended December 31, 2020 subsequent periods are presented under Topic 842.

Rent expense recognized under the lease, including additional rent charges for utilities, parking, maintenance, and real estate taxes, was \$0.5 million for each of the three months ended September 30, 2021 and 2020, and \$1.5 million for each of the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021 and December 31, 2020, the Company has future commitments of \$55.1 million and \$56.7 million from debt repayments and office space under a non-cancelable operating lease expiring October 2023, respectively.

Future minimum annual operating lease and debt repayments are as follows (in thousands):

	Minimum Lease Payments	Debt Repayments	Total
<b>As of September 30, 2021</b>			
2021	\$ 604	\$ —	\$ 604
2022	2,445	—	2,445
2023	2,092	12,500	14,592
2024	—	37,500	37,500
Total minimum payments	5,141	50,000	55,141
Less: amount representing interest/unamortized debt discount	(559)	(238)	(797)
Present value of future payments	4,582	49,762	54,344
Less: current portion	(2,032)	—	(2,032)
Non-current portion	\$ 2,550	\$ 49,762	\$ 52,312
<b>As of December 31, 2020</b>			
2021	\$ 2,179	\$ —	\$ 2,179
2022	2,445	6,250	8,695
2023	2,092	25,000	27,092
2024	—	18,750	18,750
Total minimum payments	6,716	50,000	56,716
Less: amount representing interest/unamortized debt discount	(912)	(1,042)	(1,954)
Present value of future payments	5,804	48,958	54,762
Less: current portion	(1,708)	(4,551)	(6,259)
Non-current portion	\$ 4,096	\$ 44,407	\$ 48,503

As of September 30, 2021 and December 31, 2020, the Company's security deposit is in the form of, and recorded as, restricted cash. In January 2021, in connection with the Company's amended loan agreement with modified terms, the interest-only period was modified from 24 months beginning October 1, 2021 to 36 months

beginning October 1, 2022, and accordingly, the current portion of the amount due was reclassified to non-current. Upon the completion of the Company raising over \$50 million in its IPO in September 2021, interest-only payments were extended an additional 12 months followed by 12 months of amortization of principal and interest.



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

*The following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in the section titled "Risk Factors" and elsewhere in this report. Please also see the section titled "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

We are a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. We develop, manufacture and sell the AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive urologic surgery, with an initial focus on treating benign prostatic hyperplasia, or BPH. BPH is the most common prostate disease and impacts approximately 40 million men in the United States. The AquaBeam Robotic System employs a single-use disposable handpiece to deliver our proprietary Aquablation therapy, which combines real-time, multi-dimensional imaging, personalized treatment planning, automated robotics and heat-free waterjet ablation for targeted and rapid removal of prostate tissue. We designed our AquaBeam Robotic System to enable consistent and reproducible BPH surgery outcomes. We believe that Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing compromises associated with alternative surgical interventions. We designed Aquablation therapy to deliver effective, safe and durable outcomes for males suffering from lower urinary tract symptoms, or LUTS, due to BPH that are independent of prostate size and shape or surgeon experience. We have developed a significant and growing body of clinical evidence, which includes nine clinical studies and over 100 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy. As of September 30, 2021, we had an install base of 125 AquaBeam Robotic Systems globally and 75 in the United States.

Our U.S. pivotal trial, the WATER study, is the only FDA pivotal study randomized against transurethral resection of prostate, or TURP, which is the historical standard of care for the surgical treatment of BPH. In this study, Aquablation therapy demonstrated superior safety and non-inferior efficacy compared to TURP across prostate sizes between 30 ml and 80 ml, and superior efficacy in a subset of patients with prostates larger than 50 ml. We have established strong relationships with key opinion leaders, or KOLs, within the urology community and collaborated with key urological societies in global markets. This support has been instrumental in facilitating broader acceptance and adoption of Aquablation therapy. As a result of our strong KOL network and our compelling clinical evidence, Aquablation therapy has been added to clinical guidelines of various professional associations, including the American Urological Association.

In the United States, we sell our products to hospitals. We are initially targeting 860 high-volume hospitals that perform, on average, more than 200 resective procedures annually and account for approximately 70% of all hospital-based resective procedures. Over time, we will gradually expand our focus to also include mid- and low-volume hospitals. These customers in turn bill various third-party payors, such as commercial payors and government agencies, for treatment payment of each patient. Effective in 2021, all local Medicare Administrative Contractors, or MACs, which represent 100% of eligible Medicare patients, issued final positive local coverage determinations to provide Medicare beneficiaries with access to Aquablation therapy in all 50 states. We also have favorable coverage decisions from several large commercial payors, including Anthem, BlueCross – Massachusetts, Cigna, Emblem Health, Health Care Service Corp, and Humana. We plan to leverage these recent successes in our active discussions with all commercial payors to establish additional positive national and regional coverage policies. Outside of the United States, we have ongoing efforts in key markets to expand established coverage and improve payment which we believe will expand patient access to Aquablation therapy.

We manufacture the AquaBeam Robotic System, the handpiece, integrated scope and other accessories at our facility in Redwood City, California. This includes supporting the supply chain distribution and logistics of the various components. Components, sub-assemblies and services required to manufacture our products are purchased

from numerous global suppliers. Each AquaBeam Robotic System is shipped to our customers with a third-party manufactured ultrasound system and probe. We utilize a well-known third-party logistics provider located in the United States and the Netherlands to ship our products to our customers globally.

We generated revenue of \$24.3 million and incurred a net loss of \$41.5 million for the nine months ended September 30, 2021, compared to revenue of \$4.5 million and a net loss of \$37.7 million for the nine months ended September 30, 2020. As of September 30, 2021, we had cash and cash equivalents of \$320.5 million and an accumulated deficit of \$243.2 million.

We completed our IPO in September 2021, which raised \$172.4 million, net of issuance costs. Previously, our primary sources of capital have been from private placements of redeemable convertible preferred securities and debt financing agreements. As of September 30, 2021, we have raised \$337.1 million from private placements of redeemable convertible preferred securities from our investors. We expect our expenses will increase for the foreseeable future, in particular as we continue to make substantial investments in sales and marketing, operations and research and development. Moreover, we expect to incur additional expenses as a result of operating as a public company, including legal, accounting, insurance, compliance with the rules and regulations of the SEC and those of any stock exchange on which our securities are traded, investor relations, and other administrative and professional services expenses. Based on our operating plan, we currently believe that our existing cash and cash equivalents, anticipated revenue and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the issuance date of these financial statements. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional public equity or debt securities or obtain an additional credit facility. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products.

### ***Factors Affecting Our Performance***

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations for the foreseeable future. While these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address. See the section titled “Risk Factors” for more information. These factors include:

- *Grow our install base of AquaBeam Robotic Systems:* As of September 30, 2021, we had an install base of 125 AquaBeam Robotic Systems globally and 75 in the United States. In the United States, we are initially focused on driving adoption of Aquablation therapy among urologists that perform hospital-based resective BPH surgery. We are initially targeting 860 high-volume hospitals that we estimate perform, on average, more than 200 resective procedures annually and account for approximately 70% of all hospital-based resective procedures. To penetrate these hospitals, we will continue to increase our direct team of capital sales representatives, who are focused on driving system placement within hospitals by engaging with key surgeons and decision makers to educate them about the compelling value proposition of Aquablation therapy. As we increase our install base of AquaBeam Robotic systems our revenue will increase as a result of the system sale and resulting utilization.
- *Increase system utilization:* Our revenue is significantly impacted by the utilization of our AquaBeam robotic system. Once we place a system within a hospital our objective is to establish Aquablation therapy as the surgical treatment of choice for BPH. Within each hospital we are initially focused on targeting urologists who perform medium-to-high volumes of resective procedures and converting their resective cases to Aquablation therapy. To accomplish this, we will continue expanding our team of highly trained Aquablation representatives and clinical specialists who are focused on driving system utilization within the hospital, providing education and training support and ensuring excellent user experiences. As urologists

gain experience with Aquablation therapy we will leverage their experiences to capture more surgical volumes and establish Aquablation therapy as the surgical standard of care.

- *Reimbursement and coverage decisions by third-party payors.* Healthcare providers in the United States generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to cover all or part of the cost of procedures using our AquaBeam Robotic System. The revenue we are able to generate from sales of our products depends in large part on the availability of sufficient reimbursement from such payors. Effective in 2021, all local MACs, representing 100% of eligible Medicare patients, issued final positive local coverage determinations to provide Medicare beneficiaries with access to Aquablation therapy in all 50 states. We believe that these favorable coverage decisions have been a catalyst for hospital adoption of our AquaBeam Robotic System. Our strong body of clinical evidence and support from key societies, supplemented by the momentum from Medicare coverage, have led to favorable coverage decisions from several large commercial payors, including Anthem, BlueCross – Massachusetts, Cigna, Emblem Health, Health Care Service Corp and Humana. We plan to leverage these recent successes in our active discussions with commercial payors to establish additional positive national and regional coverage policies. We believe that additional commercial payor coverage will contribute to increasing utilization of our system over time. Outside of the United States, we have ongoing efforts in key markets to expand established coverage and further improve patient access to Aquablation therapy.
- *Cost of sales.* The results of our operations will depend, in part, on our ability to increase our gross margins by more effectively managing our costs to produce our AquaBeam Robotic System and single-use disposable handpieces, and to scale our manufacturing operations efficiently. We anticipate that as we expand our sales and marketing efforts and drive further sales growth, our purchasing costs on a per unit basis may decrease, and in turn improve our gross margin. As our commercial operations continue to grow, we expect to continue to realize operating leverage through increased scale efficiencies.
- *Investment in research and development to drive continuous improvements and innovation.* We are currently developing additional and next generation technologies to support and improve Aquablation therapy to further satisfy the evolving needs of surgeons and their patients as well as to further enhance the usability and scalability of the AquaBeam Robotic System. We also plan to leverage our treatment data and software development capabilities to integrate artificial intelligence and machine learning to enable computer-assisted anatomy recognition and improved treatment planning and personalization. Our future growth is dependent on these continuous improvements which require significant resources and investment.

### ***Impact of the COVID-19 Pandemic***

The COVID-19 outbreak and the consequential economic disruptions have negatively impacted and may continue to negatively impact our operations, revenue and overall financial condition. In response to the pandemic, numerous state and local jurisdictions imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders, and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our headquarters are located, issued “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel, and business operations, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in our headquarters closing, slowdowns and delays, travel restrictions, and cancellation of training and other events, among other effects, thereby negatively impacting our operations. Additionally, in the United States, governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19.

These measures and challenges have decreased the number of BPH procedures generally, and consequently slowed adoption of our AquaBeam therapy and impacted our ability to sell our AquaBeam Robotic System. We believe the number of our systems sold has been impacted as health care organizations globally have prioritized the treatment of patients with COVID-19, and as health care organizations continue to experience consequential economic disruptions from the COVID-19 pandemic such as budget shortfalls and staffing shortages. Numerous

procedures have been and in certain jurisdictions in which we operate are continuing to be cancelled or delayed as a result of local public health measures and hospital policies. We have also experienced disruptions, and may experience future disruptions, including: delays in sales personnel becoming fully trained and productive; difficulties and delays in physician outreach and training physicians to use our AquaBeam Robotic System; restrictions on personnel to travel; delays in follow-ups of our clinical studies; challenges with maintaining adequate supply from third-party manufacturers of components and finished goods and distribution providers; and access to physicians for training and case support.

While many restrictions associated with COVID-19 have more recently been relaxed, the longevity and extent of the various COVID-19 pandemic remains uncertain, including due to the emergence and impact of the COVID-19 variants and continued economic disruptions. These measures and challenges may continue for the duration of the pandemic and may negatively impact our revenue growth while the pandemic continues.

## Components of Our Results of Operations

### Revenue

We generate our revenue primarily from the capital portion of our business, which includes sales and rentals of our AquaBeam Robotic System, and from the recurring revenue associated with sales of our single-use disposable handpieces that are used during each surgery performed with our system. The initial sale of an AquaBeam Robotic System involves a capital purchase by the hospital, which may require approval of senior management at the hospital, or in some cases, inclusion in the hospital's budget process. Other revenue is derived primarily from service and repair and extended service contracts with our existing customers. We expect our revenue to increase in absolute dollars for the foreseeable future as we continue to focus on driving adoption of Aquablation therapy, and increased system utilization, though it may fluctuate from quarter to quarter.

The following table presents revenue by significant geographical locations for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
United States	85 %	53 %	83 %	46 %
Outside the United States	15 %	47 %	17 %	54 %
Germany	*	41 %	*	32 %

\* Less than 10% of total net revenues for the period indicated.

We expect that both our U.S. and international revenue will increase in the near term as we continue to expand the install base of AquaBeam Robotic Systems and increase the related customer utilization in the United States. We expect our increase in revenues in absolute dollars to be larger in the United States.

### Cost of Sales and Gross Margin

Cost of sales consists primarily of manufacturing overhead costs, material costs, warranty and service costs, direct labor and other direct costs such as shipping costs. A significant portion of our cost of sales currently consists of manufacturing overhead costs. These overhead costs include compensation for personnel, including stock-based compensation, facilities, equipment and operations supervision, quality assurance and material procurement. We expect our cost of sales to increase in absolute dollars for the foreseeable future primarily as, and to the extent, our revenue grows, or we make additional investments in our manufacturing capabilities, though it may fluctuate from quarter to quarter.

We calculate gross margin percentage as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily, product and geographic mix and the resulting average selling prices, production volumes, manufacturing costs and product yields, and to a lesser extent the implementation of cost reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and as we spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby significantly reducing our per unit manufacturing costs, though it may fluctuate

from quarter to quarter. Our gross margins can fluctuate due to geographic mix. To the extent we sell more systems and handpieces in the United States, we expect our margins will increase due to the higher average selling prices as compared to sales outside of the United States.

### ***Operating Expenses***

#### *Research and Development*

Research and development, or R&D, expenses consist primarily of engineering, product development, regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies being developed. These expenses include employee and non-employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses, consulting, related travel expenses and facilities expenses. We expect our R&D expenses to increase in absolute dollars for the foreseeable future as we continue to develop, enhance and commercialize new products and technologies, though it may fluctuate from quarter to quarter. However, we expect our R&D expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts.

#### *Selling, General and Administrative*

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling, marketing, clinical affairs, professional education, finance, information technology, and human resource functions. SG&A expenses also include commissions, training, travel expenses, promotional activities, conferences, trade shows, professional services fees, audit fees, legal fees, insurance costs and general corporate expenses including allocated facilities-related expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management and travel expenses. We expect our SG&A expenses to increase in absolute dollars for the foreseeable future as we expand our commercial infrastructure and incur additional fees associated with operating as a public company, including legal, accounting, insurance, compliance with the rules and regulations of the SEC and those of any stock exchange on which our securities are traded, investor relations, and other administrative and professional services expenses, though it may fluctuate from quarter to quarter. However, over time, we expect our SG&A expenses to decrease as a percentage of revenue.

### ***Interest and Other Income (Expense), Net***

#### *Interest Expense*

Interest expense consists primarily of interest expense from our loan payable.

#### *Interest and Other Income (Expense), Net*

Interest and other income (expense), net, consists primarily of interest income from our cash and cash equivalents balances, and fair value adjustments from our redeemable convertible preferred stock warrant liabilities and our loan facility derivative liability.

In connection with our sales of redeemable convertible preferred stock, we issued warrants to purchase shares of our Series D and Series E redeemable convertible preferred stock. We classify these warrants as a liability on our balance sheets that we remeasure to fair value at each reporting date with the corresponding change in fair value being recognized in our statements of operations. Upon completion of our IPO in September 2021, the redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital in stockholders' equity (deficit) for warrants exercised and statement of operations for warrants expired.

Additionally, in connection with the loan facility, we are obligated to pay a fee upon the earlier occurrence of a defined liquidity event, including but not limited to, a merger or sale of our assets or voting stock, or our achieving a \$200 million trailing twelve months revenue target, in each case, by September 2029. The fee is calculated at the time of the liquidity event occurrence to be \$1.0 million if only the first installment has been drawn, \$2.0 million if the first two installments have been drawn, \$2.4 million if the first three installments have been drawn, or \$3.0 million if all four installments have been drawn, in each case, upon the occurrence of the liquidity event. We adjust

the carrying values of the loan facility derivative liability for changes in fair value and recognize those changes in interest and other income (expense), net.

## Results of Operations

The following tables show our results of operations for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
Revenue	\$ 8,668	\$ 2,107	\$ 6,561	311 %
Cost of sales	4,428	2,138	2,290	107
Gross profit	4,240	(31)	4,271	13,777
Gross margin	49 %	(1)%		
Operating expenses:				
Research and development	4,919	3,893	1,026	26
Selling, general and administrative	12,118	7,054	5,064	72
Total operating expenses	17,037	10,947	6,090	56
Loss from operations	(12,797)	(10,978)	(1,819)	(17)
Interest expense	(1,469)	(1,387)	(82)	(6)
Interest and other income (expense), net	163	357	(194)	(54)
Net loss	\$ (14,103)	\$ (12,008)	\$ (2,095)	(17)

	Nine Months Ended September 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
Revenue	\$ 24,335	\$ 4,496	\$ 19,839	441 %
Cost of sales	12,986	6,221	6,765	109
Gross profit	11,349	(1,725)	13,074	758
Gross margin	47 %	(38)%		
Operating expenses:				
Research and development	13,917	11,732	2,185	19
Selling, general and administrative	34,765	21,138	13,627	64
Total operating expenses	48,682	32,870	15,812	48
Loss from operations	(37,333)	(34,595)	(2,738)	(8)
Interest expense	(4,370)	(3,490)	(880)	(25)
Interest and other income (expense), net	198	344	(146)	(42)
Net loss	\$ (41,505)	\$ (37,741)	\$ (3,764)	(10)

### Comparison of Three and Nine Months Ended September 30, 2021 and 2020

## Revenue

	Three Months Ended September 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
System sales and rentals	\$ 5,519	\$ 1,015	\$ 4,504	444%
Handpieces and other consumables	2,850	1,047	1,803	172
Service	299	45	254	564
Total revenue	\$ 8,668	\$ 2,107	\$ 6,561	311

  

	Nine Months Ended September 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
System sales and rentals	\$ 16,093	\$ 2,217	\$ 13,876	626%
Handpieces and other consumables	7,617	2,208	5,409	245
Service	625	71	554	780
Total revenue	\$ 24,335	\$ 4,496	\$ 19,839	441

Revenue increased \$6.6 million, or 311%, to \$8.7 million during the three months ended September 30, 2021, compared to \$2.1 million during the three months ended September 30, 2020, and increased \$19.8 million, or 441%, to \$24.3 million during the nine months ended September 30, 2021, compared to \$4.5 million during the nine months ended September 30, 2020. The growth in revenue was primarily attributable to an increase of \$6.1 million and \$17.8 million in the sales volumes of both our AquaBeam Robotic System and our single-use disposable handpieces in the United States for the three and nine months ended September 30, 2021, respectively, resulting from the expansion of insurance coverage and the increase in personnel in our sales and marketing organizations. In addition, sales of both our AquaBeam Robotic System and our single-use disposable handpieces outside of the United States increased by \$0.2 million and \$1.5 million in sales volume for the three and nine months ended September 30, 2021, respectively.

### Cost of Sales and Gross Margin

Cost of sales increased \$2.3 million, or 107%, to \$4.4 million during the three months ended September 30, 2021, compared to \$2.1 million during the three months ended September 30, 2020, and increased \$6.8 million, or 109%, to \$13.0 million during the nine months ended September 30, 2021, compared to \$6.2 million during the nine months ended September 30, 2020. The increase in cost of sales was primarily attributable to the growth in the number of units sold.

Gross margin increased to 49% during the three months ended September 30, 2021, compared to a negative 1% for the three months ended September 30, 2020, and increased to 47% during the nine months ended September 30, 2021, compared to a negative 38% for the nine months ended September 30, 2020. The increase in gross margin was primarily attributable to the growth in unit sales, which allowed us to spread the fixed portion of our manufacturing overhead costs over more production units, and a higher percentage of sales in the United States at higher average selling prices.

### Research and Development Expenses

R&D expenses increased \$1.0 million, or 26%, to \$4.9 million during the three months ended September 30, 2021, compared to \$3.9 million during the three months ended September 30, 2020, and increased \$2.2 million, or 19%, to \$13.9 million during the nine months ended September 30, 2021, compared to \$11.7 million during the nine months ended September 30, 2020. The increase in R&D expenses was primarily due to employee-related expenses of our R&D organization. These expenses support ongoing product improvements and the development of additional and next generation technologies.

### *Selling, General and Administrative Expenses*

SG&A expenses increased \$5.1 million, or 72%, to \$12.1 million during the three months ended September 30, 2021, compared to \$7.0 million during the three months ended September 30, 2020, and increased \$13.7 million, or 64%, to \$34.8 million during the nine months ended September 30, 2021, compared to \$21.1 million during the nine months ended September 30, 2020. The increase in SG&A expenses was primarily due to employee-related expenses of our sales and marketing, reimbursement and administrative organizations as we expanded our infrastructure to drive and support the anticipated growth in revenue.

### *Interest Expense*

Interest expense increased \$0.1 million to \$1.5 million during the three months ended September 30, 2021, compared to \$1.4 million during the three months ended September 30, 2020, and increased \$0.9 million to \$4.4 million during the nine months ended September 30, 2021, compared to \$3.5 million during the nine months ended September 30, 2020. The increase was due to increased borrowings under our debt financing arrangements.

### *Interest and Other Income (Expense), Net*

Interest and other income (expense), net, decreased \$0.2 million to \$0.2 million during the three months ended September 30, 2021, compared to \$0.4 million during the three months ended September 30, 2021, and decreased \$0.1 million to \$0.2 million during the nine months ended September 30, 2021, compared to \$0.3 million during the nine months ended September 30, 2020. The decrease in other income (expense), net during the three months ended September 30, 2021 was primarily attributable to a decrease in other expenses. The decrease in other income (expense), net during the nine months ended September 30, 2021 was primarily attributable to a decrease in the fair value of loan facility derivative liability.

## **Liquidity and Capital Resources**

### ***Overview***

We completed our IPO in September 2021, which raised \$172.4 million, net of issuance costs. Previously, our primary sources of capital have been from private placements of redeemable convertible preferred securities and debt financing agreements.

As of September 30, 2021, we had cash and cash equivalents of \$320.5 million, an accumulated deficit of \$243.2 million, and \$50.0 million outstanding on our loan facility. We expect our expenses will increase for the foreseeable future, in particular as we continue to make substantial investments in sales and marketing, operations and research and development. Moreover, we expect to incur additional expenses as a result of operating as a public company, including legal, accounting, insurance, compliance with the rules and regulations of the SEC and those of any stock exchange on which our securities are traded, investor relations, and other administrative and professional services expenses. Our future funding requirements will depend on many factors, including:

- the degree and rate of market acceptance of our products and Aquablation therapy;
- the scope and timing of investment in our sales force and expansion of our commercial organization;
- the impact on our business from the ongoing and global COVID-19 pandemic and the end of the COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease;
- the scope, rate of progress and cost of our current or future clinical trials and registries;
- the cost of our research and development activities;
- the cost and timing of additional regulatory clearances or approvals;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels;



- the costs of attaining, defending and enforcing our intellectual property rights;
- whether we acquire third-party companies, products or technologies;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the emergence of competing technologies or other adverse market developments; and
- the rate at which we expand internationally.

Based on our operating plan, we currently believe that our existing cash and cash equivalents, anticipated revenue and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the issuance date of these financial statements. We have based this estimate on assumptions that may prove to be wrong, and we may need to utilize additional available capital resources. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional public equity or debt securities or obtain an additional credit facility. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products.

### ***Indebtedness***

In September 2019, we entered into a loan facility for up to \$75.0 million available in four installments. We borrowed \$25.0 million in September 2019 and an additional \$25.0 million in March 2020. The third installment is for \$10.0 million and was originally available for draw through March 31, 2021 contingent upon our achieving \$20.0 million trailing six months revenue in any month before March 31, 2021.

The remaining \$15.0 million was originally available for draw through June 30, 2021 contingent upon achieving \$25.0 million in trailing six months revenue. In January 2021, the third installment was amended to be available for draw through March 31, 2022 contingent upon our achieving \$6.4 million trailing six months revenue prior to June 30, 2021, and the fourth installment was amended to be available for draw through June 30, 2022. The facility bears an interest rate of the greater of (i) 9.37% and (ii) 7.17% plus 30-day LIBOR. The facility includes customary negative covenants that, among other things, restrict our ability to incur indebtedness or enter into certain change of control transactions. It also contains customary events of default that would result in the termination of the commitments under the facility and permit the lender to accelerate payment on outstanding borrowings. As of September 30, 2021, we were in compliance with all covenants under the facility. The initial term of the facility is 60 months with interest-only payments, with the repayment of principal being amortized over a period of: 36 months, if we fail to achieve the revenue target for the third installment, 24 months if we achieve the revenue target for the third installment but have not raised at least \$50.0 million in an initial public offering, or 12 months if we achieve the revenue target for the third installment and raise at least \$50.0 million in an initial public offering. Upon completion of raising over \$50.0 million in our IPO in September 2021, interest-only payments was extended an additional 12 months followed by 12 months amortization of principal and interest. We pledged substantially all of our assets as collateral for the loan. Commencing with the quarter ended June 30, 2021, we are required to achieve revenue for the previous six months ended equal to 70% of the forecast for the commensurate quarterly period. Additionally, in connection with the loan facility, we are obligated to pay a fee upon the earlier occurrence of a defined liquidity event, including but not limited to, a merger or sale of our assets or voting stock, or our achieving a \$200.0 million trailing twelve months revenue target, in each case, by September 2029. The fee is calculated at the time of the liquidity event occurrence to be \$1.0 million if only the first installment has been drawn, \$2.0 million if the first two installments have been drawn, \$2.4 million if the first three installments have been drawn, or \$3.0 million if all four installments have been drawn, in each case, upon the occurrence of the liquidity event. As of September 30, 2021, we had \$50.0 million outstanding under the loan facility.

## Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash (used in) provided by:		
Operating activities .....	\$ (40,858)	\$ (34,898)
Investing activities .....	(260)	(224)
Financing activities .....	261,472	106,534
Net increase in cash, cash equivalents and restricted cash .....	<u>\$ 220,354</u>	<u>\$ 71,412</u>

### *Net Cash Used in Operating Activities*

During the nine months ended September 30, 2021, net cash used in operating activities was \$40.9 million, consisting primarily of a net loss of \$41.5 million and an increase in net operating assets of \$4.3 million, partially offset by non-cash charges of \$4.9 million. The cash used in operations was primarily due to our net loss due to the increase in operating expenses to support our commercialization and development activities. The expansion of our commercialization resulted in an increase in accounts receivable and inventory, partially offset by an increase in accounts payable. Non-cash charges consisted primarily of depreciation and stock-based compensation.

During the nine months ended September 30, 2020, net cash used in operating activities was \$34.9 million, consisting primarily of a net loss of \$37.7 million and an increase in net operating assets of \$0.4 million, partially offset by non-cash charges of \$3.2 million. The cash used in operations was primarily due to our net loss. The increase in net operating assets was primarily due to an increase in inventory and accounts receivable, partially offset by an increase in accrued compensation. Non-cash charges consisted primarily of depreciation and stock-based compensation.

### *Net Cash Used in by Investing Activities*

During the nine months ended September 30, 2021, net cash used in investing activities was \$0.3 million, consisting of purchases of property and equipment. During the nine months ended September 30, 2020, net cash used in investing activities was \$0.2 million, consisting of purchases of property and equipment.

### *Net Cash Provided by Financing Activities*

During the nine months ended September 30, 2021, net cash provided by financing activities was \$261.5 million, consisting primarily of net proceeds from our IPO of \$172.4 million and the issuance of shares of our Series G redeemable convertible preferred stock of \$84.7 million. During the nine months ended September 30, 2020, net cash provided by financing activities was \$106.5 million, consisting primarily of net proceeds from the issuance of shares of our Series F redeemable convertible preferred stock of \$76.5 million and notes payable of \$24.7 million.

## Contractual Commitments and Contingencies

The information included in Note 9 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

## Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have any off-balance sheet arrangements, such as structured finance, special purpose entities or variable interest entities.

## **Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in our audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in our prospectus dated September 14, 2021 and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our prospectus dated September 14, 2021". There have been no material changes to our significant accounting policies during the three and nine months ended September 30, 2021.

## **JOBS Act Accounting Election and Smaller Reporting Company Status**

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that 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 consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

## **Recent Accounting Pronouncements**

The information included in Note 2 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

### ***Interest Rate Risk***

Cash and cash equivalents of \$320.5 million as of September 30, 2021, consisted of securities carried at quoted market prices with an original maturity of three months or less and therefore there is minimal risk associated with fluctuating interest rates. We do not currently use or plan to use financial derivatives in our investment portfolio.

In addition, as described above under the subsection titled "Indebtedness," amounts outstanding under our loan facility bear interest at a floating rate equal to 7.17% plus the greater of 2.2% or 30-day LIBOR. As a result, we are exposed to risks from changes in interest rates. We do not believe that a hypothetical 100 basis point increase or decrease in interest rates or 30-day LIBOR would have had a material impact on our financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### ***Credit Risk***

We maintain our cash and cash equivalents with two financial institutions in the United States, and our current deposits are in excess of insured limits. We have reviewed the financial statements of these institutions and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenue from the sale or rental of our products. No customer accounted for more than 10% of accounts receivable at September 30, 2021. We believe that credit risk in our accounts receivable is mitigated by our credit evaluation process, relatively short collection terms and diversity of our customer base.

### ***Foreign Currency Risk***

A portion of our net sales and expenses are denominated in foreign currencies, most notably the Euro. Future fluctuations in the value of the U.S. Dollar may affect the price competitiveness of our products outside the United States. For direct sales outside the United States, we sell in both U.S. Dollars and local currencies, which could expose us to additional foreign currency risks, including changes in currency exchange rates. Our operating expenses in countries outside the United States, are payable in foreign currencies and therefore expose us to currency risk. We do not believe that a hypothetical 10% increase or decrease in the relative value of the U.S. dollar to other currencies would have had a material impact on our financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies.

### ***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe that inflation had a material effect on our financial statements included elsewhere in this Quarterly Report on Form 10-Q.

## **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 the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by 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 on Form 10-Q, our disclosure controls and procedures were not effective at the reasonable assurance level because of a material weakness in our internal control over financial reporting 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***

We previously identified a material weakness in our internal control over financial reporting that continues to exist. 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 is the result of our failure to design and maintain effective controls over certain information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain:

- program change management controls to ensure that information technology program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, and
- user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs and data to appropriate company personnel.

These IT general control deficiencies did not result in a material misstatement to the consolidated financial statements; however, the deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management determined these deficiencies in the aggregate constitute a material weakness.

#### ***Management's Plan to Remediate the Material Weakness***

We are in the process of designing, implementing, and testing the operating effectiveness of measures to remediate the material weakness in our internal control over financial reporting. During the three months ended September 30, 2021, we completed the design and implementation of controls over the review and update of user access rights and privileges, and controls over program changes to our information systems that contain data used for financial reporting. We plan to complete the design and implementation of controls over segregation of duties subsequent to the three months ended September 30, 2021. The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

#### ***Limitations on Effectiveness of Disclosure 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 Proceeding**

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputation harm, and other factors.

#### **Item 1A. Risk Factors**

*Our operations and financial results are subject to various risks and uncertainties including those described below. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks or others not specified below materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline.*

#### **Risks Related to Our Business**

***We are an early-stage company with a history of significant net losses, we expect to continue to incur operating losses for the foreseeable future and we may not be able to achieve or sustain profitability.***

We have incurred significant net losses in each reporting period since our inception. For the nine months ended September 30, 2021 and 2020, we had a net loss of \$41.5 million and \$37.7 million, respectively. For the year ended December 31, 2020, we had a net loss of \$53.0 million. We expect to continue to incur additional losses in the future. As of September 30, 2021, we had an accumulated deficit of \$243.2 million. To date, we have financed our operations primarily through net proceeds from the sale of our redeemable convertible preferred stock in private placements, indebtedness, including our loan and security agreement, and, to a lesser extent, product revenue from sales of our AquaBeam Robotic System and single-use disposable handpieces. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, costs related to our sales and marketing efforts, including costs related to clinical and regulatory initiatives to obtain marketing approval, and infrastructure improvements.

We may also encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage medical technology companies in rapidly evolving fields. In addition, as a 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 to incur significant operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our capital requirements needed to operate 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.

***Our revenue is primarily generated from sales of our AquaBeam Robotic System and the accompanying single-use disposable handpieces, and we are therefore highly dependent on the success of those products.***

To date, substantially all of our revenue has been derived, and we expect it to continue to be substantially derived, from sales of our AquaBeam Robotic System and its accompanying single-use disposable handpieces. Our products deliver our Aquablation therapy, the first and only image-guided, heat-free robotic therapy for BPH. We began commercializing our products in the United States in 2017 and physician awareness of, and experience with, our products has been and is currently limited. As a result, our products have limited product and brand recognition

within the medical industry for the treatment of BPH. We do not have a long history operating as a commercial company, and the novelty of our products, together with our limited commercialization experience, makes it difficult to evaluate our current business and predict our future prospects with precision. These factors also make it difficult for us to forecast our financial performance and future growth, and such forecasts are subject to a number of uncertainties, including those outside of our control.

***Our quarterly and annual operating results may fluctuate significantly and may not fully reflect the underlying performance of our business. This makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.***

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 operating results may fluctuate significantly as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Such fluctuations in quarterly and annual operating results may decrease the value of our common stock. Because our quarterly operating 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. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of surgeon and hospital adoption and demand for our products and Aquablation therapy;
- changes in reimbursement rates by government or commercial payors;
- positive or negative coverage in the media or clinical publications, or changes in public, patient and/or physician perception, of our products or competing products and treatments, including our brand reputation;
- the degree of competition in our industry and any change in the competitive landscape, including consolidation among competitors or future partners;
- any safety, reliability or effectiveness concerns that arise regarding our products or other procedures to treat BPH;
- unanticipated pricing pressures in connection with the sale of our products and downward pressure on healthcare costs in general;
- the effectiveness of our sales and marketing efforts, including our ability to deploy a sufficient number of qualified sales representatives to sell and market our products;
- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- unanticipated delays in product development or product launches;
- 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;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products and services;
- our ability to obtain, maintain and enforce our intellectual property rights;

- our ability and our third-party suppliers' ability to supply the components of our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and
- introduction of new products, technologies or alternative treatments for BPH that compete with our products.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. 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 deviate materially from our expectations and our business could suffer.

This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations.

***The terms of our loan and security agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

As of September 30, 2021, we had \$50.0 million outstanding in the form of a term loan under our loan and security agreement with Oxford Finance LLC, which was entered into in September 2019. The loan is secured by substantially all of our assets, including all of the capital stock held by us, if any. The loan and security agreement contains a number of restrictive covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. See the section of this Quarterly Report on Form 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness."

The loan and security agreement contains customary representations and warranties and affirmative covenants and also contains certain restrictive covenants, including, among others, limitations on: the incurrence of additional debt, liens or other encumbrances on property, acquisitions and investments, loans and guarantees, mergers, consolidations, liquidations and dissolutions, asset sales, dividends and other payments in respect of our capital stock, prepayments of certain debt, transactions with affiliates and changes to our type of business, management of the business, control of the business or business locations. The loan and security agreement also includes financial covenants that require us to, among other things, meet certain revenue targets detailed in an approved forecast. The loan and security agreement also contains customary events of default. If we fail to comply with such covenants, payments or other terms of the agreement, our lender could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our lender would have the right to proceed against the assets we provided as collateral pursuant to the loan and security agreement. If the debt under the loan and security agreement were accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition.

***We may need additional funding to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate one or more of our product development programs and future commercialization efforts.***

Since our inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily by net proceeds from the sale of our redeemable convertible preferred stock in private placements, indebtedness and, to a lesser extent, product revenue from sales of our AquaBeam Robotic System and single-use disposable handpieces. As of September 30, 2021, we had \$320.5 million in cash and cash equivalents, and an accumulated deficit of \$243.2 million. Based on our current operating plan, we currently believe that our cash and cash equivalents, anticipated revenue and available debt financing arrangements, will be sufficient to meet our capital requirements and fund our operations through at



least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Changing circumstances could result in lower revenues or cause us to consume capital significantly faster than we currently anticipate, and we may need to raise capital sooner or in greater amounts than currently expected because of circumstances beyond our control.

We may require additional capital in the future as we expect to continue to invest in clinical trials and registries that are designed to provide clinical evidence of the safety and efficacy of our products, expanding our sales and marketing organization, and research and development of product improvements and future products. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. To the extent additional capital is necessary, there are no assurances that we will be able to raise additional capital on favorable terms or at all, and therefore we may not be able to execute our business plan. Our future funding requirements will depend on many factors, including:

- the degree and rate of market acceptance of our current and future products and Aquablation therapy;
- the scope and timing of investment in our sales force and expansion of our commercial organization;
- the impact on our business from the ongoing and global COVID-19 pandemic and the end of the COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease;
- the scope, rate of progress and cost of our current or future clinical trials and registries;
- the cost of our research and development activities;
- the cost and timing of additional regulatory clearances or approvals;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels;
- the costs of attaining, defending and enforcing our intellectual property rights;
- whether we acquire third-party companies, products or technologies;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the emergence of competing technologies or other adverse market developments; and
- the rate at which we expand internationally.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing 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, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in our prior offerings.

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. For example, our current loan and security agreement prohibits us from incurring additional indebtedness

without the prior written consent of our lender. 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 be required to terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities 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.

***The commercial success of our AquaBeam Robotic System and Aquablation therapy will depend upon the degree of market acceptance of our products among hospitals, surgeons and patients.***

Our success will depend, in large part, on the acceptance of our AquaBeam Robotic System as safe, effective, reliable and durable and, with respect to hospitals, healthcare providers and patients, as cost-effective. We believe Aquablation therapy represents a new approach for treating BPH, employing a computer-assisted patient-specific visualization system, a heat-free waterjet and automated robotic system to target and remove prostate tissue. We believe that market acceptance will be driven primarily by surgeons and hospitals, and if they do not adopt the concept of computer-assisted robotics-enabled technology and perceive such technology as having significant advantages over other surgical alternatives, patients will be less likely to accept or be offered Aquablation therapy and we will fail to meet our business objectives. Surgeons' and hospitals' perceptions of such technology having significant advantages are likely to be based on a determination that, among other factors, our products are safe, cost-effective and represent acceptable methods of treatment. Even if we can prove the effectiveness of Aquablation therapy through clinical trials, there may not be broad adoption and use of our products and surgeons may elect not to use our products for any number of other reasons, including:

- lack of experience with our products and concerns that we are relatively new to market;
- perceived liability risk generally associated with the use of new products and treatment options;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits or the cost-effectiveness of our products over existing treatment alternatives;
- the failure of key opinion leaders to provide recommendations regarding our products, or to assure surgeons, patients and healthcare payors of the benefits of our products as an attractive alternative to other treatment options;
- perception that our products are unproven;
- long-standing relationships with companies and distributors that sell other products or treatment options for BPH;
- concerns over the capital investment required to purchase our AquaBeam Robotic System and perform Aquablation therapy procedures;
- lack of availability of adequate third-party payor coverage or reimbursement;
- pricing pressure, including from Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs, seeking to obtain discounts on our AquaBeam Robotic System based on the collective buying power of the GPO and IDN members;
- competitive response and negative selling efforts from providers of alternative treatments;

- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

Even if our AquaBeam Robotic System achieves widespread market acceptance, it may not maintain such level of market acceptance over the long term if competing products or technologies, which are more cost-effective or received more favorably, are introduced. In addition, our limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects. We cannot predict how quickly, if at all, hospitals, surgeons and patients will accept our AquaBeam Robotic System or, if accepted, how frequently it will be used. Failure to achieve or maintain market acceptance and/or market share could materially and adversely affect our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

***We have limited experience in training and marketing and selling our products and we may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop and maintain broad brand awareness in a cost-effective manner.***

We have limited experience marketing and selling our products. We currently rely on our direct sales force and distributors to sell our products in targeted geographic regions and territories, and any failure to maintain and grow our direct sales force and distributor relationships could harm our business. The members of our direct sales force are adequately trained and possess technical expertise, which we believe is critical in driving the awareness and 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 comparable expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our product sales, revenues and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to significantly expand and leverage our commercial infrastructure to increase our customer base and increase awareness and adoption by existing customers to drive our growth. Identifying and recruiting qualified sales and marketing professionals and training them on our products and Aquablation therapy, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It can take several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products or treatments that can utilize independent third parties, placing us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in product sales and revenue, and our higher 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 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 will depend, to a significant extent, on our ability to expand our sales and marketing and educational efforts. We plan to dedicate significant resources to our sales and marketing and educational programs. Our business may be harmed if these efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our Aquablation therapy in a cost-effective manner is critical to achieving broad acceptance of our products and reaching new physicians, hospitals and patients. Promotion and educational activities may not generate hospital or surgeon awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur. If we fail to successfully promote Aquablation therapy in a cost-effective manner, we may fail to attract or retain the market acceptance necessary to realize a sufficient return on our promotional and educational efforts, or to achieve broad adoption of our products.

***We may not be able to obtain or maintain adequate levels of third-party coverage and reimbursement, and third parties may rescind or modify their coverage or delay payments related to our products.***

We derive the majority of our revenue from sales of our AquaBeam Robotic System and single-use disposable handpieces to hospitals. Sales of our products will depend, in part, on the extent to which the procedures using our products are covered and reimbursed by third-party payors, including private insurers and government healthcare

programs. Even if a third-party payor covers a particular treatment that uses our products, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase our products or ensure such purchase is profitable for the provider. As a result, access to adequate coverage and reimbursement for our products by third-party payors is essential to the acceptance and adoption of our products

Coverage and reimbursement by governmental and third-party payors may depend upon a number of factors, including the determination that the product or service and its use or administration for a particular patient is:

- a covered benefit;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional societies;
- cost-effective; and
- neither experimental nor investigational.

Our customers typically bill third-party payors for the costs and fees associated with the procedures in which our products are used. Because there is often no separate reimbursement for supplies used in surgical procedures or for the purchase of the capital equipment needed to perform a procedure, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost. In addition, customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor's coding, billing or coverage policies were not followed. These events, or any other decline in the amount payors are willing to reimburse our customers, could make it difficult for existing 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 could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs by limiting coverage and the amount of reimbursement for particular products. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Obtaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our products should be covered and reimbursed.

Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our products are used. Many third-party payors do not currently cover our products and the related procedures because they have determined that our products and the related procedures are experimental or investigational. When our products and the related procedures are reimbursed, they are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in relevant international markets in which we plan to operate. If Medicare no longer covers any of our products, there would be a material adverse effect on our business, financial condition and results of operations. In addition, Medicare Administrative Contractors could issue a local coverage determination decision that could restrict the patients eligible for the treatment with our

products or in another manner unfavorable to our business. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory clearance or approval may not be available or adequate in either the United States or international markets. Further, other BPH treatments may be more widely covered or subject to different co-pay policies and requirements, which could impact demand for our products. If hospital, surgeon and/or patient demand for our products is adversely affected by changes in third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition and results of operations.

***We face competition from many sources, including larger companies, and we may be unable to compete successfully.***

The medical device industry is highly competitive, subject to rapid change and significantly affected by the introduction of new products and technologies and other activities of industry participants. We compete with pharmaceutical products marketed to treat BPH, such as Flomax marketed by Boehringer Ingelheim, Rapaflo marketed by Allergan plc, Avodart marketed by GlaxoSmithKline plc, and Proscar marketed by Merck & Co., Inc., and with medical device companies that manufacture resective or non-resective surgical alternatives for treating BPH. Resective alternatives include devices for the TURP procedure, laser-based therapies and simple prostatectomy, each of which is intended to remove the prostate tissue, and non-resective alternatives such as UroLift marketed by Teleflex Incorporated and Rezum marketed by Boston Scientific Corporation, which are intended to reshape the prostate and widen the cavity. Our primary medical device competitors are Boston Scientific Corporation and smaller companies that have single products or a limited range of products. Moreover, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and market acceptance than our products.

We compete, or may compete in the future, against other companies which have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution and other resources, which may prevent us from achieving significant market penetration or improved operating results. These companies may enjoy several competitive advantages, including:

- established treatment patterns pursuant to which drugs are generally first-line or concurrent therapies for the treatment of BPH;
- established relationships with hospitals and physicians who are familiar with other surgical alternatives for the treatment of BPH;
- greater financial and human capital resources;
- significantly greater name recognition;
- 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.
- Our continued success depends on our ability to:
  - improve outcomes for patients;
  - maintain product safety, efficacy, reliability and durability;
  - expand the quality and volume of our clinical data;
  - effectively market to and educate patients, physicians and hospitals;
  - maintain company, product and brand recognition;
  - broaden our sales force experience and access;

- maintain product support and service;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis;
- develop successful pricing and revenue strategies;
- continue to maintain and expand reimbursement coverage for procedures using our products;
- achieve desired regulatory status and speed to market; and
- maintain dedicated clinical representatives.

One of the major hurdles to adoption of our products will be overcoming established treatment patterns, which will require education of surgeons and supportive clinical data. However, because of the size of the market opportunity for the treatment of BPH, we believe current and potential future competitors will dedicate significant resources to aggressively promote their products or develop new products or treatments. New treatment options may be developed that could compete more effectively with our products due to the prevalence of BPH and the research and technological progress that exist within the market.

***If we are unable to continue to innovate and improve our AquaBeam Robotic System, we could lose customers or market share.***

Our success will depend on our ability to keep ahead of innovative developments in the treatment of BPH. It is critical to our competitiveness that we continue to innovate and make improvements to our AquaBeam Robotic System's functionality and efficiency. If we fail to make improvements to our AquaBeam Robotic System's functionality over time, our competitors may develop products that offer features and functionality similar or superior to those of our AquaBeam Robotic System. If we fail to make improvements to our AquaBeam Robotic System's efficiency, our competitors may develop products that are more cost-effective than our AquaBeam Robotic System. Our failure to make continuous improvements to our AquaBeam Robotic System to keep ahead of the products of our competitors could result in the loss of customers or market share that would adversely affect our business, results of operations, and financial condition.

***We have limited experience manufacturing our products in large-scale commercial quantities, and we face a number of manufacturing risks that may adversely affect our manufacturing abilities which could delay, prevent or impair our growth.***

Our growth strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs in our current manufacturing facility or any future manufacturing facilities. We have a sole manufacturing facility located in Redwood City, California, where we manufacture, assemble, inspect, test, package and ship our products. We currently assemble all of our AquaBeam Robotic System and single-use disposable handpieces at this one facility, and we do not have additional facilities. If this facility, or any of our future manufacturing facilities, suffers damage, or a force majeure event, such damage or event could materially impact our ability to operate, which could materially and adversely affect our business and financial performance.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, almost all of whom are single source suppliers for the items and materials that they supply;
- our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;

- our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- our failure to increase production capacity or volumes to meet demand;
- potential risks associated with disruptions in our supply chain, such as on account of the COVID-19 pandemic or other macroeconomic events;
- lead times associated with securing key components;
- our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. For instance, in both 2019 and 2021, we initiated voluntary recalls for a limited number of lots of our handpiece. These were both due to certain issues related to our supply chain and manufacturing processes. We remedied the issue leading to the 2019 recall and are remedying the issue leading to the 2021 recall as we continue to develop and improve our manufacturing processes to scale the production of our handpieces at a higher volume. As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although some future products may share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

***We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.***

We rely on third-party suppliers, almost all of whom are single source suppliers, to provide us with certain components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and, for certain items, there are relatively few alternative sources of supply. These single source suppliers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products in a reliable manner and at the levels we anticipate or at levels adequate to satisfy demand for our products. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for such products, either because of acts of nature, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us.

We have not been qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials. While we currently believe that alternative sources of supply or sterilization may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers or providers would be able to provide the quantity and quality of components, materials and sterilization that we would need to manufacture and ship our products if our existing suppliers and providers were unable to satisfy our requirements. To utilize other sources, we would need to identify and qualify new providers to our quality standards and obtain any additional regulatory approvals required to change providers, which could result in manufacturing delays and increase our expenses.

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

- interruption of supply or sterilization resulting from modifications to, or discontinuation of, a third party's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a third party's failure to produce components or complete sterilizations that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our third parties for key components or sterilization requirements;
- inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative third parties for the supply of components or for sterilization of our products in a timely manner;
- inability of third parties to comply with applicable provisions of the FDA's Quality System Regulations, or QSR, or other applicable laws or regulations enforced by the FDA, state and global regulatory authorities;
- inability to ensure the quality of products manufactured or sterilization conducted by third parties;
- production delays related to the evaluation and testing of products and services from alternative third parties and corresponding regulatory qualifications;
- trends towards consolidation within the medical device manufacturing supplier industry; and
- delays in delivery by our suppliers and service providers.

Although we require our third-party suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner.

***If we receive a significant number of warranty claims or our AquaBeam Robotic Systems require significant amounts of service after sale, our operating expenses may substantially increase and our business and financial results will be adversely affected.***

We currently warrant each AquaBeam Robotic System against defects in materials and workmanship for a period of approximately 12 months from the installation of our product by a customer. We also expect to provide technical and other services to customers beyond the warranty period pursuant to a supplemental service plan that we sell for our AquaBeam Robotic System. We have a limited history of commercial placements from which to judge our rate of warranty claims, and we expect that the number of warranty claims we receive may increase as we scale our operations and as our existing commercial placements age. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional operating expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve the level of market acceptance that we are targeting in order to achieve and maintain profitability. Unforeseen warranty exposure could negatively impact our business and financial results.

***We need to ensure strong product performance and reliability to maintain and grow our business.***

We need to maintain and continuously improve the performance and reliability of our AquaBeam Robotic System to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. In addition, software and hardware incorporated into our AquaBeam Robotic System may contain errors or defects, especially when first introduced and while we have made efforts to test this software



and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems.

***Our business, financial condition, results of operations and growth have been adversely impacted by the effects of the COVID-19 pandemic and may continue to be adversely impacted.***

We are subject to risks related to the public health crises such as the global pandemic associated with COVID-19. The COVID-19 outbreak and the consequential economic disruptions have negatively impacted and may continue to negatively impact, including the emergence and impact of the various COVID-19 variants, our operations and revenues and overall financial condition by decreasing the number of BPH procedures generally, which has slowed adoption of our AquaBeam Robotic System during the course of the pandemic. We believe the number of our systems sold has also been impacted as health care organizations globally have prioritized the treatment of patients with COVID-19, and as health care organizations have dealt with other consequential economic disruptions from the COVID-19 pandemic such as budget shortfalls and staffing shortages. For example, for a period of time in the United States, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges led to our decision to reforecast our revenue for 2020, and they may continue or resume for the duration of the pandemic, which is uncertain, and may negatively impact our revenue growth while the pandemic continues. Further, once the pandemic subsides, we anticipate that health care organizations may face budgetary and personnel disruptions during the recovery, and that there may be a backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals relating to a variety of medical conditions. As a result, patients seeking to have our Aquablation therapy performed will have to navigate limited provider capacity. We also experienced a slowdown of enrollment in certain clinical trials.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders, and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our headquarters are located, issued “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel, and business operations, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in our headquarters closing, slowdowns and delays, travel restrictions, and cancellation of training and other events, among other effects, thereby negatively impacting our operations. Employees whose tasks can be performed offsite have been encouraged to work from home. Additionally, if the COVID-19 situation persists or worsens in certain geographies around the world, shutdowns and continued government restrictions may impact our sales activities, supply chain, and business.

Identifying and recruiting qualified sales and marketing personnel and training them has been, and continues to be, more difficult as a result of the COVID-19 pandemic as many of these activities must be conducted remotely, and we believe that some candidates are reluctant to change jobs during the pandemic. In addition, even when we are able to hire additional sales and marketing personnel, we must then train them on our product, applicable federal and state laws, and regulations, and on our internal policies and procedures. This training process was initially conducted remotely, which made training more challenging. We recently resumed partial in-person training with respect to training sales and marketing personnel, among others. Upon completion of the training, the lead time that our territory managers typically require in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory, has been, and continues to be, prolonged during and as a result of the COVID-19 pandemic. We have also experienced disruptions, and may experience future disruptions, including: delays in territory managers becoming fully trained and productive; challenges in analyzing territory manager performance and in recruiting and hiring new employees; difficulties and delays in physician outreach and training physicians to use our AquaBeam Robotic System; restrictions on personnel to travel; delays in initiation, enrollment and follow-ups of our clinical studies; challenges with maintaining adequate supply from third-party manufacturers of components and finished goods and distribution providers; and access to physicians for training and case support. In addition, our customers have experienced and may continue to experience financial and staffing hardship during the COVID-19 pandemic and the consequential economic disruptions, and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for

bankruptcy, or being acquired by larger health systems, leading to reduced procedures or additional pricing pressure on our products.

In addition, to the extent the recovery from the COVID-19 pandemic is prolonged for any reason, including due to the emergence and impact of the various COVID-19 variants or other consequential economic disruptions, and continues to adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

***We may encounter difficulties in managing our growth, which could disrupt our operations.***

We have experienced substantial growth in our operations, and we expect to experience continued substantial growth in our business. Over the next several years, we expect to increase significantly the scope of our operations, particularly in the areas of manufacturing, sales and support, research and development, product development, regulatory affairs, marketing and other functional areas, including finance, accounting, quality control, and legal, especially as we transition to operating as a public company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our AquaBeam Robotic System and manage our inventory.***

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our AquaBeam Robotic System console and the single-use disposable handpieces based on our estimates of future demand for, and utilization of, our AquaBeam Robotic System. Our ability to accurately forecast demand and utilization could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand and utilization, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand or utilization, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

***Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations.***

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, inventory management and other related functions. We do not have redundant information technology in all aspects of our systems at this time. Despite the implementation of security and back-up measures, our internal computer, server, and other information technology systems as well as those of our third-party consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, accidental or intentional exposure of our data by employees or others with authorized access to our networks, computer viruses, malware, ransomware, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/or proprietary data, including

personal information, including health-related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. If we or our third-party consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems and networks could also have a material adverse effect on our business. The COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. Our reliance on internet technology and the number of our employees who are working remotely may create additional opportunities for cybercriminals to exploit vulnerabilities. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems or data or systems of our commercial partners, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm. Failure to maintain or protect our information technology systems effectively could negatively affect our business, financial condition and results of operations.

***Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.***

We may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, processing, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose obligations on “covered entities,” including certain health care providers, health plans, and health care clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by the Department of Health and Human Services, or HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers’ personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights

with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households and may apply to us in the future. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, as other states or the federal government may follow California's lead and increase protections for U.S. residents. For example, on March 2, 2021, the Virginia Consumer Data Protection Act, which will take effect on January 1, 2023, was signed into law. The CCPA has already prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, add layers of complexity to compliance in the U.S. market, increase its compliance costs and adversely affect its business.

Foreign data protection laws, including the General Data Protection Regulation, or GDPR, which went into effect in May 2018, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area, or EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect, process, and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom, or UK, governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions involve the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the UK to jurisdictions deemed to have inadequate, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the UK and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, during which time the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU Member States to the UK for a four-year period, subject to subsequent extensions.

Implementing mechanisms that endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory

investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with US, foreign, and local privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with US and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

***Natural or man-made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.***

A significant portion of our employee base, and our primary operating facility and infrastructure are centralized in Northern California. Our facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, public health emergencies such as infectious disease outbreaks, including the COVID-19 pandemic, power outages and other infrastructure failures, which may render it difficult or impossible for us to operate our business for some period of time. Our facilities would likely be costly to repair or replace, and any such efforts would likely require substantial time. Any disruptions in our operations could adversely affect our business and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. Any such losses or damages could have a material adverse effect on our business and results of operations. In addition, the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man-made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business, financial condition and results of operations.

***The sizes of the addressable markets for our AquaBeam Robotic System have not been established with precision and our potential market opportunity may be smaller than we estimate and may decline.***

Our estimates of the annual total addressable market for our AquaBeam Robotic System are based on a number of internal and third-party estimates, including, without limitation, the assumed prices at which we can sell our AquaBeam Robotic System and the single-use disposable handpieces. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our AquaBeam Robotic System may prove to be incorrect. If the actual number of patients who would benefit from our AquaBeam Robotic System, the price at which we can sell our AquaBeam Robotic System, or the total addressable market for our AquaBeam Robotic System is smaller than we have estimated, it may impair our sales growth and materially and adversely affect our business, financial condition and results of operations.

***Until we are able to achieve broader market acceptance of our AquaBeam Robotic System and Aquablation therapy, we may face risks associated with a more concentrated customer base.***

No customers accounted for more than 10% of revenue during the nine months ended September 30, 2021 and 2020, and year ended December 31, 2020. No customer accounted for more than 10% of accounts receivable at September 30, 2021. Two of our customers accounted for 22% and 13% of accounts receivable at December 31, 2020. While we believe this concentration is primarily attributable to our limited history of commercial operations,

until we are able to achieve broader market acceptance of our AquaBeam Robotic System and Aquablation therapy, we may face risks associated with a more concentrated customer base. There are risks whenever a significant percentage of revenue is concentrated with a limited number of customers. For example, revenue from these customers may fluctuate from time to time based on these customers' business needs, the timing of which may be affected by market conditions or other facts outside of our control. These customers could also potentially pressure us to reduce the prices we charge for our single-use disposable handpieces, which could have an adverse effect on our margins and financial position and could negatively affect our revenue and results of operations. If any of our largest customers terminates its relationship with us, such termination could negatively affect our revenues and results of operations.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.***

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our AquaBeam Robotic System, the single-use disposable handpiece or any of their component parts causes, or is perceived to cause, injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. We may also be subject to product liability claims if our products or services are deemed non-compliant with applicable laws or regulations. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health conditions of the patient. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies, or manufacturers who produce our AquaBeam Robotic System and the single-use disposable handpieces.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- harm to our reputation;
- initiation of investigations by regulators, which could result in enforcement action against us or our contract manufacturers;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- exhaustion of any available insurance and our capital resources.

The risk of a product liability lawsuit may increase if our products were deemed to be non-compliant with applicable laws and regulation. In the event we face a product liability lawsuit, we believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of our products. We may have to pay any amounts awarded by a court or negotiated in a

settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

***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 GPOs and 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 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 may reduce market prices for our AquaBeam Robotic System, thereby reducing our revenue and 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 typically are terminable 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.

***We may seek strategic alliances, joint ventures or collaborations, or enter into licensing or partnership arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will compliment or augment our sales and marketing efforts with respect to our AquaBeam Robotic System. We may not be successful in our efforts to establish such collaborations. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for our products. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

***Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

We currently market and sell our products in 11 countries outside of the United States, including Germany, France, Italy, Spain and the United Kingdom. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import and export and customs laws and regulations. Compliance with these laws and regulations is costly and exposes us to penalties for non-compliance. We expect our international activities will be

dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations, to the extent we establish non-U.S. operations;
- differing and multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties in determining and creating the proper sales pathway in new, international markets;
- compliance with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs and trade barriers, export regulations, sanctions and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;
- potential adverse tax consequences, including imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- imposition of differing labor laws and standards;
- armed conflicts or economic, political or social instability in foreign countries and regions;
- fluctuations in foreign currency exchange rates;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

We are assessing the opportunity to expand into other international markets. However, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory hurdles to overcome, and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business.

***We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.***

We are highly dependent on our senior management, including our chief executive officer, Reza Zadno, Ph.D., and other key personnel. Our success will depend on our ability to retain senior management and to attract, recruit, retain, manage and motivate qualified personnel in the future, particularly with respect to an expected increase in hiring in connection with becoming a public company, including sales and marketing professionals, scientists, clinical specialists, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, we have issued and may continue to issue equity awards that vest over time, in addition to salary and cash incentives. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock



price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

***We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws, as well as violations of export or import controls or economic sanctions laws and regulations. Any investigation, and the outcome of any investigation, by government agencies of possible violations by us of such laws and regulations could have a material adverse effect on our business.***

We are subject to anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute in 18 U.S.C. 201, the International Travel Act of 1961, as amended, or the U.S. Travel Act, the U.K. Bribery Act 2010, or the Bribery Act, and similar anti-bribery laws in jurisdictions in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, and intermediaries from corruptly authorizing, promising, providing, or offering, directly or indirectly, improper payments or anything else of value to government officials and persons in the private sector for the purpose of obtaining or retaining business. In addition, an organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act, unless the organization can establish the defense of having implemented adequate procedures to prevent bribery.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may require us to obtain licenses and authorizations prior to export, create delays in the introduction of our products in certain international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions.

We are in the process of further enhancing policies designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the Bribery Act, OFAC laws and regulations, and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. In the future, we may operate in parts of the world that pose a heightened corruption risk. 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, nor can we assure you that our business partners have not engaged and will not engage in improper conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of anti-corruption laws, economic sanctions laws, and export control and import laws. In addition, 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.

***Our ability to utilize our net operating loss carryforwards and research and development credit may be limited.***

As of December 31, 2020, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately \$170.8 million and \$100.7 million, respectively, and U.S. federal and state research and development credit carryforwards of \$3.1 million and \$2.5 million, respectively. NOLs incurred in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of current year taxable income. In general, under Sections 382

and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50 percentage point change by value in its equity ownership over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset post-change taxable income. Similar rules may apply under state tax laws. Our existing NOLs and research and development credit carryforwards have been, and may in the future be, subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a future change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability. In addition, for state income tax purposes, the extent to which states will conform to the federal laws is uncertain and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs and tax credits in tax years beginning after 2019 and before 2023.

In addition, the tax benefit of NOLs, temporary differences and credit carryforwards are required to be recorded as an asset to the extent that we assess that realization is more likely than not. We believe that recognition of the deferred tax asset arising from these future tax benefits is not likely to be realized and, accordingly, have provided a full valuation allowance against our net deferred tax asset.

***We may acquire other businesses which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.***

As part of our business strategy, we may in the future make acquisitions or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our existing and potential customers. However, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, one-time charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

Also, the anticipated benefit of any acquisition may not materialize, or such acquisition may be prohibited. In September 2019, we entered into the loan and security agreement with Oxford Finance LLC which also restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

## **Risks Related to Governmental Regulation**

### ***Changes to the reimbursement rates for BPH treatments and measures to reduce healthcare costs may adversely impact our business.***

We derive our revenue from sales of our products to hospitals, ambulatory surgery centers and other healthcare facilities, which typically bill all or a portion of the costs and fees associated with using our products to various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations. Because a vast majority of U.S. patients with BPH are covered by Medicare, the Medicare coverage policy and reimbursement rate are important factors in a physician's decision to use Aquablation therapy and limits the prices we may charge for our products. In order to facilitate access for Medicare beneficiaries to new devices, the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, grants approval for transitional pass-through payments under the Medicare hospital outpatient prospective payment system, or OPPS, and ambulatory surgical center, or ASC, payment system for medical devices that meet certain criteria. Effective January 1, 2020, hospitals and ASCs receive an additional payment for the single-use handpiece when performing Aquablation therapy in the hospital outpatient setting until December 31, 2022. When that payment expires, hospitals will no longer receive separate reimbursement for our device and instead, receive a single bundled payment rate intended to cover the costs of all items and services, including our products, using during the Aquablation therapy. Accordingly, the additional cost associated with the use of our products may affect the profit margin of the hospital or ASC where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost.

Many BPH patients have Medicaid coverage that is supplemental to Medicare coverage, and some BPH patients may have Medicaid as their primary coverage. Because Medicaid is a state-administered program, Medicaid coverage policies and reimbursement vary by state. Changes in state Medicaid or other non-Medicare government-based programs or payment rates could have an adverse effect on our customer's business.

Finally, some patients may have coverage through private insurance, for example through a marketplace plan set up under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, or through an employer or union group health plan. Private insurance coverage policies can vary and reimbursement is generally higher than government reimbursement, but it varies by sponsor and plan. Commercial payment rates are negotiated between our customers and insurers or other third-party administrators, and commercial payors may also exert downward pressure on payment rates.

Any reduction in reimbursement rates for Aquablation therapy may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include reducing the scope of their programs, which could result in a reduced demand for our product or additional pricing pressures.

### ***Healthcare reform measures could hinder or prevent the commercial success of our AquaBeam Robotic System.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our AquaBeam Robotic System. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative and regulatory proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our AquaBeam Robotic System. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our AquaBeam Robotic System.

By way of example, in the United States, the ACA was enacted in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which have impacted existing government healthcare programs and will result in the development of new programs. Since its enactment, there have been numerous

amendments to the ACA and revisions to implementing regulations, along with judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the Supreme Court ruled that states and individuals lacked standing to challenge the constitutionality of the ACA's individual mandate, post-repeal of its associated tax penalty. Additionally, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. 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. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. We cannot predict what effect further changes related to the ACA, including under the Biden administration, will have on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, and in connection with subsequent legislation, reduced Medicare payments to providers of, on average, 2% per fiscal year, which went into effect 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 from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several categories of healthcare providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our AquaBeam Robotic System;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

The current presidential administration and Congress may continue to pursue significant changes to the current healthcare laws. We cannot predict what other laws and regulations will ultimately be enacted and implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition, and results of operations. Future changes in healthcare policy could increase our costs and subject us to additional requirements that may interrupt commercialization of our current and future solutions, decrease our revenue and impact sales of and pricing for our current and future products.

***We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.***

Our current and future operations are subject to various federal and state healthcare laws and regulations. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales, placement and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. The laws that affect our practices and arrangements include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a

person or entity had actual knowledge of, or a specific intent to violate, the law. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the U.S. federal civil False Claims Act, which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are subject to enforcement under the False Claims Act. Actions under the False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government and to share in any monetary recovery. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties (adjusted annually for inflation) per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes large settlement amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Many device manufacturers have resolved investigations of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non reimbursable uses, and other interactions with prescribers and other customers including those that may have affected their billing or coding practices and submission to the federal government. Moreover, to avoid the risk of exclusion from federal healthcare programs as a result of a False Claims Act settlement, companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim or statement to the federal government;
- criminal healthcare statutes that were added by HIPAA, and its implementing regulations, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate them in order to have committed a violation;
- the Physician Payments Sunshine Act, or Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family

members. Beginning January 1, 2022, manufacturers will also be required to report payments and other transfers of value made during the prior calendar year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives; and

- foreign and state laws and regulations, including state payment reporting, anti-kickback and false claims laws, that may apply to items or services reimbursed by any third-party payor, including private insurers; foreign and state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government and other national governments, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and foreign and state laws and regulations that require drug and device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The scope and enforcement of these laws is substantial and subject to rapid change. The shifting compliance environment and the need to build and maintain robust compliance programs, systems, and processes to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. 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 government investigation, even if we are able to successfully defend against it, will require the expenditure of significant resources, is likely to generate negative publicity, harm our reputation and potentially our financial condition and divert the attention of our management. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment of individuals, exclusion from government funded healthcare programs, such as Medicare and Medicaid, imposition of compliance obligations and monitoring, and the curtailment or restructuring of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***Our AquaBeam Robotic System and our operations are subject to extensive government regulation and oversight in the United States. If we fail to maintain necessary marketing authorizations for our AquaBeam Robotic System, or if approvals or clearances for future products or modifications to existing products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.***

Our AquaBeam Robotic System is a medical device subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations, including relationships with healthcare providers;
- record keeping;
- product marketing, promotion and advertising, registration, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;

- post-market approval 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 enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our AquaBeam Robotic System;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or approval of new products, new intended uses or modifications to existing products;
- withdrawal or suspension of regulatory clearance or approval that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it will negatively affect our business, financial condition and results of operations.

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

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a premarket approval application, or PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our AquaBeam Robotic System is a Class II device subject to 510(k) clearance.

Before a new medical device, or a new intended use of, claim for, or significant modification to an existing device, can be marketed in the United States, a company must first submit an application for and receive either

510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the FDCA, de novo classification, or approval of a PMA from the FDA, unless an exemption applies. Most Class I devices and some Class II devices are exempt from these premarket review requirements. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. 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 are sometimes required to support substantial equivalence.

In the process of obtaining PMA approval the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, clinical trial, manufacturing and labeling data.

In the de novo classification process, a manufacturer whose novel device 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. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination.

The 510(k), de novo or PMA processes can be expensive, lengthy and unpredictable. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

We originally obtained de novo classification of our AquaBeam Robotic System for use in patients with BPH, and have subsequently obtained 510(k) clearances for modifications to the system. Any 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 depending on the change, we may be required to submit a PMA and obtain FDA approval before implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to 510(k)-cleared products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to 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 or other regulators can delay, limit, or deny clearance or approval 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 AquaBeam Robotic System, or any other future device, and any accessories are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses;
- the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the insufficiency of the data from preclinical studies or clinical trials to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the failure of our manufacturing process or facilities to 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.

***Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products on a timely basis, if at all, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.***

It is important to our business that we build a pipeline of product offerings that address limitations of current BPH products. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these products may not be accepted by physicians or users.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to, among others:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with the FDA and foreign regulations on marketing of new products or modified products; and
- provide adequate training to potential users of our AquaBeam Robotic System.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

Some of our future products will require FDA clearance of a 510(k). Other products may require the approval of a PMA. In addition, some of our future products may require clinical trials to support regulatory approval and we

may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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

Modifications to our AquaBeam Robotic System and associated consumables may require new regulatory approvals or clearances, including 510(k) clearances or PMAs, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our AquaBeam Robotic System in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our AquaBeam Robotic System as modified, which could require us to redesign our AquaBeam Robotic System and/or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a PMA application. Where we determine that modifications to our AquaBeam Robotic System require a new 510(k) clearance or PMA application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

***Even though we have obtained marketing authorization for our AquaBeam Robotic System, we are subject to ongoing regulatory review and scrutiny. 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 marketing authorization for our AquaBeam Robotic System, it and any other product for which we obtain clearance or approval, and the manufacturing processes, post-market surveillance, post-approval clinical data and promotional activities for such product, are or, in the case of future products, will be, subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's QSR and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;
- operating restrictions;
- withdrawal of 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

***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, and if we fail to do so, we would be subject to sanctions that could harm 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 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 to us 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 could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury 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 an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

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.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA 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, will distract management from operating our business and may harm our reputation and financial results.

***Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.***

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We or our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. For instance, in 2019 we initiated a voluntary recall for a limited number of lots of our handpiece due to certain issues related to our supply chain and manufacturing processes. We have remedied these issues as we developed our manufacturing processes to scale the production of our handpieces at a higher volume. 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; 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; 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 products, such as our AquaBeam Robotic System, may in the future be subject to product recalls that could harm our reputation, business and financial results.***

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our AquaBeam Robotic System in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

***We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our AquaBeam Robotic System.***

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as “off-label” use. Physicians may use our AquaBeam Robotic System off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our AquaBeam Robotic System, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, including, but not limited to, through a whistleblower action under the federal civil False Claims Act, or FCA, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring 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. Product liability claims are expensive to defend and could divert our management’s attention, result in substantial damage awards against us, and harm our reputation.

Product liability claims are expensive to defend and could divert our management’s attention, result in substantial damage awards against us, and harm our reputation.

***Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products and to manufacture, market and distribute our products after clearance or approval is obtained.***

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

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 forthcoming steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the 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. The FDA also announced that it intended to finalize guidance to establish a premarket review pathway for “manufacturers of certain well-understood device types” as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

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 maintains a list device types appropriate for the “safety and performance based” pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices similar to ours, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain marketing authorization 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 be subject to enforcement action, and we may not achieve or sustain profitability.

Clinical trials may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support any future PMA applications, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and

earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit an investigational device exemption application, or IDE, to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or an Institutional Review Board, or IRB, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

***If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.***

We may not have the ability to independently conduct our pre-clinical and clinical trials for our future products and we may need to rely on third parties, such as CROs, medical institutions, collaborators, clinical investigators and contract laboratories to conduct such trials. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites.



If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before clearing or approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our future clinical trials complies with the GCP regulations. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

***Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of 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 may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone inspections of foreign manufacturing facilities and products, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, 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. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, 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.

***Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these persons could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA requirements, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; 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 are subject to extensive laws and regulations intended to prevent fraud, 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. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or exclusion by OIG could result in penalties, a loss of business from third parties, and severe reputational harm.

It is not always possible to identify and deter misconduct by our employees and other agents, 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 be in compliance with such 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

***We must comply with environmental and occupational safety laws.***

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. In the event of an accident or failure to comply with environmental or occupational safety laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage.

**Risks Related to Our Intellectual Property**

***We have to obtain, maintain and protect our intellectual property and failure to do so may adversely impact our competitive position.***

Our commercial success and ability to compete will depend in part in our ability to obtain, maintain and enforce issued patents, trademark and other intellectual property rights and proprietary technology in the United States and elsewhere. If we cannot adequately obtain, maintain and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses.

We rely on a combination of contractual provisions, confidentiality procedures and patent, trade secret, copyright and trademark laws to protect our proprietary technology, products, services, brands, trade secrets, know-how and data and prevent others from duplicating our AquaBeam Robotic System or its disposable components, and our other current and future products, services and technology. However, these legal means afford only limited protection and may not:

- prevent our competitors from duplicating our AquaBeam Robotic System or its disposable components, and our other current and future products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- permit us to gain or maintain a competitive advantage.

Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining, maintaining and enforcing other intellectual property rights. We may not be able to obtain, maintain and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

Failure to obtain, maintain and/or enforce 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 patents, trademarks, data, technology and other intellectual property rights, products and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely in part on our portfolio of issued patents and pending patent applications in the United States and other countries to protect our intellectual property and competitive position. However, our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development, manufacture and commercialization activities before it is too late to obtain patent protection on them. If we fail to timely file for a patent in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee of a third party's patents or patent applications, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained and/or enforced in a manner consistent with the best interests of our business. While we generally apply for patents in those countries where we intend to make, have made, use, import, offer to sell or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from manufacturing and/or commercializing our own products or services, or otherwise practicing our own technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing, manufacturing and commercializing a product or a service in a non-infringing manner that would be competitive with one or more of our products or services, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Further, if we encounter delays in any future regulatory approvals, the period of time during which we could market a product or a service under patent protection could be reduced, and, given the amount of time required for the development, testing and regulatory review of planned or future products or services, patents protecting such products or services might expire before or shortly after such products or services are commercialized. As a result, our patent rights may not provide us with sufficient rights to exclude others from manufacturing or commercializing products or services similar or identical to ours.

If we are unable to obtain, maintain and enforce our issued patent, trademarks and other intellectual property rights related to our products, services or technology, or if the scope of the issued patents, trademarks or other intellectual property right protection is insufficient, our competitors could develop, manufacture and commercialize products, services or technology similar or superior to ours, and our competitive position may be adversely affected. In addition, the patent prosecution process 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 or in a timely manner.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the patent owner or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license to itself. We cannot be sure that if we acquire intellectual property rights in the future it will be free from government rights or regulations pursuant to the Bayh-Dole Act. If, in the future, we own, co-own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software as a trade

secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

***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 U.S. Patent and Trademark Office, or 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, renewal fees, annuity fees and various other government fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent and/or applications and any patent rights we may obtain in the future. While an unintentional lapse of a patent or patent application 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 non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or services, we may not be able to stop a competitor from marketing products or services that are the same as or similar to our products or services, which would have a material adverse effect on our business, financial condition and results of operations.

***We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful, and if unsuccessful, the commercial value of our products and services will be adversely affected and our competitive position may be harmed.***

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful. While we are not aware of any unauthorized use of our intellectual property rights, we do not regularly conduct monitoring for unauthorized use at this time. In the future, we may, from time to time, seek to analyze our competitors' products and services, or seek to enforce our rights against potential infringement, misappropriation or violation of our intellectual property rights. The steps we have taken to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and services.

In the future, we may become involved in lawsuits to protect or enforce our intellectual property rights. An adverse result in any litigation proceeding could harm our business. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to stop the other party from using the technology at issue on grounds that our intellectual property rights do not cover the technology in question. If we initiate legal proceedings against a third party to enforce a patent covering a product or a service, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Grounds for a validity challenge could be an alleged failure to meet any of several statutory

requirements, including lack of patentable subject matter, novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from USPTO, or made a misleading statement, during prosecution. Mechanisms for such challenges include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents and other intellectual properties owned by us. A court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Furthermore, even if our patents or other intellectual property rights 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. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other 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 adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

***We may be unsuccessful in licensing or acquiring intellectual property rights from third parties that may be necessary to develop, manufacture and/or commercialize our current and/or future products or services.***

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development, manufacture and/or commercialization of our current and/or future products or services, in which case we would be need to acquire or obtain a license to such intellectual property rights from such third party. A third party that perceive us to be a competitor may be unwilling to assign or license its intellectual property rights to us. In addition, the licensing or acquisition of third party intellectual property rights is a competitive area, and other companies may also pursue similar strategies to license or acquire such third party's intellectual property rights. Some of these companies may be established and may have a competitive advantage over us due to their size, capital resources and greater development, manufacture and commercialization capabilities. We also may be unable to license or acquire third party intellectual property rights on commercially reasonable terms that would allow us to make an appropriate return on our investment, or at all, or we may be unable to obtain any such license or acquisition at all. If we are unable to successfully obtain rights to necessary third party intellectual property rights, we may not be able to develop, manufacture or commercialize our current and/or future products or services, which could have a material adverse effect on our business, financial condition and results of operations.

***We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of our AquaBeam Robotic System and our other current and future products.***

We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our current or future patents, patent applications, trade secrets or other intellectual property rights as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our AquaBeam Robotic System or our other current or future products, services or technology. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property rights that we regard as our own, and we cannot 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property rights, and other owners may be able to license their rights to other third parties, including our competitors. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Additionally, we may be subject to claims from third parties challenging ownership interest in or inventorship of intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign their intellectual property rights to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against such claims, and it may be necessary or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim, however, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our AquaBeam Robotic System and our other current and future products, services or technology. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such 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 our AquaBeam Robotic System, or our other current or future products, services and technologies, and we could be prohibited from using our other technologies, features or intellectual property rights that are essential to our products or services, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another person or entity, including another or former employers. An inability to incorporate technologies, features or other intellectual property rights that are important or essential to our products or services could have a material adverse effect on our business, financial condition, results of operations, and competitive position, and may prevent us from developing, manufacturing and/or selling our products or services. 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 and our employees. 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 develop, manufacture and/or commercialize our products or services, which could materially and adversely affect our business, financial condition and results of operations. 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 products. Even if we are successful in defending against such

claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

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

In addition to seeking patent protection for our AquaBeam Robotic System and our other current and future products and services, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information and we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property rights. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. In addition, despite the protections we place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property rights by employees, consultants and other third parties who have access to such intellectual property or other proprietary rights 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. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors or third parties, despite the existence generally of these confidentiality restrictions. These agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets, know-how or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurances that such employees, consultants, advisors or 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 third parties, including our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our technology, which could adversely affect our pricing and market share.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, the movement of personnel within the industry and from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and



we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***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 AquaBeam Robotic System or our other current and future products or services, 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 product could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our AquaBeam Robotic System or our other current and future products or services. 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 product, which could have an adverse effect on our business, financial condition and results of operations.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products or services, and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.***

Our ability to obtain patents and the breadth of any patents obtained is uncertain in part because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other countries. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products and services.

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.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

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. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property rights or narrow the scope of our patent protection. 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. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***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 our trademarks, trade names and brand names to distinguish our products and services from the products and services of our competitors, and have registered or applied to register many of these trademarks in the United States and certain countries outside the United States. There can be no assurance that our trademark applications will be approved for registration. 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 may also oppose our trademark applications and may seek to cancel trademark registrations or otherwise challenge our use of the trademarks. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. While we may be able to continue the use of our trademarks in the event registration is not available, particularly in the United States, where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court.

Our trademarks or trade names may be challenged, invalidated, infringed, circumvented and circumvented by third parties, and our trademarks could also be diluted, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners and customers in our markets of interest. If any of the foregoing occurs, we could be forced to re-brand our products or services, 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. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. At times, competitors or other third parties 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 may be adversely affected. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, operating results and prospects.

***We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time-consuming, unsuccessful, and could interfere with our ability to sell and market our products or services.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and services and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. 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. While we take steps to ensure that we do not infringe upon, misappropriate or otherwise violate the intellectual property rights of others, there may be other more pertinent rights of which we are presently unaware.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products and services, or that we may be accused of misappropriating third parties' trade secrets or infringing third parties' trademarks. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products or services, including interference proceedings, post grant review and inter partes review before the USPTO or equivalent foreign regulatory authority. Furthermore, we may also become involved in other proceedings, such as reexamination, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. 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 or services 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. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid and enforceable, and infringed by the use of our products and/or services, which could have a negative impact on the commercial success of our current and any future products or services. If we were to challenge the validity of any such third party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, in the United States, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third party claim of patent infringement.

Our defense of any litigation or interference proceedings may fail and, even if successful, defending such claims brought against us would cause us to incur substantial expenses. If such claims are successfully asserted against us, they may result in substantial costs and distract our management and other employees and could cause us to pay substantial damages. Further, if a patent infringement or other intellectual property rights-related lawsuit were brought against us, we could be forced, including by court order, to cease developing, manufacturing and/or commercializing the infringing product or service. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. 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. We may not be able to obtain licenses on commercially reasonable terms, or at all, in which event our business would be materially and adversely affected.

Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors and other third parties gaining access to the same intellectual property. Ultimately, if we are unable to obtain such licenses or make any necessary changes to our products or services, we could be forced to cease some aspect of our business operations, which could harm our business significantly.

A finding of infringement, or an unfavorable interference or derivation proceedings outcome could prevent us from developing, manufacturing and/or commercializing our products or services, or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. We could encounter delays in product or service introductions while we attempt to develop alternative products or services.

If third parties assert infringement, misappropriation or other claims against our customers, these claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Additionally, our products include components that we purchase from suppliers 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, services or to use our technologies or product names. 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 may increase. Moreover, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” purchase 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, services and business operations infringe, misappropriate or otherwise 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. In addition, suppliers 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.

Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or services. Two of our applications filed in Europe are currently subject to opposition challenges. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products or services. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our

common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

***Our use of “open source” software could subject our proprietary software to general release, adversely affect our ability to sell our AquaBeam Robotic System or our other current or future products and services and subject us to possible litigation.***

A portion of the products or technologies licensed, developed and/or distributed by us incorporate so-called “open source” software and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our software that uses particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our AquaBeam Robotic System and our technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our AquaBeam Robotic System and our other current and future products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations.

***Intellectual property rights do not necessarily address all potential threats.***

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 AquaBeam Robotic System and our other current or future products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our AquaBeam Robotic System and our other current and future 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;
- 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;
- 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;
- 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 may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- 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 have a material adverse effect on our business, financial condition and results of operations.

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

Third parties may attempt to develop, manufacture and/or commercialize competitive products or services in foreign countries utilizing our proprietary technology, design, trademarks or tradenames in foreign countries where we do not have any patents or patent applications, trademarks, and/or other forms of intellectual property rights and/or 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 AquaBeam Robotic System and all of our other current and future products and services in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries particularly those of developing countries, may not protect our rights to the same extent as the laws of the United States. For example, as of May 1, 2021, the Patent Cooperation Treaty had 153 contracting states, and it is only economically feasible to file for protection in a portion of these countries. With the COVID-19 pandemic, some of our foreign associates have requested instructions well in advance of deadlines, which could adversely affect our ability to meet foreign deadlines for filing and prosecuting patent applications. Also, it is unclear to what extent the COVID-19 pandemic will adversely impact operations at some foreign patent offices where we have sought protection. Consequently, we may not be able to prevent third parties from practicing our inventions or trademarks in all jurisdictions outside the United States to the same extent as the United States, or from developing, manufacturing, selling or importing products or services using or incorporating our inventions or trademarks in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent or trademark protection to develop, manufacture and/or market their own products or services and, further, may export otherwise infringing products or services to territories where we have patent or trademark protection, but enforcement on infringing activities is inadequate or not as strong as that in the United States. These products or services may compete with our AquaBeam Robotic System or other current or future products or services, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to manufacture or market our products or services. Accordingly, our efforts to protect our intellectual property rights in such countries

may be inadequate, which may have an adverse effect on our ability to successfully manufacture or commercialize our products or services in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. 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, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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 at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing 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. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected.

***We heavily depend on intellectual property licensed from third parties and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.***

We are dependent on patents, know-how and other proprietary technology licensed from AquaBeam LLC. This and other licenses we currently possess or may possess in the future may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Moreover, if we fail to comply with our obligations under such licenses, or if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or products.

Certain provisions in our intellectual property agreements with third parties may also be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, results of operations, financial condition, cash flows and prospects. In spite of our efforts, our current and future licensors might also conclude that we have breached our obligations under our license agreements and might therefore seek to terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. As a result, any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our products, including, for example, the AquaBeam Robotic System, and our financial results.

In addition, we may need to obtain additional licenses from our existing licensors and others to allow commercialization of products we may develop. Moreover, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or products. Even if we are able to obtain such additional licenses, they may be non-exclusive thereby giving our competitors and other third parties access to

the same technology licensed to us. Any of the foregoing could have an adverse impact on our business and financial results.

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

*The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, which could result in substantial losses for holders of our common stock, and we may not be able to meet investor or analyst expectations.*

The market price of our common stock may be highly volatile and fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- variations between our actual operating results, or those of companies that are perceived to be similar to us, and the expectations of securities analysts, investors and the financial community;
- any forward-looking financial or operating information we may provide to the public or securities analysts, any changes in this information or our failure to meet expectations based on this information;
- actions of securities analysts who initiate or maintain coverage of us, changes in financial estimates by any securities analysts who follow our Company or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders, or the anticipation of such sales, including if existing stockholders sell shares into the market when applicable “lock-up” period ends;
- hedging activities by market participants;
- announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in operating performance and stock market valuations of companies in our industry, including our competitors;
- changes in third-party payor reimbursement policies;
- an inability to obtain additional funding;
- general economic, industry and market conditions, including price and volume fluctuations in the overall stock market;
- expiration of market stand-off or lock-up agreements;
- lawsuits threatened or filed against us;
- developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and
- other events or factors, including those resulting from political conditions, election cycles, war or incidents of terrorism, or responses to these events, many of which are outside of our control.

In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many life sciences and technology companies’ stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies’ operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. This risk is especially relevant for us because medical technology companies have experienced significant stock price volatility in recent years. 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 seriously harm our business.



Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide.

***Future sales of shares by existing stockholders could cause our stock price 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 lock-up and legal restrictions on resale discussed in our prospectus lapse, the trading price of our common stock could decline. As of September 30, 2021, we had a total of 43,471,678 shares of common stock outstanding. Of these shares, only the shares of common stock sold in our IPO are currently freely tradable, without restriction, in the public market. Each of our directors, executive officers and other holders of substantially all our outstanding equity securities are subject to lock-up and market standoff agreements that restrict their ability to, among other things and subject to certain exceptions, sell or transfer their shares until March 13, 2022, subject to certain exceptions. However, BofA Securities, Inc. and Goldman Sachs & Co. LLC may, in their sole discretion, waive the contractual lock-up before the lock-up agreements expire. After the lock-up agreements expire, all shares outstanding will be eligible for sale in the public market, of which the shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 of the Securities Act, and various vesting agreements. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off agreements, the perception that such sales may occur or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

In addition, 6,606,871 shares of our common stock were issuable upon the exercise of options outstanding as of September 30, 2021. These shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 of the Securities Act. We filed a registration statement on Form S-8 under the Securities Act covering all the shares of common stock subject to stock options outstanding and reserved for issuance under our stock plans. Shares covered by that registration statement are eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and the lock-up agreement described above. If these additional shares are sold, or if it is perceived that they will be sold in the public market, the trading price of our common stock could decline.

***We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. In addition, the terms of our loan and security agreement with Oxford Finance LLC restrict our ability to pay dividends to limited circumstances. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of September 30, 2021, our executive officers, directors and 5% stockholders beneficially owned more than 25% of our outstanding shares of common stock. Therefore these stockholders will have the ability to influence us through this ownership position. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of us, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets, and might affect the

prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

***Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.***

Future issuances of shares of our common stock, or the perception that these sales may occur, could depress the market price of our common stock and result in dilution to existing holders of our common stock. Also, to the extent outstanding options to purchase shares of our common stock are exercised or options, restricted stock units or other stock-based awards are issued or become vested, there will be further dilution. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common stock. As a result, holders of our common stock bear the risk that future issuances of debt or equity securities may reduce the value of our common stock and further dilute their ownership interest.

***Delaware law and provisions in our amended and restated certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our amended and restated certificate of incorporation and bylaws currently in effect contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include the following:

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting our board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- providing that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of our capital stock;
- requiring the approval of holders of two-thirds of our outstanding common stock to amend some provisions in our amended and restated certificate of incorporation and bylaws;
- authorizing the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibiting stockholders from calling special meetings of stockholders;
- prohibiting stockholder action by written consent, which has the effect of requiring all stockholder actions to be taken at a meeting of our stockholders;
- providing that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- restricting the forum for certain litigation involving us to Delaware or federal courts, as applicable; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our amended and restated certificate of incorporation currently in effect or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

The provisions of our amended and restated certificate of incorporation requiring exclusive forum in the Court of Chancery of the State of Delaware and the federal district courts of the United States for certain types of lawsuits may have the effect of discouraging lawsuits against our directors and officers.

Our amended and restated certificate of incorporation currently in effect provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (iv) any action to interpret, apply, enforce, or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws, or (v) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation will provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. These provisions may also result in increased costs for investors seeking to bring a claim against us or any of our directors, officers or other employees.

### **Risks Related to Being a Public Company**

***We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.***

In connection with the preparation of our consolidated financial statements, a material weakness in our internal control over financial reporting was identified as of December 31, 2020. 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 is the result of our failure to design and maintain effective controls over certain information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain:

- program change management controls to ensure that information technology program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, and
- user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel.

These IT general control deficiencies did not result in a material misstatement to the financial statements; however, the deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts

and disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. Accordingly, our management determined these deficiencies in the aggregate constitute a material weakness.

We are in the process of designing and implementing measures to remediate the material weakness in our internal control over financial reporting, which includes designing and implementing controls over the review and update of user access rights and privileges, including segregation of duties, and controls over program changes to our information systems that contain data used for financial reporting. While we are designing and implementing measures to remediate the material weakness, we cannot predict the success of such measures or the outcome of our assessment of these measures at this time. We can give no assurance that these measures will remediate the material weakness in our internal control over financial reporting or that additional material weaknesses in our internal control over financial reporting will not be identified in the future. The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Our failure to design and maintain effective internal control over financial reporting could result in errors in our financial statements that may lead to a restatement of our financial statements or cause us to fail to meet our reporting obligations.

As a public company, our management is required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. When we lose our status as an “emerging growth company,” our independent registered public accounting firm will be required to audit the effectiveness of our internal control over financial reporting. Failure to comply with the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Failure to remediate any material weakness in our internal control over financial reporting, or to design and maintain effective internal control over financial reporting, could also restrict our future access to the capital markets.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***The requirements of being a public company may strain our resources, result in more litigation, and divert management’s attention.***

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our

disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Quarterly Report on Form 10-Q and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

## **General Risks**

### ***Litigation and other legal proceedings may adversely affect our business.***

From time-to-time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our AquaBeam Robotic System, even if the regulatory or legal action is unfounded or not material to our operations.

### ***General economic and financial market conditions may exacerbate our business risks.***

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. Our customers and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. Furthermore, unfavorable changes in foreign exchange rates versus the U.S. dollar could increase our product and labor costs, thus reducing our gross profit.

***If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.***

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

***We are an emerging growth company and a “smaller reporting company,” and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller growth companies could make our common stock less attractive to investors.***

We are an “emerging growth company” as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue;
- the date we qualify as a “large accelerated filer;”
- the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or
- December 31, 2026.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, for new or revised accounting standards applicable to public companies, we will be subject to an extended transition period until those standards would otherwise apply to private companies. As a result, our consolidated 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, which may make comparison of our financials to those of other public companies more difficult.

Even after we no longer qualify as an “emerging growth company,” we may still qualify as a “smaller reporting company,” which would allow us to continue to take advantage of many of the same exemptions from disclosure

requirements, including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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

On September 17, 2021, we closed our initial public offering (“IPO”) of our common stock in which we issued and sold 6,556,000 shares of our common stock, and sold an additional 983,400 shares of common stock upon the full exercise of the underwriters’ option to purchase additional shares at a price to the public of \$25.00 per share. The shares were offered pursuant to registration statements on Form S-1 (File Nos. 333-258898 and 333-259527), which became effective on September 14, 2021. The underwriters of the offering were led by BofA Securities, Inc. and Goldman Sachs & Co. LLC. The offering did not terminate until after the sale of all shares of common stock registered on the registration statements.

We raised approximately \$172.4 million in proceeds, net of underwriting discounts and commissions of \$13.2 million and estimated offering costs of \$2.9 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds from our IPO have been used and will be used, together with our cash and cash equivalents: (i) to hire additional sales and marketing personnel; (ii) to fund product development and research and development activities; and (iii) for working capital and other general corporate purposes.

We may also use a portion of the net proceeds from the IPO to acquire, in-license or invest in products, technologies or businesses that are complementary to our business.

There has been no material change in the intended use of proceeds from our IPO as described in our final prospectus dated September 14, 2021 and filed with the SEC pursuant to Rule 424(b)(4) on September 16, 2021.

## **Item 3. Defaults Upon Senior Securities**

None.

## **Item 4. Mine Safety Disclosures**

None.

## **Item 5. Other Information**

None.

## Item 6. Exhibits

The following exhibits are filed or furnished as a part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a> (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on September 21, 2021)
3.2	<a href="#">Amended and Restated Bylaws</a> (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed on September 21, 2021)
10.1+	<a href="#">Non-Employee Director Compensation Program</a> (incorporated by reference to Exhibit 10.10 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.2+	<a href="#">2021 Equity Incentive Award Plan</a> (incorporated by reference to Exhibit 10.11 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.2(a)+	<a href="#">Form of Stock Option Agreement under the 2021 Equity Incentive Award Plan</a> (incorporated by reference to Exhibit 10.11(a) to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.2(b)+	<a href="#">Form of Restricted Stock Unit Agreement under the 2021 Equity Incentive Award Plan</a> (incorporated by reference to Exhibit 10.11(b) to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.3+	<a href="#">2021 Employee Stock Purchase Plan</a> (incorporated by reference to Exhibit 10.12 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.4+	<a href="#">Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Reza Zadno, Ph.D., dated September 17, 2021</a> (incorporated by reference to Exhibit 10.13 to the registrant's registration statement on Form S-1 (File No. 333-258898)).
10.5+	<a href="#">Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Kevin Waters, dated September 17, 2021</a> (incorporated by reference to Exhibit 10.14 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.6+	<a href="#">Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Hisham Shibliq, dated September 17, 2021</a> (incorporated by reference to Exhibit 10.15 to the registrant's registration statement on Form S-1 (File No. 333-258898)).
31.1**	<a href="#">Certification of Principal Executive Officer 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.</a>
31.2**	<a href="#">Certification of Principal Financial Officer 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.</a>
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.



101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document.  
104\* Cover Page Interactive Data File (embedded within the Inline XBRL document)

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\* Filed herewith.

\*\* Furnished herewith.

+ Indicates management contract or compensatory plan.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 5, 2021

**PROCEPT BIROBOTICS CORPORATION**  
(Registrant)

/s/ Reza Zadno

Reza Zadno, Ph.D.

President and Chief Executive Officer

(principal executive officer)

/s/ Kevin Waters

Kevin Waters

SVP, Chief Financial Officer

(principal financial and accounting officer)