**This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.**

**As confidentially submitted with the Securities and Exchange Commission on June 25, 2021**

**Registration No. 333-**

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM S-1**
**REGISTRATION STATEMENT**
***UNDER***
***THE SECURITIES ACT OF 1933***

# PROCEPT BIOROBOTICS CORPORATION

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **3841** | **26-0199180** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Primary Standard Industrial Classification Code Number)** | **(I.R.S. Employer Identification No.)** |

**900 Island Drive**
**Redwood City, CA, 94065**
**(650) 232-7200**
**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Reza Zadno, Ph.D.**
**Chief Executive Officer**
**900 Island Drive**
**Redwood City, CA, 94065**
**(650) 232-7200**
**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

***Copies to:***

| **B. Shayne Kennedy**<br>**Drew Capurro**<br>**Latham & Watkins LLP**<br>**650 Town Center Drive, 20th Floor**<br>**Costa Mesa, CA 92626**<br>**(714) 540-1235** | **Alaleh Nouri**<br>**General Counsel**<br>**Jonathan Stone**<br>**Senior Corporate Counsel**<br>**900 Island Drive**<br>**Redwood City, CA, 94065**<br>**(650) 232-7200** | **Charles S. Kim**<br>**Kristin VanderPas**<br>**Dave Peinsipp**<br>**Denny Won**<br>**Cooley LLP**<br>**4401 Eastgate Mall**<br>**San Diego, CA 92121**<br>**(858) 550-6000** |
|---|---|---|

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

| | | | |
|---|---|---|---|
| Large accelerated filer | o | Accelerated filer | o |
| Non-accelerated filer | x | Smaller reporting company | x |
| | | Emerging growth company | x |

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 7(a)(2)(B) of the Securities Act. ☐

**CALCULATION OF REGISTRATION FEE**

| **Title of each class of securities to be registered** | **Proposed maximum aggregate offering price[(1)(2)]** | **Amount of registration fee[(3)]** |
|---|---|---|
| Common stock, par value $0.00001 per share | $ | $ |

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the offering price of shares of common stock that may be sold if the underwriters fully exercise their option to purchase additional shares of common stock.

(3) To be paid in connection with the initial filing of the registration statement.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**EXPLANATORY NOTE**

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of and for the three months ended March 31, 2020 and 2021 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time of the first public filing of the registration statement. We intend to include all financial information required by Regulation S-X at the date of such public filing of the registration statement.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion

Preliminary Prospectus dated , 2021

# Shares


## Common Stock

This is an initial public offering of shares of common stock of PROCEPT BioRobotics Corporation. We are selling shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between $ and $ per share. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "PRCT."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

**Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 13 of this prospectus.**

| | Per Share | Total |
|---|---|---|
| Initial public offering price | $ | $ |
| Underwriting discounts and commissions[(1)] | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option to purchase up to an additional shares of common stock from us at the initial public offering price less the underwriting discounts and commissions.

**Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2021.

**BofA Securities** **Goldman Sachs & Co. LLC**

**Cowen** **Guggenheim Securities** **SVB Leerink**

The date of this prospectus is , 2021

PROCEPT®
BioRobotics

# Treatment of Choice
## for All Prostates

AQUABLATION®
Therapy by PROCEPT BioRobotics

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

## MARKET AND INDUSTRY DATA

This prospectus includes estimates regarding market and industry data that we prepared based on our management's knowledge and experience in the markets in which we operate, together with information obtained from various sources, including publicly available information, industry reports and publications, surveys, our customers, distributors, suppliers, trade and business organizations and other contacts in the markets in which we operate. In some cases, we do not expressly refer to the sources from which this data is derived. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data and our knowledge of such industry and markets which we believe to be reasonable.

In presenting this information, we have made certain assumptions that we believe to be reasonable based on such data and other similar sources and on our knowledge of, and our experience to date in, the markets for the products we distribute. Market share data is subject to change and may be limited by the availability of raw data, the voluntary nature of the data gathering process and other limitations inherent in any statistical survey of market shares. In addition, customer preferences are subject to change. Accordingly, you are cautioned not to place undue reliance on such market share data.

## CERTAIN TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This prospectus includes trademarks and service marks owned by us, including, without limitation, PROCEPT BioRobotics®, AquaBeam®, Aquablation®, and our logo, which are our property and are protected under applicable intellectual property laws. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all the information that may be important to you. You should read the entire prospectus carefully, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our consolidated financial statements and related notes included elsewhere in this prospectus, before deciding to invest in our common stock. In this prospectus, unless the context requires otherwise, references to "PROCEPT," the "Company," "we," "us," and "our," refer to PROCEPT BioRobotics Corporation.*

### Our Company

We are a commercial-stage 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. Our proprietary AquaBeam Robotic System employs a single-use disposable handpiece to deliver our Aquablation therapy, which combines real-time, multidimensional imaging, personalized treatment planning, automated robotics and heat-free waterjet ablation for targeted and rapid removal of prostate tissue. We believe that Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing compromises associated with alternative surgical interventions to deliver effective, safe and durable outcomes 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 June 30, 2021, we have an installed base of more than AquaBeam Robotic Systems, and Aquablation therapy has been utilized in the treatment of more than patients whose prostates have ranged in size from less than 30 ml to over 300 ml.

The main goal of BPH treatment is to alleviate the symptoms associated with the disease and improve the patient's quality of life. While drug therapy is typically a first line treatment option, limited efficacy and negative side effects contribute to low compliance, high failure rates and drop outs. On the other hand, surgical intervention is proven to provide effective and durable symptom relief compared to drug therapy, but the use of surgery is significantly underpenetrated, largely due to the compromise patients must make between the incidence of irreversible side effects associated with alternative resective surgical interventions or the lower rates of efficacy and durability associated with non-resective surgical interventions. In addition, most alternative surgical interventions are limited by prostate size and shape, with no single procedure capable of effectively addressing the full range of prostate anatomies regardless of surgeon experience level.

We developed our proprietary AquaBeam Robotic System to address many of the shortcomings of alternative surgical interventions by delivering our Aquablation therapy, the first and only image-guided robotic therapy for the treatment of BPH. The AquaBeam Robotic System combines real-time image guidance, personalized treatment planning, automated robotic execution and heat-free waterjet ablation. We believe our Aquablation therapy addresses the compromise between safety and efficacy of alternative surgical interventions, providing the following unique combination of benefits:

- ***Significant and durable symptom relief***. Aquablation therapy has demonstrated significant and long-lasting levels of symptom relief similar to those of alternative resective procedures.
- ***Favorable safety profile***. Aquablation therapy has demonstrated low rates of irreversible complications, including urinary incontinence, erectile dysfunction and ejaculatory dysfunction, compared to published rates observed for other resective surgeries.
- ***Outcomes independent of prostate size and shape and surgeon experience***. Aquablation therapy delivers outcomes that are effective, safe and durable across all prostate sizes and shapes. Compared to other resective procedures, we believe Aquablation therapy is relatively simple to learn, enabled by the intuitive interface of the CPU and automated robotic resection, and delivers outcomes that are independent of surgeon experience.

- ***Personalized treatment planning and improved decision-making***. Aquablation therapy combines cystoscopic visualization, ultrasound imaging and advanced planning software to provide the surgeon with a multidimensional view of the treatment area and enable personalized treatment planning for the patient's unique anatomy, improved decision-making and real-time monitoring during the procedure.

- ***Targeted and controlled resection with consistent resection times***. Aquablation therapy utilizes automated robotic resection to remove prostate tissue using a precise, heat-free waterjet. These features enable targeted and controlled tissue removal with rapid resection times that are highly consistent across prostate sizes and shapes and surgeon experience.

In the United States, we currently sell our products to hospitals primarily through our direct sales organization. These hospitals 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. 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, 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. Outside of the United States, we have ongoing efforts in key markets to expand established coverage and improve payment which we will believe will expand patient access to Aquablation therapy. We sell our products outside of the United States through both our direct sales organization and, in certain regions, our network of distribution partners.

We generated revenue of $7.7 million and a net loss of $53.0 million for the year ended December 31, 2020, compared to revenue of $6.2 million and a net loss of $$42.0 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $201.7 million.

**Market Overview**

BPH refers to the non-malignant enlargement of the prostate gland, a small gland in the male reproductive system, and in the United States is the number one reason men visit a urologist. BPH is estimated to occur in more than 50% of men in their 50s, growing to 70% of men in their 60s, and is the fourth most common diagnosed disease in men above 50 years old, ranking behind coronary artery disease, hypertension and type 2 diabetes. BPH often results in uncomfortable lower urinary tract symptoms, or LUTS, which can have a significant impact on quality of life. If left untreated, BPH may eventually lead to more serious complications.

In the United States, we estimate that approximately 40 million men are impacted by symptoms of BPH, with aging demographics expected to drive future growth. Over the next ten years, we expect that the number of men over 65 years old in the United States will double and include a corresponding increase in the number of men with enlarged prostates. Of these men, approximately 12 million are being managed by a physician for symptoms related to their disease. While drug therapy is typically a first line treatment option, limited efficacy and negative side effects contribute to low patient compliance, high failure rates and drop outs. On the other hand, surgical intervention is proven to provide effective and durable symptom relief compared to drug therapy, but the use of surgery is significantly underpenetrated largely due to the compromise patients must make between (1) the incidence of irreversible side effects associated with current resective surgical interventions, or (2) the lower rates of efficacy and durability associated with non-resective surgical interventions. Our total addressable patient population in the United States includes approximately 8.2 million patients, comprised of 6.7 million receiving drug therapy, 1.1 million who have tried but failed drug therapy and 400,000 undergoing surgical intervention each year. Based on the average selling price of our single-use handpiece, we estimate that our total addressable market opportunity is in excess of $20 billion in the United States. The global incidence of BPH among men over 50 years old is similar to that of the United States, representing a significant incremental market opportunity outside of the United States.

**BPH Treatment Options and Their Limitations**

The main goal of BPH treatment is to alleviate the symptoms associated with the disease and improve the patient's quality of life. As such, a patient's recommended course of treatment is largely based on the patient's

degree of symptoms, typically measured using validated scoring systems such as International Prostate Symptom Score, or IPSS. Patients with mild symptoms who have not developed other complications of BPH may choose watchful waiting, meaning that before proceeding with active treatment, the physician and patient wait to see if symptoms get worse or if new symptoms develop. Patients who choose this approach are generally advised to implement lifestyle changes and return for yearly visits with their physician to determine if symptoms are changing. For most men, the prostate will continue to grow and symptoms will worsen. As symptoms become more bothersome, active treatment may be recommended. The two primary categories of active treatment for BPH are drug therapy and surgical intervention.

- ***Drug therapy***. Drug therapy is often the first step in actively treating mild-to-moderate symptoms of BPH. While there is no pharmacological cure for BPH, drugs may be used to manage symptoms. Available drugs address symptoms by either shrinking (5-alpha reductase inhibitors) the prostate or relaxing (alpha blockers) muscles surrounding the prostate. In some instances, patients may be prescribed a combination of both medications. Most men with BPH who start drug therapy will need to continue it indefinitely in order to relieve symptoms, unless they choose to undergo surgical intervention. While drug therapy can provide relief for some men, two out of three patients are not satisfied with the effectiveness of their medication. In general, drug therapy provides IPSS reduction of approximately five points. Drug therapy is also often associated with negative side effects, including headaches, dizziness, nausea, erectile dysfunction, ejaculatory dysfunction, cardiac failure and dementia. These side effects often contribute to poor treatment compliance, with drug therapy failing in up to 30% of men. Furthermore, drug therapy may be costly, particularly in light of limited symptom relief. For example, a recent study has shown that payor costs for branded combination drug therapy over a two-year period was the least cost-effective of all treatment options included in the study, as drug therapy requires extended use and yields the least symptom relief.

- ***Surgical intervention***. Surgical intervention is recommended for patients who have failed or are unwilling to consider drug therapy, or are suffering from complications due to their BPH. Although more invasive than drug therapy, surgical intervention generally provides more significant, longer-lasting symptom relief. There are two categories of surgical intervention, resective and non-resective. We estimate that approximately 400,000 BPH surgeries were performed in the United States in 2019, growing at a compounded annual growth rate, or CAGR, of 11% since 2016. We believe that growth in the use of surgical intervention over the past several years is due to the introduction of new technologies that better balance the compromise between efficacy and safety as well as growing awareness of surgical intervention an effective way to manage BPH symptoms compared to drug therapy.

Two factors that surgeons and patients commonly consider when evaluating surgical intervention are efficacy and safety. Efficacy is generally measured by symptom relief as well as durability of relief, and safety by the occurrence of irreversible complications such as urinary incontinence, erectile dysfunction and ejaculatory dysfunction. We believe that alternative surgical interventions for BPH require patients to compromise between efficacy and safety. Alternative interventions either provide significant symptom relief with a heightened risk of irreversible complications or a lower risk of complications with significantly less symptom relief. In addition, most alternative surgical interventions are limited by prostate size and shape, with no single procedure capable of effectively addressing the full range of prostate anatomies regardless of surgeon experience level. We believe that the compromise and limitations associated with alternative surgical interventions have contributed to the relatively low penetration rate of surgical intervention.

**Our Solution**

We have developed the AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive urologic surgery. Our proprietary AquaBeam Robotic System delivers our Aquablation therapy, the first and only image-guided robotic therapy for the treatment of BPH. We market the AquaBeam Robotic System in the United States pursuant to FDA 510(k) clearance.

The AquaBeam Robotic System combines the following highly differentiated features that enable Aquablation therapy to deliver effective, safe and durable outcomes that are consistent across all prostate sizes and shapes and independent of surgeon experience:

- ***Real-time image guidance***. Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area, enabling improved decision-making and real-time treatment monitoring.
- ***Personalized treatment planning***. Using ultrasound imaging integrated with advanced planning software, the surgeon is able to map the treatment contour that precisely targets the resection area, personalizing the optimal tissue removal plan based on each patient's unique anatomy.
- ***Automated robotic execution***. Once the treatment plan is finalized, the robot automatically executes the plan, guiding the precisely calibrated waterjet with speed and accuracy while the surgeon monitors.
- ***Heat-free waterjet resection***. Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet, minimizing the risk of complications arising from prolonged thermal injury.

**Our Success Factors**

We believe the continued growth of our company will be driven by the following success factors:

- ***First and only image-guided, heat-free robotic therapy for BPH that addresses the compromise between safety and efficacy of alternative surgical interventions.*** We believe that alternative surgical interventions for BPH have a number of shortcomings which require patients to compromise between safety and efficacy, either providing significant symptom relief but with a heightened risk of irreversible complications or a lower risk of complications but with significantly less symptom relief. Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing this compromise and delivering effective, safe and durable outcomes that are consistent across all prostate sizes and shapes and independent of surgeon experience.
- ***Large, growing and underpenetrated market opportunity.*** Based on the average selling price of our single-use handpiece and the approximately 8.2 million BPH patients in the United States, we estimate that our total U.S. addressable market opportunity is in excess of $20 billion. The global incidence of BPH among men over 50 years old is similar to that of the United States, representing a significant incremental market opportunity outside of the United States.
- ***Significant and growing body of clinical evidence and strong support from key opinion leaders, or KOLs, resulting in the inclusion of Aquablation therapy into societal guidelines and rapid expansion of positive reimbursement coverage policies.*** Our robust clinical evidence includes nine clinical studies and more than 100 peer-reviewed publications, and demonstrates the efficacy, safety and durability of Aquablation therapy, consistent across all prostate sizes and shapes and independent of surgeon experience. Additionally, we have established strong relationships with 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.
- ***Compelling value proposition and benefits to hospitals, surgeons and patients.*** We designed our AquaBeam Robotic System to enable consistent and reproducible BPH surgery outcomes that are independent of surgeon experience and require minimal training. Furthermore, the AquaBeam Robotic System is highly mobile and compact, requiring no retrofitting of the operating room, and we believe is competitively priced compared to other robotic systems and capital equipment devices. For patients, Aquablation therapy offers significant and durable symptom relief with an attractive safety profile.
- ***Recurring revenue model.*** We generate revenue primarily from hospitals making capital purchases of our AquaBeam Robotic System and purchasing our single-use handpieces for individual patient use. We also

generate revenue by providing post-warranty service for the AquaBeam Robotic System. We believe our business model of selling capital equipment that generates corresponding disposables utilization and post-warranty service contracts provides a path to predictable, recurring revenue.

- ***Broad research and development capabilities and a robust intellectual property portfolio.*** We have invested in establishing strong research and development capabilities for over a decade, including in surgical robotics and imaging-enabled surgery as well as integrating hardware and software to create an exceptional user and patient experience. We believe our focus on this experience will allow us to continue to bring new upgrades, capabilities and products to market, allowing us to innovate and maintain our competitive positioning, and that our intellectual property and know-how present a significant barrier to entry for our competitors.

- ***Proven leadership team and board members with deep industry experience.*** We are led by a highly experienced management team and board with a successful track record of building businesses by identifying and providing solutions for underserved markets in the medical device industry.

**Our Growth Strategy**

Our mission is to establish Aquablation therapy as the surgical standard of care for BPH. The key elements of our growth strategy are:

- ***Grow our installed base of AquaBeam Robotic Systems by driving adoption of Aquablation therapy among urologists.*** 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. We also intend to increase awareness of Aquablation therapy by continuing to publish clinical data in various industry and scientific journals, present our clinical data at various industry conferences and sponsor peer-to-peer education programs and proctorships.

- ***Increase system utilization by establishing Aquablation therapy as the surgical treatment of choice for BPH.*** 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. Over time, we intend to leverage our relationships with urologists to drive utilization of Aquablation therapy beyond the current surgical market.

- ***Continue to broaden private payor coverage.*** We plan to leverage our recent successes, including the addition of Aquablation therapy to American Urological Association clinical guidelines in May 2019 and the final positive local coverage determinations by all local MACs to provide Medicare beneficiaries with access to Aquablation therapy in all 50 states, in our active discussions with private payors to establish additional positive national and regional coverage policies. We believe that additional private 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.

- ***Build upon our strong base of clinical evidence.*** We are committed to continuing to build upon our foundation of clinical evidence, which we believe will help drive increased awareness and adoption of our products. We also plan to further build our base of clinical evidence by supporting new clinical studies intended to support commercial, regulatory and reimbursement efforts.

- ***Invest 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.

- ***Drive increased awareness of Aquablation therapy beyond the urology community.*** As we expand our network of urologists and grow our installed base, we intend to increase awareness and brand recognition of Aquablation therapy beyond urologists, primarily among primary care physicians who manage BPH patients. To achieve this objective, we will invest in marketing initiatives direct at primary care physicians in order to optimize referral pathways and expand networks for BPH patients to visit a urologist.

- ***Further penetrate and expand into existing and new international markets.*** While the United States remains our primary focus in the near-term, we are growing our existing presence in the large European markets by continuing to promote the clinical benefits of Aquablation therapy, supporting investments in clinical studies to improve coverage and reimbursement and fostering relationships with KOLs. In addition, we intend to expand our reach to selected new markets in the Asia-Pacific region over time.

**Summary Risk Factors**

We are subject to a number of risks, including risks that may prevent us from achieving our business objectives or that may adversely affect our business, financial condition and results of operations. You should carefully consider the risks discussed in the section titled "Risk Factors," including the following risks, before investing in our common stock:

- 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.

- Even if this offering is successful, 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 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.

- 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.
- 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 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.
- 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.
- 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.
- 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.
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.
- 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.

Our business also faces a number of other challenges and risks discussed throughout this prospectus. You should read the entire prospectus carefully, including the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our consolidated financial statements and related notes included elsewhere in this prospectus, before deciding to invest in our common stock.

**Our Corporate Information**

We were incorporated in Delaware in April 2021 when our predecessor, PROCEPT BioRobotics Corporation, a California corporation, merged with and into us, and we continued as the surviving entity.

Our principal executive office is located at 900 Island Drive, Redwood City, CA, 94065 and our telephone number is (650) 232-7200. Our website address is *www.procept-biorobotics.com*. The information contained on, or that can be accessed through, our website is not incorporated by reference into, and is not a part of, this prospectus or the registration statement of which this prospectus forms a part. We have included our website in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

**Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

We qualify as an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements

that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- the option to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding nonbinding, advisory stockholder votes on executive compensation or on any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the first fiscal year in which our annual gross revenue exceeds $1.07 billion; (ii) the date that we become a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates as of the end of the second quarter of that fiscal year; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings with the U.S. Securities and Exchange Commission, or the SEC. As a result, the information that we provide may be different than the information you receive from other public companies in which you hold stock.

Emerging growth companies can also take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. As a result of these elections, some investors may find our common stock less attractive than they would have otherwise. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

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 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.

**The Offering**

| | |
|---|---|
| Common stock offered by us | shares. |
| Option to purchase additional shares | We have granted the underwriters an option exercisable for a period of 30 days to purchase up to additional shares of our common stock at the public offering price, less the underwriting discounts and commissions. |
| Common stock to be outstanding immediately after this offering | shares (or shares if the underwriters exercise their option to purchase additional shares of common stock in full). |
| Use of proceeds | We estimate that the net proceeds to us from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.<br><br>We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to hire additional sales and marketing personnel and expand marketing programs both in the United States and in Europe, to fund product development and research and development activities and the remainder for working capital and other general corporate purposes. See the section titled "Use of Proceeds." |
| Risk factors | Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" for a discussion of factors you should carefully consider before investing in our common stock. |
| Proposed Nasdaq Global Market symbol | "PRCT" |

The number of shares of common stock to be outstanding after this offering is based on shares of common stock outstanding as of June 30, 2021 (including the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the completion of this offering), and excludes the following:

- shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock issuable upon the exercise of options granted after June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock that remain available for issuance under our Amended and Restated 2008 Stock Plan, or 2008 Plan, as of June 30, 2021;
- shares of our common stock reserved for future issuance under our Plan, or 2021 Plan, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the 2021 Plan); and
- shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the ESPP).

Unless otherwise indicated, this prospectus reflects and assumes the following:

- a -for- reverse stock split of our common stock, which was effected on , 2021;

- the issuance of shares of Series E redeemable convertible preferred stock upon the exercise for cash, at an exercise price of $2.89 per share, of warrants to purchase our redeemable convertible preferred stock outstanding as of June 30, 2021, prior to the warrants expiration upon the completion of this offering;
- the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the completion of this offering;
- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and the adoption and effectiveness of our amended and restated bylaws immediately after the completion of this offering;
- no exercise of the outstanding options referred to above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

## Summary Consolidated Financial Data

The following tables summarize our historical consolidated financial data for the periods and as of the dates indicated. We derived our summary consolidated statements of operations data for the years ended December 31, 2019 and 2020 and our summary consolidated balance sheet data as of December 31, 2020 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future. You should read the following information in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| | (in thousands, except share and per share data) | |
| **Consolidated Statements of Operations Data:** | | |
| Revenue | $ 6,169 | $ 7,717 |
| Cost of sales | 8,054 | 8,972 |
| Gross profit | (1,885) | (1,255) |
| *Gross margin* | *-31 %* | *-16 %* |
| Operating expenses: | | |
| Research and development | 13,147 | 16,275 |
| Selling, general and administrative | 28,518 | 30,272 |
| Total operating expenses | 41,665 | 46,547 |
| Loss from operations | (43,550) | (47,802) |
| Interest expense | (724) | (5,261) |
| Interest and other income, net | 2,299 | 44 |
| Net loss | $ (41,975) | $ (53,019) |
| Net loss per share, basic and diluted[1] | $ (4.00) | $ (3.05) |
| Weighted-average common shares used to compute net loss per share attributable to common shareholders, basic and diluted[1] | 10,486 | 17,398 |
| | | |
| **Pro forma (unaudited):** | | |
| Net loss per share, basic and diluted | | $ |
| Weighted-average common shares used to compute pro forma net loss per share attributable to common shareholders, basic and diluted | | |

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical basic and diluted net loss per share.

| | As of December 31, 2020 | | |
|---|---|---|---|
| | Actual | Pro Forma[1] | Pro Forma As Adjusted[2][3] |
| | | (unaudited) | |
| | | (in thousands) | |
| **Consolidated Balance Sheet Data:** | | | |
| Cash and cash equivalents | $ 100,130 | $ | $ |
| Working capital[4] | 95,614 | | |
| Total assets | 126,087 | | |
| Total liabilities | 65,127 | | |
| Redeemable convertible preferred stock | 243,854 | | |
| Total stockholders' (deficit) equity | (182,894) | | |

_____

(1) The pro forma column in the consolidated balance sheet data table above gives effect to the conversion of outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 into an aggregate of shares of common stock immediately prior to the completion of this offering.

(2) The pro forma as adjusted column in the consolidated balance sheet data table above gives effect to (i) the pro forma adjustments described in footnote (1) above and (ii) the sale and issuance by us of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ , assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of $ per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price, the number of shares we sell and other terms of this offering that will be determined at pricing.

(4) We define working capital as current assets less current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further detail regarding our current assets and current liabilities.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment. This prospectus also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.*

### Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

***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 years ended December 31, 2019 and 2020, we had a net loss of $42.0 million and $53.0 million, respectively. For the six months ended June 30, 2020 and 2021, we had a net loss of $37.9 million and $ million, respectively. We expect to continue to incur additional losses in the future. As of June 30, 2021, we had an accumulated deficit of $ 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 June 30, 2021, we had 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 prospectus 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.

***Even if this offering is successful, 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.***

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 June 30, 2021, we had $ million in cash and cash equivalents, and an accumulated deficit of $ million. Based on our current operating plan, we currently believe that our cash and cash equivalents, anticipated revenue and available debt financing arrangements, together with the net proceeds from this offering, will be sufficient to meet our capital requirements and fund our operations through at least the next 12 months from the date of this prospectus. 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.

Even after the consummation of this offering, 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 this offering.

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.

**Risks Related to Our Business and Industry**

***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, Rapaflow 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 prostrate 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 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. 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, including in some instances 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 has negatively impacted and may continue to negatively impact 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. 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 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 financial hardship 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.

For more information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Impact of COVID-19.”

In addition, to the extent the recovery from the COVID-19 pandemic is prolonged for any reason 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. For example, as of June 30, 2021, we had approximately employees compared to employees as of June 30, 2018. 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.

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.***

One of our customers accounted for 19% of revenue during the year ended December 31, 2019. No customers accounted for more than 10% of revenue during the year ended December 31, 2020. Three of our customers accounted for 20%, 18%, and 11% of accounts receivable at December 31, 2019, respectively. Two of our customers accounted for 22% and 13% of accounts receivable at December 31, 2020, respectively. 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 tour 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 15 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, onetime 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 Aquablation probe 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 others, including, for example, AquaBeam LLC. This and other licenses 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 This Offering and 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 purchasers of our common stock in this offering, and we may not be able to meet investor or analyst expectations.***

Following this offering, 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.

***An active trading market for our common stock may never develop or be sustained, and you may not be able to resell your shares at or above the initial public offering price.***

Prior to this offering, there has been no public market for our common stock. Although we have applied to list our common stock on The Nasdaq Stock Market under the symbol "PRCT," an active trading market for our common stock may never develop or be sustained following this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us, and may vary from the market price of our common stock following this offering. This initial public offering price may not be indicative of the market price of our common stock after this offering. We cannot assure you that the market price following this offering will equal or exceed prices in privately negotiated transactions of our shares that have occurred from time to time before this offering. In the absence of an active trading market for our common stock, you may not be able to sell your shares of our common stock when desired or at or above the initial public offering price. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially and adversely affect our business.

***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 this prospectus lapse, the trading price of our common stock could decline. Based on shares outstanding as of June 30, 2021, on the completion of this offering, we will have outstanding a total of shares of common stock, including the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the completion of this offering. Of these shares, only the shares of common stock sold in this offering will be freely tradable, without restriction, in the public market immediately after the offering. 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 for a period of 180 days after the date of this prospectus 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 as of June 30, 2021 (assuming the closing of the offering) 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, shares of our common stock were issuable upon the exercise of options outstanding as of June 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 intend to file 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. That registration statement will become effective immediately on filing, and shares covered by that registration statement will be 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.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution.***

The assumed initial public offering price is substantially higher than the pro forma net tangible book value per share of our common stock of $ per share as of June 30, 2021. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering.

***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.

***We have broad discretion in how we may use the net proceeds from this offering, and we may not use them effectively.***

Our management will have broad discretion in applying the net proceeds we receive from this offering, and accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds with only limited information concerning management's specific intentions. We currently intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, to hire additional sales and marketing personnel and expand marketing programs both in the United States and in Europe, to fund product development and research and development activities and the remainder for working capital and other general corporate purposes. We may use a portion of our net proceeds to acquire and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. We may also spend or invest these proceeds in a way with which our stockholders disagree. If our management fails to use these funds effectively, our business could be seriously harmed.

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

As of June 30, 2021, our executive officers, directors and 5% stockholders beneficially owned approximately % of the outstanding shares of capital stock, and, upon the closing of this offering, that same group will hold approximately % of our outstanding shares of common stock (assuming no exercise of the underwriters' option to purchase additional shares from us). Therefore, even after this offering, 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, purchasers of our common stock in this offering 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 that will be in effect on the completion of this offering 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 that will be in effect on the completion of this offering 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 or bylaws that will be in effect on the completion of this offering 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. For information regarding these and other provisions, see section titled "Description of Capital Stock—Anti-Takeover Provisions."

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 to be in effect upon the completion of this offering will 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.

**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 will be 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.***

Upon the completion of this offering, we will become 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 will be 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 prospectus 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
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

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, presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. You can generally identify forward-looking statements by our use of forward-looking terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “seek,” “vision,” or “should,” or the negative thereof or other variations thereon or comparable terminology. Forward-looking statements include those we make regarding the following matters:

- estimates of our total addressable market,
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- competitive companies and technologies and our industry;
- our ability to hire and retain our senior management and other highly qualified personnel;
- potential future impact of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business and operations;
- commercial success and market acceptance of our products;
- our ability to accurately forecast customer demand for our products and manage our inventory;
- our ability to commercialize or obtain regulatory approvals for our AquaBeam Robotic System, or the effect of delays in commercializing or obtaining regulatory approvals;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals;
- our ability to anticipate and effectively respond to disruptions or inefficiencies in our distribution network;
- our ability to establish and maintain intellectual property protection for our intellectual property and avoid claims of infringement;
- the volatility of the trading price of our common stock;
- our expectations regarding the use of proceeds from this offering and our existing cash and cash equivalents;
- estimates of our need for additional financing and our ability to obtain additional financing in the future; and
- our expectations about market trends.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. We have based these forward-looking statements on our current expectations, assumptions, estimates and projections. While we believe these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond our control. These and other important factors, including those discussed in the sections of this prospectus titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” may cause our actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Furthermore, the potential impact of the COVID-19 pandemic on our business operations and financial results and on the world economy as a whole may heighten the risks and uncertainties that affect our forward-looking statements described above. Given these risks and uncertainties, you are cautioned not to place undue

reliance on such forward-looking statements. The forward-looking statements included elsewhere in this prospectus are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements included elsewhere in this prospectus. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate, are consistent with the forward-looking statements included elsewhere in this prospectus, they may not be predictive of results or developments in future periods.

Any forward-looking statement that we make in this prospectus speaks only as of the date of such statement. Except as required by law, we do not undertake any obligation to update or revise, or to publicly announce any update or revision to, any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares sold in this offering by us, as set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming an initial public offering price of $ per share remains the same, and after deducting underwriting discounts and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for shares of our common stock, to facilitate our future access to the public equity markets and to increase awareness of our company among potential customers. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to hire additional sales and marketing personnel;
- approximately $ million to fund product development and research and development activities; and
- the remainder, if any, for working capital and other general corporate purposes.

We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses that are complementary to our business. However, we currently have no agreements or commitments to complete any such transaction.

Based on our operating plan, we currently believe that our existing cash and cash equivalents, anticipated revenue and available debt financing arrangements, together with the net proceeds from this offering, will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the date of this prospectus.

Our management will have broad discretion over the use of the net proceeds from this offering. The expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions, which could change in the future as or plans and business conditions evolve. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments or other securities.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2021:

- on an actual basis; and
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock immediately prior to the closing of this offering and (ii) the filing of our amended and restated certificate of incorporation in connection with the closing of this offering; and
- on a pro forma as adjusted basis, to give effect to the pro forma adjustments described above as well as the sale and issuance by us of shares of our common stock in this offering at the initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, net of amounts recorded in accrued expenses and other current liabilities and other assets at June 30, 2021.

The information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at the pricing of this offering. You should read this information in conjunction with the sections titled "Use of Proceeds," "Prospectus Summary—Summary Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

| | As of June 30, 2021 | | |
|---|---|---|---|
| | Actual | Pro Forma | Pro Forma As Adjusted[1] |
| | (dollars in thousands, except per share data) (unaudited) | | |
| Cash and cash equivalents | $ | $ | $ |
| Redeemable convertible preferred stock, $0.001 par value; shares authorized, shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | | | |
| Stockholders' (deficit) equity: | | | |
| Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted | | | |
| Common stock; $0.001 par value per share; shares authorized, shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma, shares authorized, shares issued and outstanding, pro forma as adjusted | | | |
| Additional paid-in capital | | | |
| Accumulated deficit | | | |
| Total stockholders' (deficit) equity | | | |
| Total capitalization | $ | $ | $ |

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital and total stockholders' equity by approximately $ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase or decrease, as applicable, each of our cash and cash equivalents, additional paid-in capital and total stockholders' equity by approximately $ , assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of $ per share and after deducting the estimated

underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price, the number of shares we sell and other terms of this offering that will be determined at pricing.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above, is based on the shares of our common stock outstanding as of June 30, 2021 (including the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the completion of this offering), and excludes:

- shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock issuable upon the exercise of options granted after June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock that remain available for issuance under our 2008 Plan as of June 30, 2021;
- shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the 2021 Plan); and
- shares of our common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the ESPP).

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently restricted by the terms of our loan and security agreement with Oxford Finance LLC. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

## DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of our common stock in this initial public offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

As of June 30, 2021, our historical net tangible book value (deficit) was $ million, or $ per share of common stock. Our historical net tangible book value (deficit) represents our total tangible assets less total liabilities and our redeemable convertible preferred stock, which is not included within stockholders' equity.

As of June 30, 2021, our pro forma net tangible book value (deficit) was $ million, or $ per share. As adjusted net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of June 30, 2021 after giving effect to (i) the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock immediately prior to the closing of this offering and (ii) the filing of our amended and restated certificate of incorporation in connection with the closing of this offering. Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the number of shares of our common stock outstanding as of June 30, 2021, after giving effect to the pro forma adjustments described above.

After giving further effect to our sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2021 would have been approximately $ million, or $ per share. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to new investors purchasing shares of our common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

| | | |
|---|---|---|
| Assumed initial public offering price per share of common stock | | $ |
| Historical net tangible book value (deficit) per share as of June 30, 2021 | $ | |
| Increase in net tangible book value (deficit) per share attributable to the pro forma effects described above | | |
| Pro forma net tangible book value (deficit) per share as of June 30, 2021 | | |
| Increase in book value per share attributable to new investors purchasing common stock in this offering | | |
| Pro forma as adjusted net tangible book value per share | | |
| Dilution per share to new investors in this offering | | $ |

Each $1.00 increase or decrease in the assumed initial offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by $ , or $ per share, and the dilution per share of common stock to new investors in this offering by $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share by $ and decrease the dilution per share to new investors by $ , assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share by $ and increase the dilution per share to new investors by $ , assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on an as adjusted basis as of June 30, 2021, after giving effect to the pro forma as adjusted adjustments described above, the difference among existing stockholders and new investors purchasing shares of our common stock in this offering with respect to the number of shares purchased from us, the total consideration paid to us and the average price per share paid by our existing stockholders or to be paid by investors purchasing shares in this offering at the initial public offering price of $ per share, which is the midpoint of the estiamted price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

| | Shares Purchased | | Total Consideration | | Weighted-Average Price Per Share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders | | % | $ | % | $ |
| New investors | | | | | $ |
| Total | | 100.0 % | $ | 100.0 % | |

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, total consideration paid by new investors by $ million and total consideration paid by all stockholders and weighted-average price per share paid by all stockholders by $ million and $ per share, respectively, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease, as applicable, total consideration paid by new investors by $ million and total consideration paid by all stockholders and weighted-average price per share paid by all stockholders by $ million and $ per share, respectively, assuming the assumed initial public offering price of $ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above assumes the underwriters do not exercise their option to purchase additional shares in this offering. If the underwriters fully exercise their option to purchase additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value per share would be $ per share and the dilution to new investors in this offering would be $ per share. If the underwriters fully exercise their option, the number of shares held by new investors will increase to shares of our common stock, or approximately % of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations (other than historical net tangible book value calculations) are based on the shares of our common stock outstanding as of June 30, 2021 (including the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the completion of this offering), and excludes:

- shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock issuable upon the exercise of options granted after June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of our common stock that remain available for issuance under our 2008 Plan as of June 30, 2021;
- shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the 2021 Plan); and
- shares of our common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (and which excludes any potential annual evergreen increases pursuant to the terms of the ESPP).

To the extent any options or similar rights are granted and exercised in the future, there may be additional economic dilution to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

## 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 the section titled "Prospectus Summary—Summary Consolidated Financial Data," and our consolidated financial statements and related notes included elsewhere in this prospectus. 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 prospectus. Please also see the section titled "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a commercial-stage 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 to deliver effective, safe and durable outcomes 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 efficacy, safety and durability of Aquablation therapy across a broad range of prostate sizes and shapes. As of June 30, 2021, we have an installed base of more than AquaBeam Robotic Systems, and Aquablation therapy has been utilized in the treatment of more than patients whose prostates have ranged in size from less than 30 ml to over 300 ml.

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, 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 primarily sell our products through our direct sales organization in the United States. As of June 30, 2021, we employed sales professionals, which includes a Vice President of U.S. sales, a sales director, sales managers, capital sales representatives, and Aquablation sales representatives who focus on driving utilization. Our sales personnel are supported by a team of three reimbursement specialists. We also employ ten clinical specialists and professional education employees, who are responsible for training and supporting surgeons, and two field service employees, who support our customers. We intend to expand the size of our direct sales organization in the United States to support our efforts for adoption and utilization of Aquablation therapy. Outside the United States, our commercialization strategy is focused on large addressable markets through a broad range of market development activities, including increasing awareness, obtaining regulatory approvals and establishing reimbursement. We sell our products using both our direct sales organization and, in certain regions, our network of distribution partners. In EMEA, our direct sales organization is currently primarily focused on Germany, France, the United Kingdom, Switzerland and Austria. In other countries, such as Italy and Spain, we engage distribution partners to assist us with market development and sales activities. As of June 30, 2021, we employed personnel to support sales and marketing activities in EMEA. We will opportunistically choose distribution partners with clinical and marketing expertise to enter new markets. In the Asia-Pacific region, we are focused on obtaining local regulatory clearances with the assistance of our distribution partners in this region. We have regulatory approval in Hong Kong, where we are engaged with a distribution partner for market development activities.

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 $7.7 million and a net loss of $53.0 million for the year ended December 31, 2020, compared to revenue of $6.2 million and a net loss of $42.0 million for the year ended December 31, 2019. We generated revenue of $ million and a net loss of $ million for the three months ended March 31, 2021. We generated revenue of $ million and a net loss of $ million for the six months ended June 30, 2021, compared to revenue of $ million and a net loss of $ million for the six months ended June 30, 2020. As of December 31, 2020, we had cash and cash equivalents of $100.1 million and an accumulated deficit of $201.7 million.

Our primary sources of capital have been from private placements of redeemable convertible preferred securities and debt financing agreements. As of December 31, 2020, we have raised $252.4 million from private placements of redeemable convertible preferred securities from our investors, net of issuance costs. Additionally, we raised $85.0 million in proceeds from the sale of Series G redeemable convertible preferred stock in June 2021. 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, together with the net proceeds from this offering, will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the date of this prospectus. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional public or private 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 installed base of AquaBeam Robotic Systems:* As of June 30, 2021, we have an installed base of more than AquaBeam Robotic Systems. 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 installed 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. As of June 30, 2021 Aquablation therapy has been utilized in the treatment of more than patients. 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, 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 has 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. 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 restrictions associated with COVID-19 are beginning to relax, the longevity and extent of the COVID-19 pandemic remains uncertain. 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 warranty 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, including eventually to mid- and low-volume hospitals, and increased system utilization, though it may fluctuate from quarter to quarter.

Sales in the United States represented approximately 34% and 53% of our revenue in the years ended December 31, 2019 and 2020, respectively. Outside the United States, sales of our products represented approximately 66% and 47% of revenue for the years ended December 31, 2019 and 2020, respectively. We expect that both our U.S. and international revenue will increase in the near term as we continue to expand the installed base of AquaBeam Robotic Systems and increase the related patient 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, 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 notes payable.

*Interest and Other Income, Net*

Interest and other income, 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 B, 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 the completion of this offering, the redeemable convertible preferred stock warrant liability will be reclassified to additional paid-in capital in stockholders' deficit.

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 million if only the first installment has been drawn, $2 million if the first two installments have been drawn, $2.4 million if the first three installments have been drawn, or $3 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.

**Results of Operations**

***Comparison of Years Ended December 31, 2019 and 2020***

The following table shows our results of operations for the years ended December 31, 2019 and 2020:

| | Year Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2019 | 2020 | $ | % |
| | (in thousands, except percentages) | | | |
| Revenue | $ 6,169 | $ 7,717 | $ 1,548 | 25 % |
| Cost of sales | 8,054 | 8,972 | 918 | 11 |
| Gross profit | (1,885) | (1,255) | 630 | (33) |
| *Gross margin* | *-31 %* | *-16 %* | | |
| | | | | |
| Operating expenses: | | | | |
| Research and development | 13,147 | 16,275 | 3,128 | 24 |
| Selling, general and administrative | 28,518 | 30,272 | 1,754 | 6 |
| Total operating expenses | 41,665 | 46,547 | 4,882 | 12 |
| Loss from operations | (43,550) | (47,802) | (4,252) | 10 |
| Interest expense | (724) | (5,261) | (4,537) | 627 |
| Interest and other income, net | 2,299 | 44 | (2,255) | (98) |
| Net loss | $ (41,975) | $ (53,019) | (11,044) | 26 |

*Revenue*

| | Year Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2019 | 2020 | $ | % |
| | (in thousands, except percentages) | | | |
| System sales and rentals | $ 3,532 | $ 4,158 | $ 626 | 18 % |
| Hand pieces and other consumables | 2,623 | 3,421 | 798 | 30 |
| Service | 14 | 138 | 124 | 886 |
| Total revenue | $ 6,169 | $ 7,717 | 1,548 | 25 |

Revenue increased $1.5 million, or 25%, to $7.7 million during the year ended December 31, 2020, compared to $6.2 million during the year ended December 31, 2019. The growth in revenue was primarily attributable to an increase of $2.0 million in unit sales of both our AquaBeam Robotic System and our single-use disposable handpieces in the United States resulting from the expansion of our sales and marketing organizations. This increase was partially offset by a decrease of $0.5 million in sales outside of the United States, resulting primarily from a decrease in system sales.

*Cost of Sales and Gross Margin*

Cost of sales increased $0.9 million, or 11%, to $9.0 million during the year ended December 31, 2020, compared to $8.1 million during the year ended December 31, 2019. The increase in cost of sales was primarily attributable to the growth in the number of units sold.

Gross margin increased to a negative 16% during the year ended December 31, 2020, compared to a negative 31% for the year ended December 31, 2019. 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.

*Selling, General and Administrative Expenses*

SG&A expenses increased $1.8 million, or 6%, to $30.3 million during the year ended December 31, 2020, compared to $28.5 million during the year ended December 31, 2019. 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.

*Research and Development Expenses*

R&D expenses increased $3.1 million, or 24%, to $16.3 million during the year ended December 31, 2020, compared to $13.1 million during the year ended December 31, 2019. 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.

*Interest Expense*

Interest expense increased $4.5 million to $5.3 million during the year ended December 31, 2020, compared to an expense of $0.7 million during the year ended December 31, 2019. The increase was due to increased borrowings under our debt financing arrangements.

*Interest and Other Income, Net*

Interest and other income, net, decreased $2.2 million to $0.1 million during the year ended December 31, 2020, compared to $2.3 million during the year ended December 31, 2019. The decrease in other income, net was primarily attributable to a decrease in interest income of $1.0 million primarily due to lower interest rates. In addition, during the year ended December 31, 2019, the fair value of our preferred stock warrant liability decreased by $1.0 due to the shorter remaining time to expiration.

**Liquidity and Capital Resources**

***Overview***

Our primary sources of capital have been from private placements of redeemable convertible preferred securities and debt financing agreements. As of December 31, 2020, we have raised $252.4 million from private placements of redeemable convertible preferred securities from our investors, net of issuance costs. Additionally, we raised $85.0 million in proceeds from the sale of Series G redeemable convertible preferred stock in June 2021.

As of December 31, 2020, we had cash and cash equivalents of $100.1 million, an accumulated deficit of $201.7 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 together with the net proceeds from this offering, will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the date of this prospectus. 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 or private 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 though 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 December 31, 2020, 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. We pledged substantially all of our assets as collateral for the loan. Commencing with the quarter ending 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 December 31, 2020, we had $50.0 million outstanding under the loan facility.

**Cash Flows**

The following table summarizes our cash flows for the years ended December 31, 2019 and 2020:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | $ (43,818) | $ (48,343) |
| Investing activities | 43,153 | (233) |
| Financing activities | 26,527 | 106,771 |
| Net increase in cash, cash equivalents and restricted cash | $ 25,862 | $ 58,195 |

***Net Cash Used in Operating Activities***

During the year ended December 31, 2020, net cash used in operating activities was $48.3 million, consisting primarily of a net loss of $53.0 million and an increase in net operating assets of $0.5 million, partially offset by non-cash charges of $5.2 million. The cash used in operations was primarily due to the increase in net loss primarily due to the increase in operating expenses and interest expense to service the loan payable all of which support the commercialization and development. The expansion resulted in an increase in inventory, partially offset by an increase in accrued compensation and interest. Non-cash charges consisted primarily of depreciation and stock-based compensation.

During the year ended December 31, 2019, net cash used in operating activities was $43.8 million, consisting primarily of a net loss of $42.0 million and an increase in net operating assets of $3.5 million, partially offset by non-cash charges of $1.7 million. The increase in net operating assets was primarily due to an increase in inventory to support our commercial launch. Non-cash charges consisted primarily of stock-based compensation and depreciation, partially offset by a decrease in the fair value of our redeemable convertible preferred stock warrants.

***Net Cash (Used in) Provided by Investing Activities***

During the year ended December 31, 2020, net cash used in investing activities was $0.2 million consisting of purchases of property and equipment. During the year ended December 31, 2019, net cash provided by investing activities was $43.2 million, consisting primarily of sales and maturities of short-term investments of $50.8 million, partially offset by purchases of property and equipment of $7.6 million, primarily related to non-recurring leasehold improvements associated with our corporate headquarters.

***Net Cash Provided by Financing Activities***

During the year ended December 31, 2020, net cash provided by financing activities was $106.8 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. During the year ended December 31, 2019, net cash provided by financing activities was $26.5 million, consisting primarily of net proceeds from the issuance of notes payable.

**Contractual Commitments and Contingencies**

The following is a schedule summarizing our obligations to make future payments under contractual obligations as of December 31, 2020:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | 1 Year | 2 Years | 3 Years | 4 Years |
| | | | (in thousands) | | |
| Note Payable[1] | $ 50,000 | $ — | $ 6,250 | $ 25,000 | $ 18,750 |
| Interest on Note Payable[1] | 12,865 | 4,750 | 4,651 | 2,868 | 596 |
| Operating lease[2] | 6,911 | 2,374 | 2,445 | 2,092 | — |
| Total | $ 69,776 | $ 7,124 | $ 13,346 | $ 29,960 | $ 19,346 |

(1) For more information, see Note 5 to our consolidated financial statements included elsewhere in this prospectus.
(2) For more information, see Note 9 to our consolidated financial statements included elsewhere in this prospectus.

Our purchase commitments and obligations include all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services, and hence, have not been included in the table above.

**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.

**Quantitative and Qualitative Disclosures About Market Risk**

***Interest Rate Risk***

Cash and cash equivalents of $100.1 million as of December 31, 2020 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 prospectus.

***Credit Risk***

We maintain our cash and cash equivalents with two financial institutions in the United States, and our current deposits are likely 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. Two customers each accounted for 22% and 13% of accounts receivable at December 31, 2020. We believe that the 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 prospectus.

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 prospectus.

**Related Parties**

For a description of our related party transactions, see the section titled “Certain Relationships and Related Party Transactions.”

**Internal Control Over Financial Reporting**

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 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.

**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.

While our significant accounting policies are more fully described in Note 2 of our consolidated financial statements included elsewhere in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

***Revenue Recognition***

Revenue is derived primarily from the sales of the AquaBeam 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 we determine are within the scope of Accounting Standards Codification, or ASC, Topic 606, "*Revenue from Contracts with Customers*," or ASC 606, we perform 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, we satisfy the performance obligations. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess 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 a contract and a purchase order from the customer. Our 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 we separately sell the products or services. If a standalone selling price is not directly observable, then we estimate 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. We regularly review standalone selling prices and updates these estimates as necessary.

We recognize revenue as the performance obligations are satisfied by transferring control of the product or service to a customer. We generally recognize 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 we transfer control to the customer, which is generally at the time of delivery. 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. Our system arrangements generally do not provide a right of return. The systems are generally covered by a one-year warranty.

*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.

We 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.

Revenue is recognized when the item is delivered, which is when control is transferred to the customer. For systems sold following an evaluation or lease period, revenue is recognized once the sales terms are mutually agreed (as the system is already installed at the customer site). The timing of revenue recognition may differ from the timing of invoicing to customers. We record 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.

Our typical payment terms are between approximately 30 to 90 days. We expense shipping and handling costs as incurred and include them in the cost of sales. In those cases where shipping and handling costs are billed to customers, we classify the amounts billed as a component of revenue. Taxes collected from customers and remitted to governmental authorities are excluded from revenue. We expense 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.

We must make significant assumptions regarding the future collectability of amounts receivable from customers to determine whether revenue recognition criteria have been met. If collectability is not assured at the time of shipment, we defer revenue until such criteria have been met. Our standard terms and conditions of sale do not allow for product returns, and we generally do not allow product returns, except in the case of damaged goods, and we have not experienced any significant returns of our products.

***Stock-Based Compensation***

We maintain 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.

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards granted, including employee stock options. Stock-based compensation expense is recognized over the requisite service period in the statements of operations and comprehensive loss. We use the straight-line method for expense attribution. We amortize all stock-based compensation over the requisite service period of the awards, which is generally the same as the vesting period of the awards. We amortize the grant date fair value on a straight-line basis over the expected service periods. For performance-based grants, we estimate when and if they will be earned. If we consider such award to be probable, we recognize expense over the estimated service period, which would be the estimated period of performance. If we do not consider such awards probable of achievement, we recognize no amount of stock-based compensation. Additionally, we have elected to account for forfeitures as they occur.

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 option pricing model requires us to make assumptions and judgments about the variables used in the calculation, including the following:

*Fair Value of Common Stock.* As discussed in the subsection titled "—Common Stock Valuations" below, the fair value of the shares of our common stock underlying the stock options has historically been determined by our board of directors. Because there has been no public market for our common stock, our board of directors has determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors.

*Expected Term.* The expected term of stock options represents the weighted-average period that the stock options are expected to remain outstanding. We estimated the expected term based on the simplified method, which is the average of the weighted-average vesting period and contractual term of the option.

*Expected Volatility.* Since there has been no public market for our common stock and lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as industry, stage of life cycle and size.

*Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

*Expected Dividend Rate.* We assumed the expected dividend rate to be zero as we have never paid dividends and have no current plans to do so.

See Note 8 to our consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumption we used in applying the Black-Scholes option pricing model to determine the fair value of our stock options granted in the years ended December 31, 2019 and 2020. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

We recorded stock-based compensation expense of $2.0 million during the year ended December 31, 2019 and $2.2 million during the year ended December 31, 2020. As of December 31, 2020, there was $6.5 million of unrecognized stock-based compensation expense related to unvested common stock options which we expect to recognize over a weighted-average period of 2.9 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods is expected to increase.

Based upon an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of , 2021 was $ million, of which $ million related to vested options and $ million related to unvested options.

***Common Stock Valuations***

Our intent has been to grant all options with an exercise price not less than the fair value of our common stock underlying those options on the date of grant. We have determined the estimated fair value of our 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*, or the Practice Aid. Our board of directors, with the assistance of management, developed these valuations using significant judgment and taking into account numerous factors, including:

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

Our board of directors determined the fair value of our common stock by first determining the aggregate equity value of our 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 our equity securities to derive a per share value of our 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. In accordance with the Practice Aid, we considered the option pricing method, or OPM, under which shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.

For all option grants our board allocated the equity value based on the OPM, which was determined to be the most appropriate method based on our stage of development and other relevant factors. 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 around the time of an equity financing that is considered arms-length, OPM derives our equity value from the price of our securities issued in the equity financing. Following the closing of this offering, the fair value of our common stock will be determined based on the closing price of our common stock on The Nasdaq Global Market.

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

We have issued freestanding warrants to purchase shares of convertible preferred stock to investors in connection with sales of certain of our redeemable convertible preferred stock. We classify these warrants as a derivative liability because they contain liquidation features that are not solely within our control. We record the fair value of the warrant on the balance sheet at the inception of such classification and adjust 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. We 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. Our assumptions with regard to the warrant valuation are based on estimates of the valuation of the underlying preferred stock, volatility, interest rate and such estimates could vary significantly.

***Loan Facility Derivative Liability***

We have determined that our obligation to pay success fees to a lender upon a successful liquidation event or achieving a revenue target represents freestanding financial instruments. The instrument is classified as a long-term liability in the consolidated balance sheets and is subject to remeasurement at each consolidated balance sheet date. Any change in fair value is recognized through other income (expense) in the consolidated statements of operations and comprehensive loss. We adjust the carrying values of the loan facility derivative liability for changes in fair value and will continue to do so until the earlier of cash payment or expiration. The assumptions used in determining the fair value of the obligation require significant judgment.

**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**

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for additional information.

## BUSINESS

### Overview

We are a commercial-stage 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. Our proprietary AquaBeam Robotic System employs a single-use disposable handpiece to deliver our Aquablation therapy, which combines real-time, multidimensional imaging, personalized treatment planning, automated robotics and heat-free waterjet ablation for targeted and rapid removal of prostate tissue. We believe that Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing compromises associated with alternative surgical interventions to deliver effective, safe and durable outcomes 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 June 30, 2021, we have an installed base of more than AquaBeam Robotic Systems, and Aquablation therapy has been utilized in the treatment of more than patients whose prostates have ranged in size from less than 30 ml to over 300 ml.

BPH refers to the non-malignant enlargement of the prostate gland, a small gland in the male reproductive system. The main role of the prostate is to produce the fluid that protects and gives nutrients to sperm. The prostate sits underneath the bladder and surrounds the top part of the urethra, which carries urine from the bladder. As the prostate enlarges, the gland presses against the urethra, which may obstruct or restrict the flow of urine from the bladder and result in uncomfortable lower urinary tract symptoms, or LUTS, such as urgency, frequency, urinary retention, straining to urinate and a weak urinary stream. Without treatment, prolonged obstruction may eventually lead to acute urinary retention, urinary tract infections or renal insufficiency.

In the United States it is estimated that approximately 40 million men are impacted by symptoms of BPH, with aging demographics expected to drive future growth. Over the next ten years, it is expected that the number of men over 65 years old in the United States will double and include a corresponding increase in the number of men with enlarged prostates. Of these men, approximately 12 million are being managed by a physician for symptoms related to their disease. Our total addressable patient population in the United States includes approximately 8.2 million patients, comprising 6.7 million receiving drug therapy, 1.1 million who have tried but failed drug therapy and 400,000 undergoing surgical intervention each year. Based on the average selling price of our single-use handpiece, we estimate that our total addressable market opportunity is in excess of $20 billion in the United States. The global incidence of BPH among men over 50 years old is similar to that of the United States, representing a significant incremental market opportunity outside of the United States.

The main goal of BPH treatment is to alleviate the symptoms associated with the disease and improve the patient’s quality of life. While drug therapy is typically a first line treatment option, limited efficacy and negative side effects contribute to low compliance and high failure rates and drop outs. On the other hand, surgical intervention is proven to provide effective and durable symptom relief compared to drug therapy, but the use of surgery is significantly underpenetrated, largely due to the compromise patients must make between the incidence of irreversible side effects associated with alternative resective surgical interventions or the lower rates of efficacy and durability associated with non-resective surgical interventions. In addition, most alternative surgical interventions are limited by prostate size and shape, with no single procedure capable of effectively addressing the full range of prostate anatomies regardless of surgeon experience level.

We developed our proprietary AquaBeam Robotic System to address many of the shortcomings of alternative surgical interventions by delivering our Aquablation therapy, the first and only image-guided robotic therapy for the treatment of BPH. The AquaBeam Robotic System combines real-time image guidance, personalized treatment planning, automated robotic execution and heat-free waterjet ablation. We believe our Aquablation therapy

addresses the compromise between safety and efficacy of alternative surgical interventions, providing the following unique combination of benefits:

- ***Significant and durable symptom relief.*** Given obstructive prostate tissue is removed during the procedure, Aquablation therapy has demonstrated significant and long-lasting levels of symptom relief similar to those of alternative resective procedures. In our U.S. pivotal trial, Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue, or the WATER study, Aquablation therapy demonstrated superior safety and non-inferior efficacy compared to transurethral resection of the prostate, or TURP, the historical standard of care for the surgical treatment of BPH. In the WATER and WATER II studies, surgical retreatment rates at three years were only 4.3% and 3.0%, respectively. In the OPEN WATER study, there were no surgical retreatments at one year.

- ***Favorable safety profile.*** Aquablation therapy has demonstrated low rates of irreversible complications, including urinary incontinence, erectile dysfunction and ejaculatory dysfunction, compared to published rates observed for other resective surgeries. In our WATER study, patients who underwent Aquablation therapy maintained a higher level of sexual function compared to those who underwent TURP.

- ***Outcomes independent of prostate size and shape and surgeon experience.*** Aquablation therapy delivers outcomes that are effective, safe and durable across all prostate sizes and shapes. Our WATER, WATER II and OPEN WATER studies enrolled men with prostate sizes between 20 ml and 150 ml; however, in the commercial setting, we have successfully treated men with prostate sizes over 300 ml. Additionally, in the WATER and WATER II studies, 50% and 83% of men, respectively, had an obstructive median lobe, and the average prostate size in each study was 54 ml and 107 ml, respectively. Compared to other resective procedures, we believe Aquablation therapy is relatively simple to learn, enabled by the intuitive interface of the CPU and automated robotic resection, and delivers outcomes that are independent of surgeon experience.

- ***Personalized treatment planning and improved decision-making.*** Aquablation therapy combines cystoscopic visualization, ultrasound imaging and advanced planning software to provide the surgeon with a multidimensional view of the treatment area and enable personalized treatment planning for the patient's unique anatomy, improved decision-making and real-time monitoring during the procedure.

- ***Targeted and controlled resection with consistent resection times***. Aquablation therapy utilizes automated robotic resection to remove prostate tissue using a precise, heat-free waterjet. These features enable targeted and controlled tissue removal with rapid resection times that are highly consistent across prostate sizes and shapes and surgeon experience.

We have developed a significant and growing body of clinical data that demonstrate the efficacy, safety and durability of Aquablation therapy, independent of prostate size and shape and surgeon experience. Our robust body of clinical evidence includes nine clinical studies and more than 100 peer-reviewed publications. Our WATER study is the only FDA pivotal study randomized against TURP. 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 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, or AUA.

In the United States, we sell our products to 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. 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, 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. Outside of the United States, we have ongoing efforts in key markets to expand established coverage and improve payment which we will believe will expand patient access to Aquablation therapy.

We primarily sell our products through our direct sales organization in the United States, which targets urologists across the United States, who we believe represent the primary physician specialty managing the care of and receiving referrals for patients with BPH. 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. We estimate that approximately 50% of BPH patients who are on drug therapy as well as 50% who have failed drug therapy are under the care of a urologist, equating to approximately 3.9 million men. We believe we can reach these patients by continuing to educate our network of urologists of the clinical benefits of Aquablation therapy, provide comprehensive training programs and deepen our relationships with key urologists and various medical societies. As of June 30, 2021, we employed a Vice President of U.S. sales, a sales director, sales managers, sales professionals, including sales managers, robotic sales representatives, Aquablation sales representatives, who focus on driving utilization. We intend to expand the size of our direct sales organization in the United States to support our efforts for adoption and utilization of Aquablation therapy. Outside the United States, we sell our products using both our direct sales organization and, in certain regions, our network of distribution partners.

We generated revenue of $7.7 million and a net loss of $53.0 million for the year ended December 31, 2020, compared to revenue of $6.2 million and a net loss of $42.0 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $201.7 million.

**Our Success Factors**

We believe the continued growth of our company will be driven by the following success factors:

- ***First and only image-guided, heat-free robotic therapy for BPH that addresses the compromise between safety and efficacy of alternative surgical interventions.*** We have developed the AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive BPH surgery. The AquaBeam Robotic System delivers our Aquablation therapy, the first and only image-guided, heat-free robotic therapy for the treatment of BPH. Aquablation therapy combines real-time, multidimensional imaging, personalized treatment planning, automated robotics and heat-free waterjet ablation for targeted and rapid removal of prostate tissue. We believe that alternative surgical interventions for BPH have a number of shortcomings which require patients to compromise between safety and efficacy, either providing significant symptom relief but with a heightened risk of irreversible complications or a lower risk of complications but with significantly less symptom relief. Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing this compromise and delivering effective, safe and durable outcomes that are consistent across all prostate sizes and shapes and independent of surgeon experience.

- ***Large, growing and underpenetrated market opportunity.*** BPH is the number one reason men visit a urologist and we estimate that approximately 40 million men in the United States alone are impacted by symptoms of BPH, with aging demographics expected to drive future growth. Of these men, approximately 12 million are being managed by a physician for symptoms related to their disease. While drug therapy is typically a first-line treatment option, limited efficacy and negative side effects, including neurologic, ophthalmic and sexual complications, contribute to low compliance and high failure rates, often as high as 30%. On the other hand, surgical intervention is proven to provide effective and durable symptom relief compared to drug therapy, but the use of surgery is significantly underpenetrated, largely due to the compromise and limitations associated with alternative surgical interventions. Our total addressable patient population in the United States includes approximately 8.2 million patients, comprised of 6.7 million who are receiving drug therapy, 1.1 million who have tried but failed drug therapy and 400,000 who are undergoing surgical intervention each year. Based on the average selling price of our single-use handpiece, we estimate that our total U.S. addressable market opportunity is in excess of $20 billion. The global

incidence of BPH among men over 50 years old is similar to that of the United States, representing a significant incremental market opportunity outside of the United States.

- ***Significant and growing body of clinical evidence and strong support from key opinion leaders, or KOLs, resulting in the inclusion of Aquablation therapy into societal guidelines and rapid expansion of positive reimbursement coverage policies.*** We have developed a significant and growing body of clinical data that demonstrates the efficacy, safety and durability of Aquablation therapy, consistent across all prostate sizes and shapes and independent of surgeon experience. Our robust clinical evidence includes nine clinical studies and more than 100 peer-reviewed publications. Our WATER study is the only FDA pivotal study randomized against 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 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 AUA; has achieved favorable coverage determinations from MACs; and has been designated by Centers for Medicare and Medicaid Services, or CMS, as demonstrating substantial clinical improvement over alternative surgical interventions and granted transitional pass-through payment status. We believe our compelling clinical evidence, strong KOL relationships and engagement with global urological societies will continue to play an important role in growing awareness and increasing adoption of Aquablation therapy.

- ***Compelling value proposition and benefits to hospitals, surgeons and patients.*** We designed our AquaBeam Robotic System to enable consistent and reproducible BPH surgery outcomes that are independent of surgeon experience and require minimal training. In addition, we believe the differentiated features of Aquablation therapy allow for improved predictability of outcomes and, as such, increase surgeon confidence in recommending surgical intervention to their patients. Given its ability to treat prostate sizes of all shapes and sizes, Aquablation therapy enables hospitals to consolidate the surgical treatment of BPH in a single therapy. We also believe that hospital administrators will be able to leverage the differentiation of Aquablation therapy as a marketing tool to attract skilled surgeons and patients to their hospital system. Furthermore, the AquaBeam Robotic System is highly mobile and compact, requiring no retrofitting of the operating room, and we believe is competitively priced compared to other robotic systems and capital equipment devices, both factors which we believe remove adoption hurdles for hospital customers and allow for a more streamlined hospital sales cycle. For patients, Aquablation therapy offers significant and durable symptom relief with an attractive safety profile. We believe these benefits will continue to support the adoption of Aquablation therapy by hospitals and surgeons.

- ***Recurring revenue model.*** We generate revenue primarily from hospitals making capital purchases of our AquaBeam Robotic System and purchasing our single-use handpieces for individual patient use. We also generate revenue by providing post-warranty service for the AquaBeam Robotic System. We believe our business model of selling capital equipment that generates corresponding disposables utilization and post-warranty service contracts provides a path to predictable, recurring revenue.

- ***Broad research and development capabilities and a robust intellectual property portfolio.*** We have invested in establishing strong research and development capabilities for over a decade, including in surgical robotics and imaging-enabled surgery as well as integrating hardware and software to create an exceptional user and patient experience. We believe our focus on this experience will allow us to continue to bring new upgrades, capabilities and products to market, allowing us to innovate and maintain our competitive positioning. We have a broad patent portfolio, including issued patents and pending patent applications as of June 30, 2021. We believe our intellectual property and know-how present a significant barrier to entry for our competitors.

- ***Proven leadership team and board members with deep industry experience.*** We are led by a highly experienced management team and board with a successful track record of building businesses by

identifying and providing solutions for underserved markets in the medical device industry. Our team has successfully led and managed dynamic growth phases in organizations and commercialized products in markets with established incumbents by addressing the unmet needs of the physicians and patients they serve. Our senior management team has an average of over 18 years of experience in the medical device industry across both public and private companies.

**Our Growth Strategies**

Our mission is to establish Aquablation therapy as the surgical standard of care for BPH. The key elements of our growth strategy are:

- ***Grow our installed base of AquaBeam Robotic Systems by driving adoption of Aquablation therapy among urologists.*** In the United States, we are initially focused on driving adoption of Aquablation therapy among urologists that perform hospital-based resective BPH surgery. We estimate that approximately 290,000 of the 400,000 annual BPH surgeries are resective procedures performed across approximately 2,700 hospitals. 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. We also intend to increase awareness of Aquablation therapy by continuing to publish clinical data in various industry and scientific journals, present our clinical data at various industry conferences and sponsor peer-to-peer education programs and proctorships. Over time, we will gradually expand our focus to also include mid- and low-volume hospitals.

- ***Increase system utilization by establishing Aquablation therapy as the surgical treatment of choice for BPH.*** 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. Over time, we intend to leverage our relationships with urologists to drive utilization of Aquablation therapy beyond the current surgical market. We estimate that approximately 50% of BPH patients who are on drug therapy as well as 50% who have failed drug therapy are under the care of a urologist, equating to approximately 3.9 million men. We believe we can reach these patients by continuing to educate our network of urologists of the clinical benefits of Aquablation therapy, provide comprehensive training programs and deepen our relationships with key urologists and various medical societies. Furthermore, we believe that additional coverage by private payors will continue to drive increased utilization.

- ***Continue to broaden private payor coverage.*** Since the addition of Aquablation therapy to AUA clinical guidelines in May 2019, we have significantly grown coverage for Aquablation therapy in the United States. Effective in 2021, all local 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 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 private payors, including Anthem, BlueCross – Massachusetts, Emblem Health, Health Care Service Corp, and Humana. We plan to leverage these recent successes in our active discussions with private payors to establish additional positive national and regional coverage policies. We believe that additional private 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.

- ***Build upon our strong base of clinical evidence.*** We are committed to continuing to build upon our foundation of clinical evidence, which we believe will help drive increased awareness and adoption of our products. For example, we are continuing to follow patients in our WATER and WATER II studies to collect five-year clinical outcomes as well as conducting sub-group analyses across our base of clinical data that we believe will further define the role of Aquablation therapy across patient populations. We also plan to further build our base of clinical evidence by supporting new clinical studies intended to support commercial, regulatory and reimbursement efforts. For example, we are supporting an investigator-initiated clinical study, called WATER III, which will be a randomized controlled trial evaluating Aquablation therapy against laser enucleation in treating BPH patients with large prostate sizes.

- ***Invest 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. In the future, we may evaluate the application of the AquaBeam Robotic System in new urologic conditions beyond BPH.

- ***Drive increased awareness of Aquablation therapy beyond the urology community.*** As we expand our network of urologists and grow our installed base, we intend to increase awareness and brand recognition of Aquablation therapy beyond urologists, primarily among primary care physicians who manage BPH patients. We estimate that approximately 3.9 million men, including approximately 3.3 million patients who are on drug therapy and 600,000 who have failed drug therapy, are under the care of a primary care physician. To achieve this objective, we will invest in marketing initiatives direct at primary care physicians in order to optimize referral pathways and expand networks for BPH patients to visit a urologist. Once we have established a broader installed base of systems, we may seek to further increase patient awareness through various direct-to-patient marketing initiatives.

- ***Further penetrate and expand into existing and new international markets.*** We plan to establish and strengthen our presence internationally. While the United States remains our primary focus in the near-term, we are growing our existing presence in the large European markets, including Germany, France, Italy, Spain and the United Kingdom, by continuing to promote the clinical benefits of Aquablation therapy, supporting investments in clinical studies to improve coverage and reimbursement and fostering relationships with KOLs. In addition, we intend to expand our reach to selected new markets in the Asia-Pacific region over time. We plan to strategically invest in new markets based on our assessment of market size and opportunity and prospects for compelling reimbursement.

**Market Overview**

***Our Addressable Market Opportunity in BPH***

In the United States, BPH is the number one reason men visit a urologist. BPH is estimated to occur in more than 50% of men in their 50s, growing to 70% of men in their 60s, and is the fourth most common diagnosed disease in men above 50 years old, ranking behind coronary artery disease, hypertension and type 2 diabetes. BPH often results in uncomfortable LUTS, which can have a significant impact on quality of life. If left untreated, BPH may eventually lead to more serious complications.

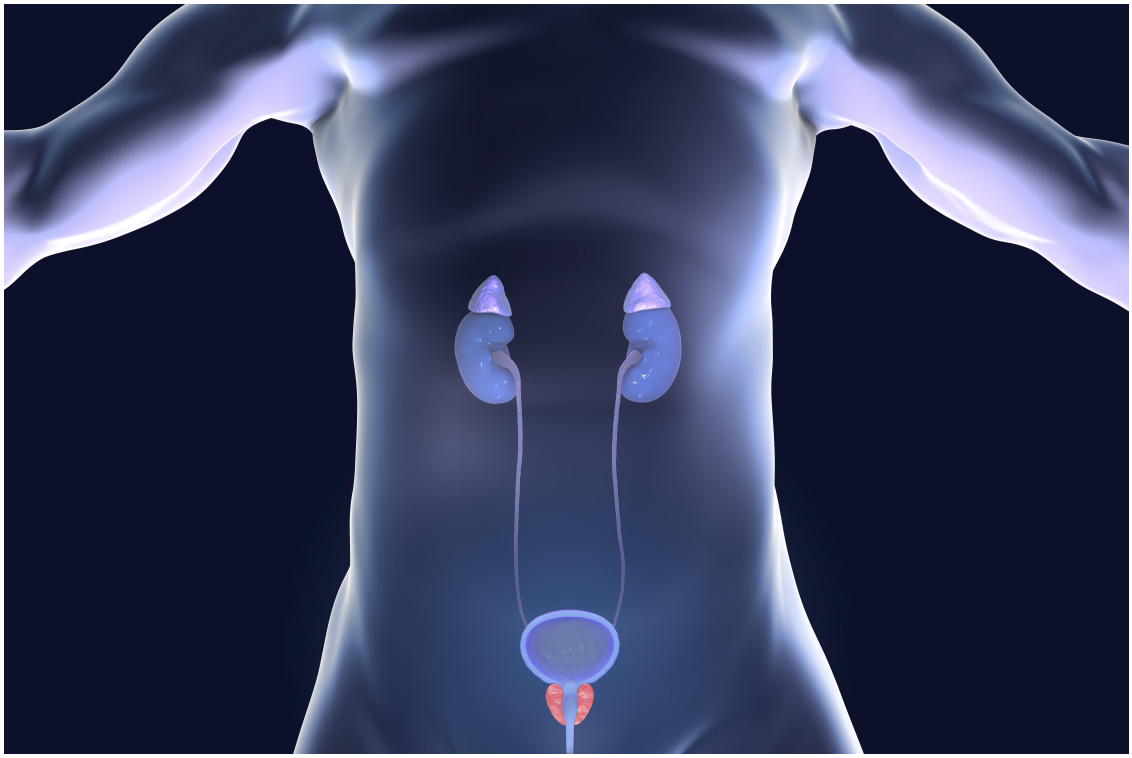
In the United States, we estimate that approximately 40 million men are impacted by symptoms of BPH, with aging demographics expected to drive future growth. Over the next ten years, we expect that the number of men over 65 years old in the United States will double and include a corresponding increase in the number of men with enlarged prostates. Of these men, approximately 12 million are being managed by a physician for symptoms related to their disease. While drug therapy is typically a first line treatment option, limited efficacy and negative side effects contribute to low patient compliance, high failure rates and drop outs. On the other hand, surgical intervention is proven to provide effective and durable symptom relief compared to drug therapy, but the use of surgery is significantly underpenetrated, largely due to the compromise patients must make between (1) the

incidence of irreversible side effects associated with current resective surgical interventions, or (2) the lower rates of efficacy and durability associated with non-resective surgical interventions. Our total addressable patient population in the United States includes approximately 8.2 million patients, comprised of 6.7 million receiving drug therapy, 1.1 million who have tried but failed drug therapy and 400,000 undergoing surgical intervention each year. Based on the average selling price of our single-use handpiece, we estimate that our total addressable market opportunity is in excess of $20 billion in the United States. The global incidence of BPH among men over 50 years old is similar to that of the United States, representing a significant incremental market opportunity outside of the United States.

***Overview of the Prostate***

The prostate is a small gland in the male reproductive system. The main role of the prostate is to produce the fluid that protects and gives nutrients to sperm. The prostate sits underneath the bladder and surrounds the top part of the urethra, which carries urine from the bladder.

***Overview of the Prostate and Surrounding Structures***



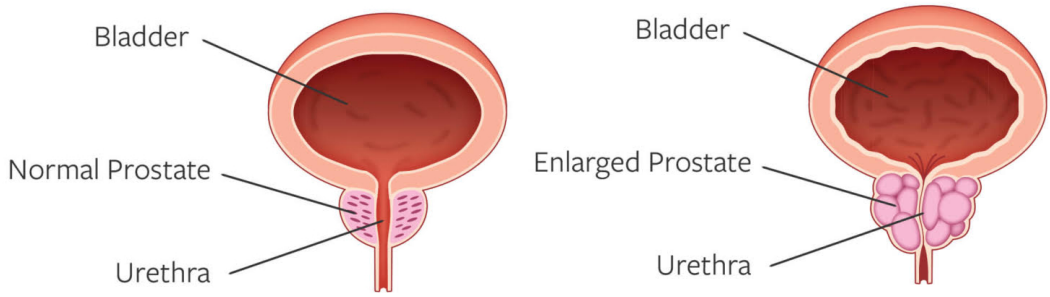
The prostate is approximately the size of a walnut in men younger than 30 years old; as men age, the prostate grows larger. At puberty, testosterone levels in boys start to increase and the prostate grows to about eight times its size. The prostate continues to grow, doubling in size between the ages of 21 and 50 years, and almost doubles again in size between the ages of 50 and 80 years. Prostate size is generally measured in volume using milliliters, or ml.

***BPH Disease Overview and Diagnosis***

BPH refers to the non-malignant enlargement of the prostate gland. As the prostate enlarges, the gland presses against the urethra, which may obstruct or restrict the flow of urine from the bladder and result in uncomfortable LUTS, such as urgency, frequency, urinary retention, straining to urinate and a weak urinary stream. Without treatment, prolonged obstruction may eventually lead to acute urinary retention, urinary tract infections or renal insufficiency. An enlarged prostate can range between roughly 30 ml to above 300 ml. As prostates increase in size

so does the complexity of shape where the obstructive tissue will grow back into the bladder (called an intravesical component).

*Normal Prostate versus Enlarged Prostate*




While some BPH patients are asymptomatic, most will experience symptoms, which generally become more bothersome with age. According to the AUA guidelines, it is estimated that 90% of men between the ages of 45 and 80 will experience LUTS, and 50% of them will experience moderate-to-severe symptoms by the time they are 85 years old, which we believe are predominantly caused by BPH. Furthermore, 50% of men between the ages of 51-60 have pathological BPH. Symptoms associated with BPH can have a significant impact on a patient's quality of life, including inability to sleep through the night, limiting activities due to proximity to the bathroom, impact on relationships, professional life and social activities, ongoing embarrassment and frustration and impact on sexual function. According to our internal marketing survey, 99% of men diagnosed with BPH say symptoms impact their quality of life.

Clinical diagnosis of BPH typically involves a number of tests that are used to assess the degree of LUTS and determine whether the symptoms are caused by BPH or another condition. A symptom score index utilizes standardized questionnaires to quantify a patient's degree of LUTS. One of the most common scoring systems is the International Prostate Symptom Score, or IPSS. Using this scoring system, LUTS are classified as either mild, moderate or severe. The IPSS questionnaire is a key tool used to evaluate treatment options and assess treatment success. Other commonly used tests include a digital rectal exam, urine sample tests, imaging scans, blood tests and uroflowmetry tests, which measure the strength and amount of urine flow during urination. Patients suffering from symptoms of BPH are typically first seen by a primary care physician, who may diagnose and manage the patient, or refer the patient to a urologist. A urologist is a physician who specializes in diseases of the urinary tract in both males and females as well as the male reproductive system. Urologists are trained to perform surgery for various types of urologic conditions, including BPH.

***BPH Treatment Options***

The main goal of BPH treatment is to alleviate the symptoms associated with the disease and improve the patient's quality of life. As such, a patient's recommended course of treatment is largely based on the patient's degree of symptoms, typically measured using validated scoring systems such as IPSS. Patients with mild symptoms who have not developed other complications of BPH may choose watchful waiting, meaning that before proceeding with active treatment, the physician and patient wait to see if symptoms get worse or if new symptoms develop. Patients who choose this approach are generally advised to implement lifestyle changes and return for yearly visits with their physician to determine if symptoms are changing. For most men, the prostate will continue to grow and symptoms will worsen. As symptoms become more bothersome, active treatment may be recommended. The two primary categories of active treatment for BPH are drug therapy and surgical intervention.

*Drug Therapy*

Drug therapy is often the first step in actively treating mild-to-moderate symptoms of BPH. While there is no pharmacological cure for BPH, drugs may be used to manage symptoms. Available drugs address symptoms by either shrinking (5-alpha reductase inhibitors) the prostate or relaxing (alpha blockers) muscles surrounding the

prostate. In some instances, patients may be prescribed a combination of both medications. Most men with BPH who start drug therapy will need to continue it indefinitely in order to relieve symptoms, unless they choose to undergo surgical intervention. While drug therapy can provide relief for some men, two out of three patients are not satisfied with the effectiveness of their medication. In general, drug therapy provides IPSS reduction of approximately five points. Drug therapy is also often associated with negative side effects, including headaches, dizziness, nausea, erectile dysfunction, ejaculatory dysfunction, cardiac failure and dementia. These side effects often contribute to poor treatment compliance, with drug therapy failing in up to 30% of men. Furthermore, drug therapy may be costly, particularly in light of limited symptom relief. For example, a recent study has shown that payor costs for branded combination drug therapy over a two-year period was the least cost-effective of all treatment options included in the study, as drug therapy requires extended use and yields the least symptom relief.

*Surgical Intervention*

Surgical intervention is recommended for patients who have failed or are unwilling to consider drug therapy, or are suffering from complications due to their BPH. Although more invasive than drug therapy, surgical intervention generally provides more significant, longer-lasting symptom relief. We estimate that approximately 400,000 BPH surgeries were performed in the United States in 2019, growing at a compounded annual growth rate, or CAGR, of 11% since 2016. We believe that growth in the use of surgical intervention over the past several years is due to the introduction of new technologies that better balance the compromise between efficacy and safety as well as growing awareness of surgical intervention an effective way to manage BPH symptoms compared to drug therapy.

There are two categories of surgical intervention, resective and non-resective.

***Resective Procedures.*** In resective surgery, prostate tissue is removed during the procedure. Resective procedures generally provide more significant and longer-lasting symptom relief than non-resective procedures, but may result in a higher incidence of irreversible complications, including urinary incontinence, erectile dysfunction and ejaculatory dysfunction. Resective procedures generally provide IPSS reduction of approximately 15 points. These procedures are typically performed in the hospital or outpatient surgery center under general or spinal anesthesia. In 2019, approximately 290,000 resective surgeries were performed in the United States, accounting for over 70% of all BPH surgeries.

Resective surgeries may be performed endoscopically or via an open or a laparoscopic procedure, called a simple prostatectomy.

Endoscopic procedures access the prostate through the urethra, so no incisions are made in the patient’s abdomen. These procedures typically use heat-based technologies to resect prostate tissue, utilizing a single camera called a cystoscope that provides limited visualization of the anatomy during the procedure. Common alternative endoscopic resective procedures include:

- *Transurethral Resection of the Prostate.* TURP is a resective procedure which uses electrocautery to cut and remove prostate tissue. Despite being used for over a century, this procedure is still the most frequently performed resective surgery and is considered the historical standard of care for the surgical treatment of BPH for prostates less than 80 ml. In 2019, approximately 135,000 TURP procedures were performed in the United States.

- *Photoselective Vaporization of the Prostate, or PVP.* PVP is a transurethral form of treatment that utilizes a laser fiber to vaporize prostate tissue sequentially outwards until the surgeon creates a sufficient cavity through which the patient may now void. PVP is generally used in patients with small- to average-sized prostates and can be used in patients who are at high risk of bleeding complications. In 2019, approximately 80,000 PVP procedures were performed in the United States.

- *Laser Enucleation of the Prostate.* Laser enucleation utilizes a surgical laser to manually resect prostate tissue through the urethra. This procedure allows the surgeon to follow anatomic planes to separate entire lobes of the prostate. In general, separated prostate lobes are then pushed into the bladder and suctioned out via a special tool. Laser enucleation is prostate size-independent; however, this procedure is more commonly used in larger prostates, and adoption has been limited due to the high degree of skill and

experience required. In 2019, approximately 30,000 enucleation procedures were performed in the United States.

A simple prostatectomy is an invasive, open procedure that requires one or more incisions to be made in the patient's abdomen to access and remove part or all of the prostate. This procedure is typically a last resort treatment for BPH in patients with very large prostates or those patients with severe complications due to BPH. This surgery may be done manually, or with the assistance of a robot, but in either case is a procedure that requires a high degree of surgeon skill. In 2019, approximately 25,000 prostatectomies procedures were performed in the United States.

***Non-Resective Procedures***. In non-resective procedures, prostate tissue is not removed at the time of surgery. By not removing tissue, symptom relief is generally less significant and durable compared to resective procedures. Non-resective procedures generally provide IPSS reduction of approximately ten points. The two most common commercially available non-resective procedures are prostatic urethral lift, or PUL, and water vapor therapy. PUL uses permanent implants of nitinol and stainless steel placed transurethrally to pin back and compress obstructing prostate tissue, thus creating a channel for improved urinary flow. Water vapor therapy utilizes principles of convection by transurethrally delivering water vapor into obstructing prostate tissue, which results in cell death and reduction of prostate volume over a period of three to six months. Non-resective procedures are generally approved for small- to average-sized prostates. In 2019, approximately 105,000 non-resective surgeries were performed in the United States.

***Limitations of Alternative Surgical Interventions***

Two factors that surgeons and patients commonly consider when evaluating surgical intervention are efficacy and safety. Efficacy is generally measured by symptom relief as well as durability of relief, and safety by the occurrence of irreversible complications such as urinary incontinence, erectile dysfunction and ejaculatory dysfunction. We believe that alternative surgical interventions for BPH require patients to compromise between efficacy and safety. Alternative interventions either provide significant symptom relief with a heightened risk of irreversible complications or a lower risk of complications with significantly less symptom relief. In addition, most alternative surgical interventions are limited by prostate size and shape, with no single procedure capable of effectively addressing the full range of prostate anatomies regardless of surgeon experience level. We believe that the compromise and limitations associated with alternative surgical interventions have contributed to the relatively low penetration rate of surgical intervention.

***Limitations of Endoscopic Resective Procedures.*** While endoscopic resective surgeries such as TURP and laser-based procedures may provide BPH patients with durable symptom relief, these procedures have a number of limitations, including:

- *High rates of irreversible complications.* Irreversible complications, are a common side effect of endoscopic resective procedures. Published studies have shown rates of erectile dysfunction as high as 14%, 20% and 8% and ejaculatory dysfunction as high as 89%, 50% and 77% for TURP, PVP and laser enucleation, respectively. We believe the high rates of irreversible complications are in large part due to these technologies utilizing heat to remove prostate tissue, which may lead to unintended thermal damage to critical parts of the anatomy. Furthermore, minimal intraoperative visualization, which is generally limited to a cystoscope, provides limited visibility of the prostate and makes it difficult for the surgeon to see and preserve critical parts of the prostate during tissue resection.

- *Prostate size limitations.* While TURP is considered the standard of care for surgical treatment of BPH, it is generally reserved for small- to average-sized prostates below 80 ml given the length and manual nature of the procedure. For laser-based therapies, PVP is also most commonly used for small- to average-sized prostates, while laser enucleation is generally reserved for treating patients with larger prostates.

- *Experience dependent outcomes and long learning curves.* Endoscopic resective procedures rely on manual resection of the prostate, with clinical outcomes often highly dependent on the surgeon's experience level. For example, a study of a large number of patients undergoing TURP found that the rate of reoperation was 1.2-fold higher in men treated by surgeons who had performed 172 or fewer TURP procedures versus surgeons that had performed more than 402 TURP procedures. In addition, a study of 200 procedures by a

surgeon performing PVP showed that the surgeon required at least 120 procedures to achieve optimal clinical outcomes. Furthermore, a study of surgeons learning to perform laser enucleation demonstrated that one-third of the surgeons failed to complete the training program.

- *Inconsistent and lengthy resection times.* Endoscopic resective procedures require manual resection of prostate tissue performed under limited visualization. This manual process contributes to highly inconsistent and lengthy resection times that are strongly correlated with prostate size.

***Limitations of a Simple Prostatectomy.*** While a simple prostatectomy typically provides maximum symptom relief by removing part or all of the prostate gland, this procedure is generally considered a treatment of last resort reserved for patients with large prostates. Limitations of a simple prostatectomy include:

- *Surgical safety concerns.* Even when performed robotically, a simple prostatectomy still requires incisions to be made in the patient's abdomen in order to access the prostate gland. Bleeding events are a key risk in these types of procedures, with transfusion rates as high as 25%.

- *High rates of irreversible complications.* Similar to endoscopic respective procedures, open procedures commonly result in high rates of irreversible complications, with studies showing erectile and ejaculatory dysfunction rates as high as 2-3% and 90%, respectively.

- *Long hospital stay and recovery time.* Given the invasiveness of open procedures, long hospital stays and post-procedure recovery are common. In addition, patients typically stay in the hospital for an average of five days after surgery and have long recovery times.

***Limitations of Non-Resective Procedures.*** While non-resective procedures are associated with favorable safety profiles and limited impact on sexual function, these procedures generally deliver lower and less durable symptom relief than respective procedures. Limitations of non-resective procedures include:

- *Limited symptom relief and durability.* By not removing obstructive prostate tissue, non-resective procedures generally results in less significant and durable symptom relief compared to resective procedures. In addition, since prostate tissue continues to grow over time, durability of symptom relief is typically less favorable in non-resective procedures, with higher rates of patients needing to undergo surgical retreatment or go back on drugs. For example, five-year surgical retreatment rates for PUL and water vapor therapy were 13.6% and 4.4%, respectively. In addition, the rates of PUL and water vapor therapy patients back on drug therapy at five years were 10.7% and 11.1%, respectively. Furthermore, since PUL requires the use of a permanent implant, there is risk of post-operative complications due to the implant which may require implant removal, with a published five-year rate of implant removal of 9.3%.

- *Limited intraoperative visualization.* Similar to endoscopic resective procedures, the surgeon's view of the prostate in endoscopic non-resective procedures is limited to a cystoscope that provides minimal visibility of the prostate.

- *Prostate size and shape limitations.* Both PUL and water vapor therapy are generally used for small- to average-sized prostates. Unlike any of the resective procedures, both of these procedures are specifically limited by the FDA for use in certain prostate sizes. The mean prostate volumes for PUL and water vapor therapy were 45 ml and 46 ml, respectively, in their respective U.S. pivotal, prospective, randomized clinical trials. In addition, the use of these procedures may be limited for certain complex prostate shapes.

**Our Solution**

We have developed the AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive urologic surgery. Our proprietary AquaBeam Robotic System delivers our Aquablation therapy, the first and only image-guided robotic therapy for the treatment of BPH. We market the AquaBeam Robotic System in the United States pursuant to FDA 510(k) clearance.

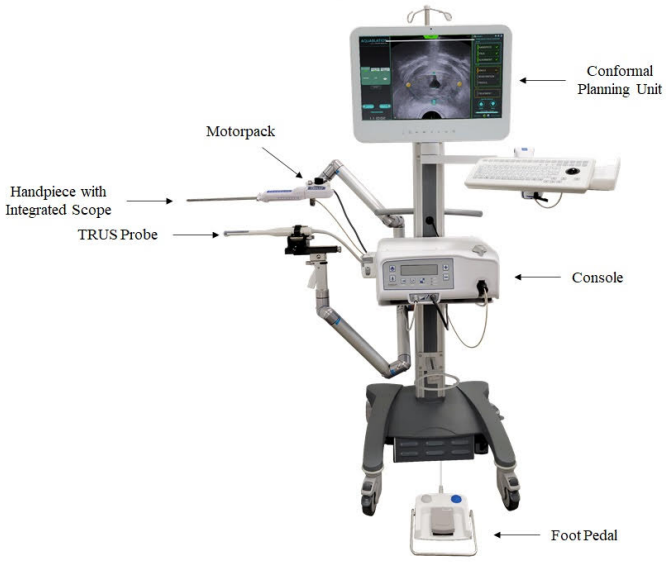
The AquaBeam Robotic System combines the following highly differentiated features that enable Aquablation therapy to deliver effective, safe and durable outcomes that are consistent across all prostate sizes and shapes and independent of surgeon experience:

- ***Real-time image guidance.*** Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area, enabling improved decision-making and real-time treatment monitoring.
- ***Personalized treatment planning.*** Using ultrasound imaging integrated with advanced planning software, the surgeon is able to map the treatment contour that precisely targets the resection area, personalizing the optimal tissue removal plan based on each patient's unique anatomy.
- ***Automated robotic execution.*** Once the treatment plan is finalized, the robot automatically executes the plan, guiding the precisely calibrated waterjet with speed and accuracy while the surgeon monitors.
- ***Heat-free waterjet resection.*** Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet, minimizing the risk of complications arising from prolonged thermal injury.

***Components of the AquaBeam Robotic System***

The AquaBeam Robotic System is highly mobile and compact, requiring no retrofitting of the operating room. The main components of the AquaBeam Robotic System are the conformal planning unit, or CPU, console, motorpack and handpiece with integrated scope.

*AquaBeam Robotic System*




The CPU serves as the primary user interface of the AquaBeam Robotic System, displaying live transrectal ultrasound, or TRUS, video which allows the surgeon to visualize the prostate and surrounding structures, identify key anatomical markers and personalize the resection based on the patient's unique anatomy. Through an intuitive user interface, the CPU allows the surgeon to map the contour of the prostate and plan the resection pathway by selecting the resection angles, length and depth. The planned parameters of the resection are transferred to the console to initiate Aquablation therapy. During the procedure, the surgeon utilizes the CPU to observe the progress of the resection in real time and has the option to make adjustments to the treatment area as needed. The CPU is

equipped with a variety of integrated safety mechanisms that provide the surgeon with advisory notifications during treatment.

The console contains a high-pressure pumping system that is responsible for generating the high-velocity waterjet used in Aquablation therapy. The high-pressure pumping system consists of a control unit and powerboards that drive the positioning and flow rates of the waterjet. In addition, the console utilizes a peristaltic pump that assists in active evacuation of saline and tissue from the bladder and prostatic urethra during the Aquablation therapy to manage fluid levels. The console interfaces with both the CPU and motorpack and handpiece assembly, generating the water flow rates based on instructions received from the CPU. The console is activated by a foot pedal and has a small screen that displays the pump level and procedure mode.

The motorpack is connected to the console with a flexible cable that provides power and control instructions to the motorpack. The motorpack consists of a motor control system that drives the movement and position of the waterjet nozzle in the handpiece and is designed to mechanically dock with the handpiece, completing the waterjet drive mechanism as well as establishing a secure electrical connection. The motorpack has buttons that allow a surgeon to manually increase or decrease the pump power level during resection, if needed.

The handpiece is the sterile, single-use component of the AquaBeam Robotic System that delivers the high-velocity waterjet. The tip of the handpiece is inserted transurethrally into the patient, advanced through the prostatic urethra into the bladder and positioned using both TRUS imaging and cystoscopic guidance from the integrated, reusable scope. The motorpack and handpiece assembly is secured to an articulating arm. The start treatment location, end treatment location, depth and angle of resection are based on the transferred planned contour and profile from the CPU to the console and motorpack.

The AquaBeam Robotic System also includes a customized ultrasound set through which ultrasound images are integrated with our system.

***Treatment with Aquablation Therapy***

Aquablation therapy is currently performed in the hospital setting in a procedure that typically takes less than one hour. On the day of surgery, the patient is given either general or spinal anesthesia and then prepped and positioned on their back with their knees bent above the hips and legs spread apart using stirrups, similar to other BPH surgical procedures. The procedure begins with the insertion of the TRUS probe, followed by the insertion of the handpiece into the patient's bladder through the urethra under visual guidance from the integrated scope. The surgeon confirms successful positioning of the TRUS probe and handpiece with visual markers on the CPU screen with adjustments made by advancing, retracting and rotating the TRUS probe. Once positioning is confirmed, the TRUS probe and motorpack and handpiece assembly are secured to articulating arms that are mounted to the bed rails to prevent movement during planning and the procedure.

The surgeon begins the planning process via the user interface of the CPU. Using real-time TRUS imaging displayed on the CPU to visualize the anatomy of the prostate, the surgeon plans the treatment area. The surgeon defines the treatment area by adjusting the boundaries of treatment along the length, width and height of the prostate. The boundaries serve as a tissue depth guide to help maintain the resection within the treatment area. If a median lobe is present, the surgeon can visualize and separately plan the resection of the median lobe. Once planning and mapping are complete, the surgeon then begins resection by depressing the foot pedal to initiate the high-velocity waterjet, with the resection automatically executed based on the defined treatment plan. As the waterjet removes prostate tissue along the planned treatment contour, excess water and ablated tissue are actively suctioned out of the patient. The surgeon monitors the progress of the resection on the CPU and, at any point during the procedure, the surgeon can pause the treatment by releasing the foot pedal. Using buttons on the motorpack, the surgeon can manually decrease the resection depths in real time as the procedure is monitored on both live ultrasound and cystoscopy. Aquablation therapy treatment stops upon reaching the planned treatment endpoint. The surgeon may decide to plan additional resection passes depending on the length or depth of the prostate.

When the procedure is complete, the motorpack and handpiece assembly is undocked from the articulating arm. The surgeon can manually scan the treatment area endoscopically by using the integrated scope of the handpiece. After post-procedural cystoscopy is complete, the handpiece is removed from the urethra. The surgeon may then use a resectoscope to remove ablated tissue to improve visualization and then perform focal, targeted and methodical bladder neck cautery to achieve post-operative hemostasis. Following the procedure, the patients are typically monitored in the Post-Anesthesia Care Unit, or PACU, with the majority of patients discharged after one overnight stay, without needing to leave with a catheter.

***Key Benefits of Aquablation Therapy***

We believe our Aquablation therapy addresses the compromise between safety and efficacy of alternative surgical interventions, providing the following unique benefits:

- ***Significant and durable symptom relief.*** Given obstructive prostate tissue is removed during the procedure, Aquablation therapy has demonstrated significant and long-lasting levels of symptom relief similar to those of alternative resective procedures. The efficacy of Aquablation therapy has been shown in nine clinical studies and over 100 peer reviewed publications. Significant symptom reduction, quality of life and uroflowmetry improvements were observed across the WATER, WATER II and OPEN WATER studies. In the WATER study, Aquablation therapy demonstrated superior safety and non-inferior efficacy compared to TURP, the historical standard of care for the surgical treatment of BPH. Our studies have also demonstrated durable outcomes with low rates of surgical retreatment and few men having to go back on drugs following surgery. In the WATER and WATER II studies, surgical retreatment rates at three years were only 4.3% and 3.0%, respectively. In the OPEN WATER study, there were no surgical retreatments at one year.

- ***Uncompromised safety profile.*** Aquablation therapy has demonstrated low rates of irreversible complications, including urinary incontinence, erectile dysfunction and ejaculatory dysfunction, compared to published rates observed for other resective surgeries. In our WATER study, patients who underwent Aquablation therapy maintained a higher level of sexual function compared to those who underwent TURP.

We believe the strong safety profile of Aquablation therapy is a result of the therapy's ability to preserve key anatomical structures and limit prolonged and unintended thermal injury. In addition, no implant remains in the body with Aquablation therapy, minimizing the risk of mid-to-long term post-operative complications resulting from the implant.

- ***Outcomes consistent across all prostate sizes and shapes and independent of surgeon experience.*** Aquablation therapy delivers outcomes that are effective, safe and durable across all prostate sizes and shapes. Our WATER, WATER II and OPEN WATER studies enrolled men with prostate sizes between 20 ml and 150 ml; however, in the commercial setting, we have successfully treated men with prostate sizes over 300 ml. Additionally, in the WATER and WATER II studies, 50% and 83% of men, respectively, had an obstructive median lobe, and the average prostate size in each study was 54 ml and 107 ml, respectively. Compared to other resective procedures, we believe Aquablation therapy is relatively simple to learn, enabled by the intuitive interface of the CPU and automated robotic resection, and delivers outcomes that are independent of surgeon experience. In the WATER study, 14 of the 17 participating surgeons had no previous experience with Aquablation therapy, and in the WATER II study surgeons had a median previous experience of only 0.5 procedures.

- ***Personalized treatment planning and improved decision-making.*** Aquablation therapy combines cystoscopic visualization, ultrasound imaging and advanced planning software. Together, these technologies provide the surgeon with a multidimensional view of the treatment area and enable personalized treatment planning for the patient's unique anatomy, improved decision-making and real-time monitoring during the procedure.

- ***Targeted and controlled resection with consistent resection times.*** Aquablation therapy utilizes automated robotic resection to remove prostate tissue using a precise, heat-free waterjet. These features enable targeted and controlled tissue removal with rapid resection times that are highly consistent across prostate sizes and shapes and surgeon experience.

**Our Clinical Results and Studies**

A significant body of clinical evidence supports the efficacy, safety and durability of Aquablation therapy across prostate sizes and shapes as well as surgeon experience. This robust body of evidence includes more than 100 peer-reviewed publications in premier journals, such as the Journal of Urology, European Urology and BJU International, as well as nine clinical studies, including our three core studies: WATER, WATER II and OPEN WATER.

- ***WATER.*** The WATER study was double-blind, randomized, controlled study of Aquablation therapy against TURP in men with prostate sizes between 30 ml and 80 ml. This study is the only FDA pivotal trial for BPH randomized against TURP. The results of our WATER study served as the basis for FDA grant of our De Novo application and were first published in the Journal of Urology in 2018.

- ***WATER II.*** The WATER II study was a prospective, multicenter study of Aquablation therapy in patients with prostate sizes between 80 ml and 150 ml. The results of the WATER II study served as the basis for increased reimbursement and coverage and were first published in BJU International in 2019.

- ***OPEN WATER.*** The OPEN WATER study was a prospective, multicenter, all-comer study conducted in a commercial setting spanning patients with prostate sizes between 20 ml and 150 ml. The results of the OPEN WATER study were first published in Journal of Clinical Medicine in 2020.

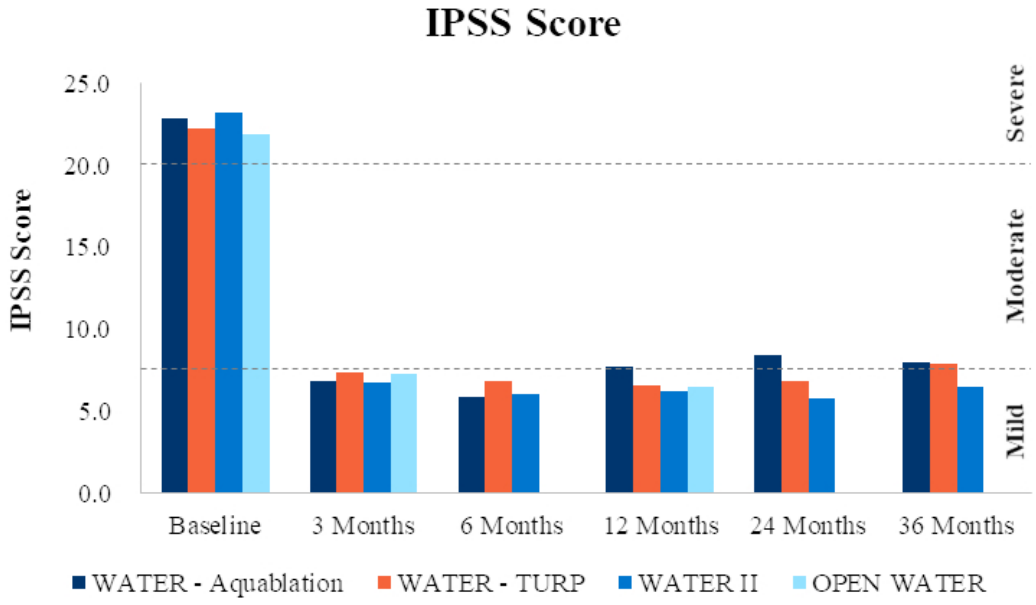
The following table highlights key findings from our three core studies.

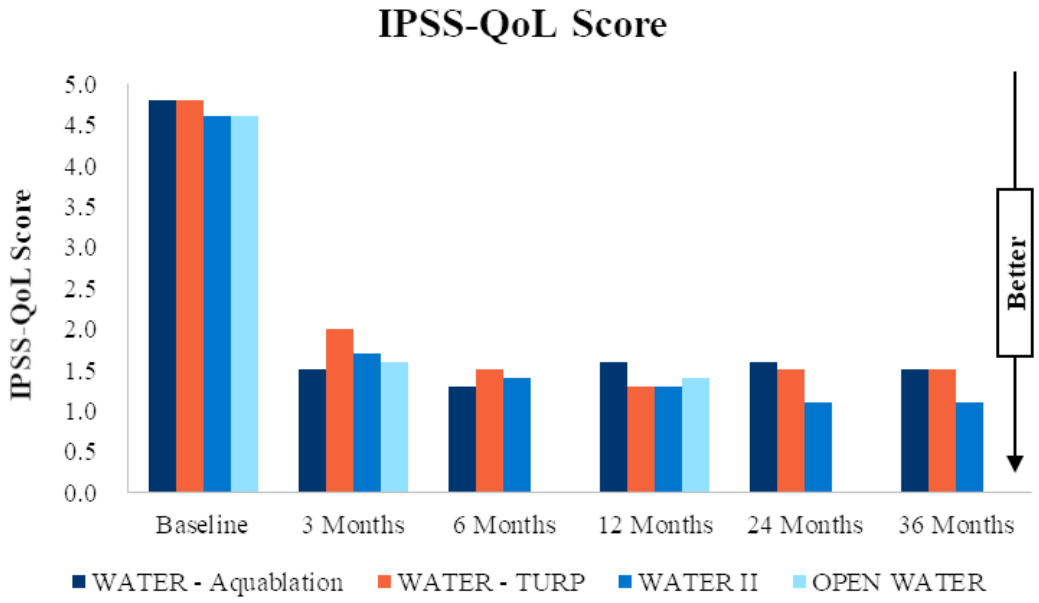
| | OPEN WATER | WATER II | WATER (Aquablation arm) | WATER (TURP arm) |
|---|---|---|---|---|
| **Number Treated** | 178 | 101 | 116 | 65 |
| Demographics (all data reported as mean) | | | | |
| Age (years) | 68 | 68 | 66 | 66 |
| Prostate size | 59ml | 107ml | 54ml | 52ml |
| Obstructive median lobe | 59% | 83% | 50% | 52% |
| Longest Duration of Follow-up | 1 year | 3 years | 3 years | |
| **Efficacy** | | | | |
| IPSS baseline | 21.6 | 23.2 | 22.9 | 22.2 |
| IPSS at longest FU | 6.4 | 6.5 | 8 | 7.9 |
| IPSS-QoL baseline | 4.7 | 4.6 | 4.8 | 4.8 |
| IPSS-QoL at longest FU | 1.4 | 1.1 | 1.6 | 1.5 |
| Qmax baseline | 9.9 ml/sec | 8.7 ml/sec | 9.4 ml/sec | 9.1 ml/sec |
| Qmax at longest FU | 20.8 ml/sec | 18.5 ml/sec | 20.6 ml/sec | 17.1 ml/sec |
| **Safety (irreversible complications assessed by protocol definitions)** | | | | |
| Incontinence | 0.0% | 2.0% | 0.0% | 0.0% |
| Erectile dysfunction | 0.0% | 0.0% | 0.0% | 0.0% |
| Ejaculatory dysfunction (% in sexually active) | 8.4% (11.9%) | 14.9% (19.5%) | 6.9% (10.3%) | 24.6% (35.6%) |
| **Durability** | | | | |
| Surgical retreatment for BPH at longest FU | 0.0% | 3.0% | 4.3% | 1.5% |
| Surgical retreatment annualized | 0.0% | 1.0% | 1.4% | 0.5% |
| Back on BPH medication at longest FU | 3.4% | 5.9% | 1.7% | 7.7% |
| Back on BPH medication annualized | 3.4% | 2.0% | 0.6% | 2.6% |

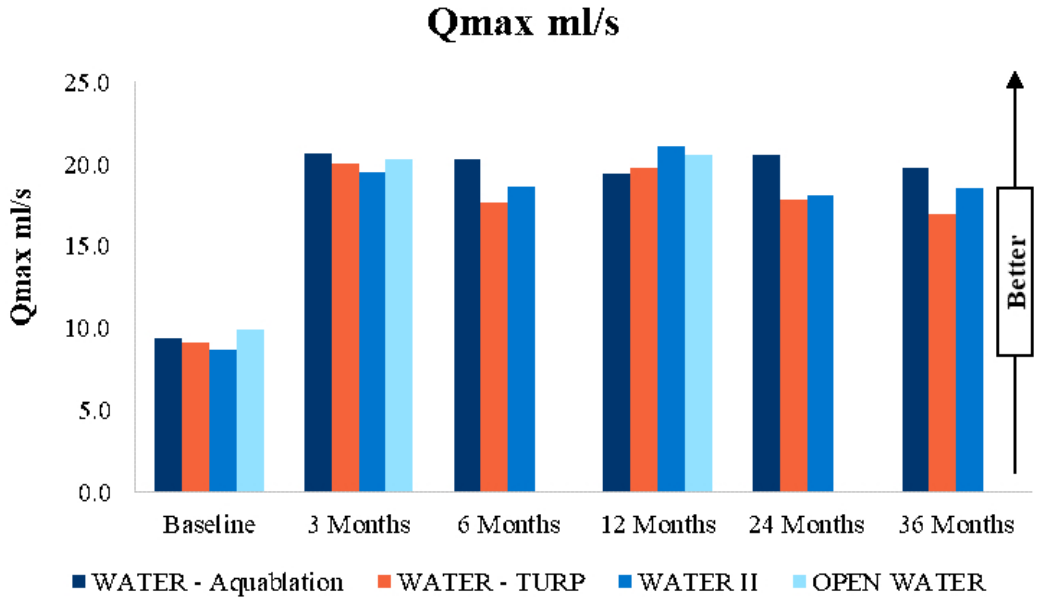
*Efficacy and Durability*

The most common measure of efficacy in BPH clinical research is symptom relief measured by improvement in IPSS. IPSS is a validated, standardized questionnaire used to quantify a patient's degree of LUTS. The questionnaire is comprised of seven questions that characterize urinary dysfunction. Scores range from 0 to 35, with a higher score indicating more severe symptoms. A total score of 7 or less indicates mild symptoms, 8 to 19 indicates moderate symptoms and 20 to 30 indicates severe symptoms. The IPSS-Quality of Life, or IPSS-QoL, is a single question with a score of 0 to 6 that asks the patient how he would feel if he had to spend the rest of his life with his current urinary symptoms. A higher score indicates a higher level of dissatisfaction. Uroflowmetry tests, which measure the strength and amount of urine flow during urination, are also used to measure efficacy, with Qmax being the primary measurement. Qmax is a measure of the max urinary flow rate. A study of 348 18-year-old males showed the majority of men had a Qmax of 20 ml/s or higher.

Our core clinical studies have demonstrated the strong efficacy of Aquablation therapy across prostate sizes and shapes. The following figures highlight efficacy results for IPSS scores, IPSS-QoL scores and Qmax at various points in time across these studies.






An important factor related to efficacy is durability, which is commonly measured by freedom from surgical retreatment due to recurrent LUTS associated with BPH. In addition, since one of the key goals of surgical intervention is to reduce or eliminate the need for drugs, the rate of patients back on drug therapy due to recurrent LUTS associated with BPH is also an important measure of durability. Lower rates of surgical retreatment and being back on drug therapy are more favorable. The table below highlights the strong durability observed across our core clinical studies.

| | OPEN WATER | WATER II | WATER (Aquablation arm) | WATER (TURP arm) |
|---|---|---|---|---|
| Longest Duration of Follow-up | 1 year | 3 years | 3 years | |
| Surgical retreatment for BPH at longest FU | 0.0 % | 3.0 % | 4.3 % | 1.5 % |
| Surgical retreatment annualized | 0.0 % | 1.0 % | 1.4 % | 0.5 % |
| Back on BPH medication at longest FU | 3.4 % | 5.9 % | 1.7 % | 7.7 % |
| Back on BPH medication annualized | 3.4 % | 2.0 % | 0.6 % | 2.6 % |

*Safety*

A key measure of safety used in BPH clinical research is the rate of irreversible complications, which includes urinary incontinence, erectile dysfunction and ejaculatory dysfunction. Urinary incontinence refers to the loss of bladder control, resulting in the occasional leak of urine. Erectile dysfunction refers to the inability to get or maintain an erection firm enough for sexual intercourse. Ejaculatory dysfunction refers to the inability of a man to efficiently ejaculate semen from the penis at the moment of sexual climax.

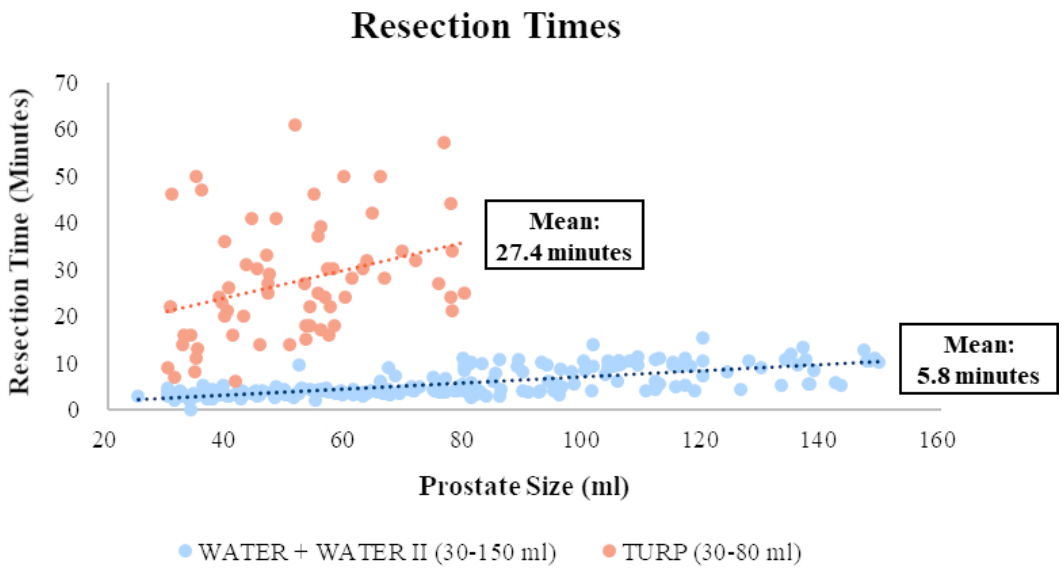
Aquablation therapy has demonstrated low rates of irreversible complications across our core studies, with consistently low rates of urinary incontinence and erectile dysfunction and ejaculatory dysfunction risk as low 10% in sexually active men. The table below highlights the strong safety profile observed across our core clinical studies.

| | OPEN WATER | WATER II | WATER (Aquablation arm) | WATER (TURP arm) |
|---|---|---|---|---|
| Incontinence | 0.0% | 2.0% | 0.0% | 0.0% |
| Erectile dysfunction | 0.0% | 0.0% | 0.0% | 0.0% |
| Ejaculatory dysfunction (% in sexually active) | 8.4% (11.9%) | 14.9% (19.5%) | 6.9% (10.3%) | 24.6% (35.6%) |

*Surgical Standardization*

The efficacy, safety and durability of Aquablation therapy across prostate sizes and shapes have been demonstrated across our three core studies. These studies have also demonstrated that outcomes are independent of surgeon experience. For example, in the WATER study, 14 of the 17 participating surgeons had no previous experience with Aquablation therapy and, in the WATER II study, participating surgeons had a median previous experience with Aquablation therapy of only 0.5 procedures. We believe the short learning curve associated with Aquablation therapy is in large part due to pre-operative planning capabilities and automated robotic execution.

Another key outcome observed across our core studies was consistency of operative and resection times. Regardless of prostate size or shape, the procedure setup and planning processes are the same. Once the surgeon has established the treatment area, the tissue resection is robotically executed, resulting in efficient resection times that are consistent across prostate sizes. The chart below demonstrates consistent resection times observed across our WATER and WATER II studies in prostate sizes between 30 ml and 150 ml. These resection times are in contrast to the highly variable data observed in the TURP arm of the WATER study, which is a key reason why TURP is generally limited to prostate sizes below 80 ml.




***WATER***

The WATER study was a prospective, multicenter, double-blind, randomized, controlled study of Aquablation therapy against TURP for the treatment of LUTS associated with BPH in men with prostate sizes between 30 ml and

80 ml. One hundred eighty-one patients were enrolled and treated in the study, with 116 undergoing Aquablation therapy and 65 undergoing TURP, across 17 investigational sites. The study commenced in October 2015, and the results were first published in May 2018 in the Journal of Urology.

At baseline for patients undergoing Aquablation therapy, the mean age was 66.0 years, the mean prostate size was 54.1 ml, with 54.1% of patients presenting with an obstructive median lobe, the mean IPSS score was 22.9, the mean IPSS-QoL score was 4.8 and the mean Qmax was 9.4 ml/s. At baseline for patients undergoing TURP, the mean age was 65.8 years, the mean prostate size was 51.8 ml, with 52.0% of patients presenting with an obstructive median lobe, the mean IPSS score was 22.2, the mean IPSS-QoL score was 4.8 and the mean Qmax was 9.1 ml/s.

The primary efficacy endpoint was the change in IPSS at six months compared to baseline for the Aquablation therapy treatment arm randomized against the TURP arm. The primary safety endpoint was the occurrence of Clavien-Dindo persistent grade 1 or grade 2 or higher perioperative complications at three months. The study is planned to follow patients for five years, with three-year data currently published.

Mean total operative time was similar for the Aquablation therapy and TURP treatment arms (33 vs 36 minutes, p = 0.2752), but resection time was lower for Aquablation therapy (4 vs 27 minutes, p <0.0001). Fourteen of the 17 participating surgeons had no previous experience with Aquablation therapy.

*Efficacy and Durability*

The study successfully achieved its primary efficacy endpoint, with Aquablation therapy showing non-inferior symptom relief compared to TURP. Analysis of a patient subgroup with prostates above 50 ml demonstrated that Aquablation therapy was superior to TURP in symptom reduction.

At six months, mean IPSS scores decreased from 22.9 at baseline to 5.9 in the Aquablation therapy treatment arm and from 22.2 at baseline to 6.8 in the TURP group. The IPSS change score at month six was 1.8 points larger for the Aquablation therapy treatment arm (95% CI -0.4 to 4.0). The lower confidence limit of the difference was above the pre-specified non-inferiority margin of 4.7, substantiating statistical and clinical non-inferiority of efficacy.

Improvements in IPSS scores were statistically similar across the two groups at three-year follow up. Mean improvements in IPSS scores at three years were 14.4 and 13.9 in the Aquablation therapy and TURP treatment arms, respectively (difference of 0.6 points, p=.6848). Similarly, for Aquablation therapy and TURP, three-year mean improvements in IPSS-QoL were 3.2 and 3.2 (difference of 0 points, p=0.7845), respectively, and Qmax were 11.6 ml/s and 8.2 ml/s (difference of 3.3 ml/sec, p=.0848), respectively.

Three-year surgical retreatment rates in the Aquablation therapy and TURP treatment arms were 4.3% and 1.5%, respectively. There were no surgical retreatments for BPH beyond 20 months for either Aquablation therapy or TURP. At three years, the rate of patients in the Aquablation therapy and TURP treatment arms that were back on drug therapy were 1.7% and 7.7%, respectively.

*Safety*

The primary safety endpoint occurred in 29 Aquablation therapy subjects, or 25.0%, and 26 TURP subjects, or 40.0%, which met the study primary non-inferiority safety hypothesis and subsequently demonstrated superiority (p = 0.0149). Among sexually active men, the rate of persistent retrograde ejaculation was lower in those treated with Aquablation therapy compared to TURP (10% vs 36%, p = 0.0003). There were no cases of urinary incontinence or erectile dysfunction among sexually active men.

***WATER II***

The WATER II study was a prospective, multicenter single-arm study for the treatment of LUTS associated with BPH in men with prostate sizes between 80 ml and 150 ml. One hundred and one patients were enrolled and treated in the study across 16 investigational sites. The study commenced in 2017, and the results were first published BJU International in March 2019.

At baseline for patients in the study, the mean age was 67.5 years, the mean prostate size was 107.4 ml, with 83.2% of patients presenting with an obstructive median lobe, the mean IPSS score was 23.2, the mean IPSS-QoL score was 4.6 and the mean Qmax was 8.7 ml/s.

The primary efficacy endpoint was IPSS reduction. Secondary efficacy endpoints include IPSS-QoL score, maximum urinary flow rate, post-void residual urine volume and prostate-specific antigen concentration. The primary safety endpoint was the percentage of Clavien–Dindo grade 2 or higher or any grade 1 event resulting in persistent disability. The study is planned to follow patients for five years, with three-year data having already been collected and analyzed.

Mean total operative and resection time was 55 minutes and eight minutes, respectively. Participating surgeons had a median previous experience with Aquablation therapy of only 0.5 procedures.

*Efficacy and Durability*

The study met its primary and secondary efficacy endpoints showing the Aquablation procedure's ability to provide significant symptom relief in large prostates and is a size independent procedure. The mean IPSS improved from 23.2 at baseline to 6.7 at three months ($P < 0.001$), which is a 17.4-point improvement and meeting the study's primary efficacy endpoint goal. At three years, mean IPSS decreased from 23.2 at baseline to 6.5, mean IPSS-QoL decreased from 4.6 to 1.1 and mean Qmax increased from 8.7 ml/s to 18.5 ml/s.

Three-year surgical retreatment rate was 3.0%. At three years, the rate of patients that were back on drug therapy was 6.0%.

*Safety*

The study met its primary safety endpoint of Clavien–Dindo grade 2 or higher or any grade 1 event resulting in persistent disability. At three months, this occurred in 45.5% of men, which met the study design goal of < 65%. Consistent with the results of the WATER study, WATER II observed low rates of irreversible complications: 2% new onset urinary incontinence and, among sexually active men, 0% erectile dysfunction and 19% ejaculatory dysfunction.

While the primary safety endpoint was achieved, the procedure was done without any cauterization for hemostasis. As a result, we experienced a peri-operative transfusion rate of 5.9%. We worked with numerous surgeons to identify the optimal hemostasis method that would work across all prostate sizes. That method, focal bladder neck cautery, was formally included as part of the Aquablation therapy training program beginning in January 2020. Since then, a number of publications have reported on transfusion rates. A key study published in April 2021 of 2,089 men undergoing Aquablation therapy with prostates ranging in size from 20 ml to 363 ml observed a transfusion rate of only 0.8%.

***OPEN WATER***

The OPEN WATER study was a prospective, multicenter, all-comer study conducted in a commercial setting spanning patients with prostate sizes between 20 ml and 150 ml. One hundred and seventy-eight patients were enrolled and treated in the study across five investigational sites. The study commenced in September 2017, and the results were first published in Journal of Clinical Medicine in February 2020.

At baseline for patients in the study, the mean age was 66.0 years, the mean prostate size was 59.3 ml, with 59.6% of patients presenting with an obstructive median lobe, the mean IPSS score was 21.6, the mean IPSS-QoL score was 4.6 and the mean Qmax was 9.9 ml/s.

The study's primary endpoint was the change in total IPSS score from baseline to three months.

*Efficacy and Durability*

The primary efficacy endpoint of IPSS reduction was met with mean IPSS scores decreasing from 21.6 at baseline to 7.1 and 6.4 at the three- and 12-month follow-up, respectively.

The secondary endpoint of IPSS-QoL reduction was also met with mean IOL-QoL scores decreasing from 4.6 at baseline to 1.5 and 1.4 at 3- and 12-month follow-up, respectively. The maximum urinary flow rate (Qmax) increased from 9.9 to 20.3 and 20.8 cc/sec at 3- and 12-month follow-up, respectively and post-void residual urinary volume decreased from 108cc at baseline to 47cc and 61cc at 3- and 12-month follow-up, respectively.

There were no cases of surgical retreatment because of recurrent LUTS due to BPH at 12-months, with 3.4% back on drug therapy.

*Safety*

In terms of safety, irreversible complications were similar to WATER and WATER II; 0% incontinence and among sexually active men 0% erectile dysfunction and 12% ejaculatory dysfunction.

Following Aquablation therapy, 2.7% of patients underwent a transfusion and 7.9% of patients were taken back to the OR for postoperative hemostasis management.

**Selected Competitor Data**

***Prostatic Urethral Lift***

The UroLift Prostate Implant, or UroLift, is a PUL system for the treatment of BPH. UroLift was cleared by the U.S. FDA in 2013, following successful completion of the Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of Lower Urinary Tract Symptoms, or L.I.F.T., pivotal study. UroLift is indicated for patients with moderate-to-severe LUTS due to BPH with prostate sizes below 100 ml. Five-year data from this study has been published in June 2017 in the Canadian Journal of Urology.

The L.I.F.T. study was designed as a prospective, multicenter, randomized, single-blinded controlled clinical trial. The study enrolled a total of 206 men randomized (140 UroLift vs 66 sham) across 19 investigational sites. At baseline for patients undergoing UroLift, the mean age was 67 years, the mean prostate size was 44.5 ml, the mean IPSS score was 22.2, the mean IPSS-QoL score was 4.6 and the mean Qmax was 7.9 ml/s. The study excluded prostates with an obstructive median lobe.

At three years, patients undergoing UroLift had a mean IPSS score of 12.7, mean IPSS-QoL score of 2.2 and mean Qmax of 11.8 ml/s. Patients undergoing UroLift experienced the following at three years: 10.7% surgical retreatment and 9.3% back on drug therapy due to recurrent LUTS due to BPH, and 7.1% having one or more implants removed.

At five years, patients undergoing UroLift had a mean IPSS score of 13.9, mean IPSS-QoL score of 2.2 and mean Qmax of 12.0 ml/s. Patients undergoing UroLift experienced the following at five years: 13.6% surgical retreatment and 10.7% back on drug therapy due to recurrent LUTS due to BPH, and 9.3% having one or more implants removed.

***Water Vapor Therapy***

The Rezūm System, or Rezūm, is a water vapor therapy for the treatment of BPH. Rezūm was granted 510(k) clearance by the U.S. FDA in 2015, following successful completion of the Rezūm II Study. Rezūm is indicated for patients with moderate-to-severe LUTS due to BPH with prostate sizes below 80 ml. Five-year data from this study has been published in April 2021 in the Journal of Urology.

The Rezūm II Study was designed as a prospective, multicenter, randomized, double-blinded controlled clinical trial. The study enrolled a total of 197 men randomized (136 water vapor therapy vs 61 sham) across 15 investigational sites. At baseline for patients undergoing water vapor therapy, the mean age was 63 years, the mean prostate size was 45.8 ml, the mean IPSS score was 22.0, the mean IPSS-QoL score was 4.4 and the mean Qmax was 9.9 ml/s.

At three years, patients undergoing water vapor therapy had a mean IPSS score of 10.5, mean IPSS-QoL score of 2.1 and mean Qmax of 13.2 ml/s. Patients undergoing water vapor therapy experienced the following at three years: 4.4% surgical retreatment and 3.7% back on drug therapy due to recurrent LUTS due to BPH.

At five years, patients undergoing water vapor therapy had a mean IPSS score of 11.1, mean IPSS-QoL score of 2.2 and mean Qmax of 14.0 ml/s. Patients undergoing water vapor therapy experienced the following at four years: 4.4% surgical retreatment and 11.1% back on drug therapy due to recurrent LUTS due to BPH.

**Sales and Marketing**

***Commercial Activities in the United States***

We designed our commercial strategy and built our direct sales team to target primarily urologists across the United States, who we believe represent the primary physician specialty managing the care of and receiving referrals for patients with BPH. We estimate that there are approximately 12,000 urologists who manage approximately 4.3 million BPH patients, comprised of 400,000 undergoing BPH surgery annually, 3.3 million who are on drug therapy and 600,000 who have tried but failed drug therapy. We are first focused on driving adoption of Aquablation therapy among urologists who perform hospital-based BPH resective surgery. We estimate that approximately 290,000 of the 400,000 annual BPH surgeries are resective procedures performed across approximately 2,700 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. Within each high-volume hospital, we are focused on targeting urologists who perform medium-to-high volumes of resective procedures and converting their resective cases to Aquablation therapy. 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. We also intend to leverage our relationships with urologists to drive utilization of Aquablation therapy beyond the current surgical market. Over time, we will gradually expand our focus to also include mid- and low-volume hospitals.

We primarily sell our products through our direct sales organization in the United States. As of June 30, 2021, we employed a Vice President of U.S. sales, a sales director, sales managers, sales professionals, including sales managers, robotic sales representatives, Aquablation sales representatives, who focus on driving utilization. This team actively engages with providers to drive awareness, adoption and utilization of our Aquablation therapy. Our direct sales organization is supported by ten clinical specialists and professional education employees, who are responsible for training and supporting surgeons, two reimbursement specialists, who are responsible for customer and physician education on coding, coverage and payment, and two field service employees, who provide preventative maintenance and support for our customers. We intend to expand the size of our direct sales organization to support our efforts for adoption and utilization of Aquablation therapy.

In addition to our direct sales efforts, we support our sales organization with marketing and market development initiatives. We plan to continue to expand and enhance our marketing capabilities to support our growing commercial organization and customer base. Our near-term marketing efforts center principally on increasing awareness and driving adoption of Aquablation therapy among urologists by continuing to publish clinical data in various industry and scientific journals, present our clinical data at various industry conferences, expand our network of KOLs and sponsor peer-to-peer education programs and proctorships. We believe these initiatives will further deepen our relationships with urologists and key medical societies, contributing to our goal of Aquablation therapy becoming the surgical standard of care for BPH surgery. Longer-term, as we expand our network of urologists and grow our installed base, we intend to increase awareness and brand recognition of Aquablation therapy beyond urologists, primarily among primary care physicians who manage BPH patients. To achieve this objective, we will invest in marketing initiatives directed at primary care physicians in order to optimize referral pathways and expand networks for BPH patients to visit a urologist. Once we have established a broader installed base of systems, we may seek to further increase patient awareness through various direct-to-patient marketing initiatives.

***Commercial Activities Outside of the United States***

Our commercialization strategy outside the United States is focused on large addressable markets through a broad range of market development activities, including increasing awareness, obtaining regulatory approvals and establishing reimbursement. We sell our products using both our direct sales organization and, in certain regions, our network of distribution partners.

In EMEA, our direct sales organization is currently primarily focused on Germany, France, the United Kingdom, Switzerland and Austria. In other countries, such as Italy and Spain, we engage distribution partners to assist us with market development and sales activities. As of June 30, 2021, we employed 9 personnel to support sales and marketing activities in EMEA. We will opportunistically choose distribution partners with clinical and marketing expertise to enter new markets. We are focused on distribution partners that have the capability to assist with surgeon training and, when required, obtaining regulatory approvals. In the Asia-Pacific region, we are focused on obtaining local regulatory clearances with the assistance of our distribution partners in this region. We have regulatory approval in Hong Kong, where we are engaged with a distribution partner for market development activities.

**Third-Party Reimbursement**

In the United States, we sell our products to hospitals. These customers in turn bill various third-party payors, such as commercial payors and government agencies, for treatment payment of each patient. Our market access team includes four professionals who are focused on all key aspects of reimbursement, which include securing appropriate coding, payment and coverage policies for our products. This team focuses both on payer engagement as well as providing support to the providers.

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.

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 exists among third-party payors. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor. Obtaining coverage and reimbursement can be a time-consuming process that could require supporting scientific, clinical and cost-effectiveness data.

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. Further, future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. In addition, Medicare Administrative Contractors could issue a local coverage determination decision that could restrict the patients eligible for a treatment with our products. Third-party coverage and reimbursement 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.

***Coding and Payment***

Third-party payors require physicians and hospitals to identify the service for which they are seeking reimbursement by using Current Procedural Terminology, or CPT, codes, which are created and maintained by the American Medical Association, or AMA. The surgical treatment of BPH using Aquablation therapy is described by CPT code 0421T, which is the code describing transurethral waterjet ablation of the prostate, a Category III code published by the AMA in January 2017. In February 2021, the AMA approved an extension for CPT code 0421T through December 31, 2026.

Physician reimbursement under Medicare generally is based on a defined fee schedule, the Physician Fee Schedule, through which payment amounts are determined by the relative values of the professional service rendered. Physician payment rates for Category III codes are determined by the MACs and vary from jurisdiction to jurisdiction. The payment to the surgeon using CPT code 0421T is similar to that for a TURP procedure.

In addition to payment to the surgeon for professional services, Medicare provides reimbursement to our hospital customers for procedures under the hospital outpatient prospective payment system, or HOPPS, and inpatient prospective payment system, or IPPS. The HOPPS and IPPS provide bundled amounts generally intended to reimburse the hospital for all facility costs related to procedures performed in the hospital outpatient setting and inpatient setting, respectively. Under the HOPPS and IPPS, the national average Medicare payment to the hospital for this procedure is slightly more than $8,200 and $5,600, respectively, which includes payment for the hospitals' costs for the device and procedure. Medicare also provides reimbursement for procedures performed in ASCs. The national average Medicare payment to an ASC for 0421T is approximately $4,000. Reimbursement rates from commercial payors vary depending on the commercial payor, contract terms, and other factors.

As part of the 2020 Outpatient Prospective Payment System ruling, the CMS granted approval for a transitional pass-through, or TPT, payment for Aquablation therapy. TPT status is intended to encourage the use of newly FDA-approved medical devices, drugs, and biologics across all fields of medicine and to boost Medicare patients' access to these innovative therapies by temporarily paying more than established facility fees. The TPT payment for Aquablation therapy is effective through December 31, 2022.

***Commercial Payor and Government Program Coverage***

A core pillar of our reimbursement strategy involves broadening our third-party payor coverage. We continue to have active discussions with commercial payors to establish positive national coverage policies by highlighting our compelling and robust clinical data, increased patient demand and support from leading medical societies and key opinion leaders. Approximately 32 commercial payors have reimbursed hospitals for the Aquablation procedure, although a number of commercial payors have adopted noncoverage policies for Aquablation therapy. We have secured positive coverage policies from two U.S. commercial payors at the national level; Anthem Blue Cross Blue Shield and Humana. We have secured positive coverage policies from two commercial payors at the local and regional level, namely Blue Cross Blue Shield Massachusetts and EmblemHealth.

As of December 27, 2020, all MACs cover procedures involving Aquablation therapy are covered for Medicare patients. We believe Medicare accounts for approximately 50% of all hospital-based resective BPH procedures performed in the United States.

***Prior Authorization Approval Process***

Our reimbursement strategy includes leveraging our market access team as advisors when needed to support in obtaining appropriate prior authorization approvals in advance of treatment. We believe we are highly effective in providing guidance to obtain prior authorizations when needed.

***Reimbursement Outside of the United States***

Outside of the United States, reimbursement levels vary significantly by country, and within some countries by region, as well as by payor type. Reimbursement is obtained from a variety of sources, including government sponsors, hospital budgets or private health insurance plans, or combinations thereof. Obtaining reimbursement is a

key part of our market development strategy outside of the United States. We currently have established reimbursement in Germany, the United Kingdom, Spain and Italy are continuing to establish new, as well as more favorable, reimbursement.

**Research and Development**

We have established a dedicated research and development team, including engineers as of June 30, 2021, with strong research and development capabilities in surgical robotics and imaging-enabled surgery as well as integrating hardware and software to create an exceptional user and patient experience. We believe our focus on this experience will allow us to continue to bring new upgrades, capabilities and products to market, allowing us to innovate and maintain our competitive positioning.

To improve customer experience, we are continually innovating our 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. In the future, we may evaluate the application of the AquaBeam Robotic System in new urologic conditions beyond BPH.

For the years ended December 31, 2019 and 2020, our research, development and clinical expenses were $13.1 million and $16.3 million, respectively.

**Manufacturing and Supply**

We directly 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 United States and the Netherlands to ship our products to our customers globally.

**Competition**

The industry in which we operate is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. While we believe Aquablation therapy and the AquaBeam Robotic System provide us with a competitive advantage against other competing BPH treatment modalities, our currently marketed products are, and any future products we commercialize will be, subject to intense competition.

Certain of our current and potential competitors may have significantly greater financial, technical, marketing and other resources than we do and may be able to devote greater resources to the development, regulatory approval, promotion, sale and support of their products. Our competitors may also have more extensive customer bases and broader customer relationships than we do, including relationships with our potential customers. In addition, many of these companies have longer operating histories and greater brand recognition than we do. Because of the size of the BPH market, we anticipate that companies will dedicate significant resources to developing competing products.

We consider our primary competition to be resective surgical treatments. These include among others, those manufacturers producing devices for the TURP procedure and laser-based therapies marketed by Boston Scientific Corporation. We also believe we will eventually compete with non-resective and non-surgical treatments. The non-resective treatments include, among others, UroLift marketed by Teleflex Incorporated and Rezum marketed by Boston Scientific Corporation. Non-surgical treatments for BPH are primarily pharmaceuticals. The primary pharmaceutical products marketed to treat BPH include Flomax marketed by Boehringer Ingelheim, Rapaflow marketed by Allergan plc, Avodart marketed by GlaxoSmithKline plc, and Proscar marketed by Merck & Co., Inc.

We believe that the primary bases on which we compete include:

- improved outcomes for patients;

- product safety, efficacy, reliability and durability;
- quality and volume of clinical data;
- effective marketing to and education of patients, physicians and hospitals;
- company, product and brand recognition;
- sales force experience and access;
- product support and service;
- technological innovation, product enhancements and speed of innovation;
- pricing and revenue strategies;
- effectiveness of reimbursement teams and strategies
- regulatory status and speed to market; and
- dedicated clinical representatives.

We cannot assure you that we will be able to compete effectively against our competitors in regard to any one or all of these factors.

**Intellectual Property**

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of June 30, 2021, we had rights to issued U.S. patents, which will expire between 2028 and 2037, pending U.S. patent applications, issued foreign patents and __ pending PCT and foreign patent applications. As of June 30, 2021, our foreign patent rights included granted European patents and pending European applications, granted Chinese patents and pending Chinese applications, granted Japanese patents and pending Japanese applications, pending Brazilian applications, and pending Indian applications. Of the granted European patents, have been validated in Germany, in Spain, in France, in the United Kingdom, in Ireland, and in Italy. As of June 30, 2021, we also had rights to pending PCT applications. Our patents and applications cover aspects of our current AquaBeam Robotic System and our current and future product concepts, including U.S. patents and foreign patents that cover aspects of our current AquaBeam Robotic System.

There is no active patent litigation involving any of our patents and we have not received any notices of patent infringement

As of June 30, 2021, we had pending and registered trademark filings worldwide, some of which may provide trademark protection in multiple countries.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants and others who may have access to our proprietary information.

Our pending patent applications may not result in issued patents, and we cannot assure you that any current or subsequently issued patents will protect our intellectual property rights or provide us with any competitive advantage. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, we may be required to enforce or defend our intellectual property rights against third parties in the future. See the section titled “Risk Factors—Risks Related to Intellectual Property Matters” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

***License Agreement with AquaBeam***

In 2008, we assigned to AquaBeam LLC, or AquaBeam, certain provisional patent applications, or AquaBeam Patent Applications, which have since issued as patents, and any future patent applications that claim priority to the AquaBeam Patent Applications, or AquaBeam Patents.

In September 2019, we entered into an amended and restated license agreement, or the AquaBeam License Agreement, with AquaBeam. Pursuant to the AquaBeam License Agreement, AquaBeam grants us a worldwide, exclusive (even as to AquaBeam), sublicensable, royalty-free license under the AquaBeam Patents and to all other patent rights owned by AquaBeam, which are filed on or before the earlier of October 28, 2021 and the date on which we are acquired by a third party, that claim certain technology related to delivering energy to tissues by directing a liquid fluid stream, or together with AquaBeam Patents, Licensed Patents, in the field of urology, or Field. Pursuant to the AquaBeam License Agreement, and subject to the terms therein, we grant AquaBeam a worldwide, exclusive (even as to us), sublicensable, royalty-free license under certain of our patents rights, which are filed on or before the earlier of October 28, 2021 and the date on which AquaBeam is acquired by a third party, that claim certain technology related to delivering energy to tissues by directing a liquid fluid stream, or PROCEPT Patents, outside the Field.

If AquaBeam desires to grant a license under the Licensed Patents to any third party outside the Field on or before the earlier of October 28, 2021 and the date on which AquaBeam is acquired by a third party, we have the first right to negotiate such license grant pursuant to the terms of the AquaBeam License Agreement.

AquaBeam has the first right to prosecute and maintain the Licensed Patents and we have the right to step-in if AquaBeam declines or fails to prosecute or maintain any of the Licensed Patents. We have the first right to prosecute and maintain the PROCEPT Patents. We have the first right to enforce the Licensed Patents and the PROCEPT Patents if a third party infringes on any such patents in the Field, provided, if such third party infringes the Licensed Patents or the PROCEPT Patents both in and outside of the Field , or Cross-Field Infringement, and AquaBeam or any of its other licensees under the Licensed Patents or the PROCEPT Patents are developing or commercializing products that are covered by the infringed Licensed Patents or the PROCEPT Patents, then AquaBeam and we will discuss which party will control the enforcement action with respect to such Cross-Field Infringement.

The AquaBeam License Agreement will remain in full force and effect on a country-by-country basis until the last to expire of the Licensed Patents and the PROCEPT Patents in such country. The AquaBeam License Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 90 days (or 30 days for payment related breaches), or bankruptcy of the other party.

**Government Regulation**

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in the EEA. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA governing clinical trials and the commercial sales and distribution of our products. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

***FDA Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or PMA approval. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its 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. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available device that was cleared to through the 510(k) process.

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 are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

***De Novo Classification***

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. 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) pre-market 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) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Our currently marketed AquaBeam Robotic System is a Class II device, which was initially granted marketing authorization pursuant to a de novo classification. We have subsequently received FDA clearance of a 510(k) pre-market notification for modifications to the AquaBeam Robotic System where we used the initially authorized device as the predicate device for our more recent 510(k) clearance.

***PMA Approval Pathway***

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR. PMA applications are also subject to the payment of user fees, which for fiscal year 2021 includes a standard application fee of $365,657.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

***Clinical Trials***

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is

scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

***Post-Market Regulation***

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers, or UDI, on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database, or GUDID;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

***Regulation of Medical Devices in the EEA***

There is currently no premarket government of medical devices in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive, and the regulations laid down in the 2017/745, or the Medical Device Regulations. There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC). The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various

standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive, Annex 7 of the Active Implantable Medical Devices Directive, and applicable European and International Organization for Standardization standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

On May 25, 2017 the new Medical Devices Regulation, or 2017/745 or MDR, was adopted by the European Parliament, which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Following its entry into application on May 26, 2021, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

On the effective date, May 26, 2021, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;

- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

We expect this revised regulation to include further controls and requirements on the following activities:

- high level of request for premarket clinical evidence for high risk devices;
- increased scrutiny of technical files for implantable devices;
- monitoring of notified bodies, by independent auditors;
- increased requirements regarding vigilance and product traceability (specifically related to labeling requirements); and
- increased regulation for non-traditional roles such as importer and distributor.

***Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws***

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including significant criminal fines and imprisonment, as well as exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with whom we do business. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of any monetary recovery. Penalties for federal civil False Claim Act violations include penalties for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. There are also criminal penalties for making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent.

HIPAA created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the

delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS, information related to payments or and other "transfers of value" made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided (beginning in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

***Healthcare Reform Measures***

In the United States, there have been, and may continue to be, a number of legislative and regulatory changes to the healthcare 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.

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 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 CMS 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 current presidential administration and Congress may continue to pursue significant changes to the current healthcare laws.

***Data Privacy and Security Laws***

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by HITECH, and their implementing regulations, impose obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, certain state and non-U.S. laws, such as the CCPA, the CPRA and the GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, 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. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

***Anti-Bribery and Corruption Laws***

Our U.S. operations are subject to the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their employees, agents and intermediaries from engaging in bribery or authorizing, promising, providing, or offering, directly or indirectly, anything of value to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which requires such companies to maintain complete and accurate books and records and maintain a system of internal accounting controls. We also are subject to similar anticorruption laws and regulations implementing the Organization for Economic Co-operation and Development’s Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

**Facilities**

Our principal office is located at 900 Island Drive, Redwood City, California, where we lease approximately 43,485 square feet of office space. We lease this space under a lease that terminates on October 29, 2023. We intend to add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

**Employees and Human Capital Resources**

As of June 30, 2021, we had employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

**Legal Proceedings**

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.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth information about our executive officers and directors, including their ages, as of May 31, 2021.

| Name | Age | Position |
|---|---|---|
| **Executive Officers and Employee Directors:** | | |
| Reza Zadno, Ph.D. | 66 | President, Chief Executive Officer and Director |
| Kevin Waters | 43 | SVP, Chief Financial Officer |
| Alaleh Nouri | 42 | SVP, General Counsel & Corporate Secretary |
| Hisham Shiblaq | 46 | SVP, Global Commercialization |
| **Non-Employee Directors:** | | |
| Frederic Moll, M.D. | 69 | Director and Chair of the Board |
| Antal Desai | 43 | Director |
| Amy Dodrill | 48 | Director |
| Taylor Harris | 45 | Director |
| Thomas Krummel, M.D. | 69 | Director |
| Rodney Perkins, M.D.[(1)] | 86 | Director |
| Eric Reuter | 60 | Director |
| Lisa Skeete Tatum | | Director |
| Colby Wood | 50 | Director |

(1) Dr. Perkins will be resigning from our board of directors immediately upon effectiveness of the registration statement of which this prospectus is a part.
(2) Member of the audit committee.
(3) Member of the compensation committee.
(4) Member of the nominating and corporate governance committee.

#### *Executive Officers and Employee Directors*

***Reza Zadno, Ph.D.*** Dr. Zadno has served as our President and Chief Executive Officer and a member of our board of directors since February 2020. He previously served as President and Chief Executive Officer of Avedro, Inc., a healthcare company, from September 2016 to November 2019, where he also served as a member of the board of directors from September 2016 to November 2020. Dr. Zadno also previously served as Innovation Advisor and Venture Partner at InterWest Partners, a venture capital firm, from January 2012 to January 2018. Dr. Zadno has also served on the boards of directors of Invuity, Inc. from January 2013 to June 2017, where he was a member of the audit committee, and Carbylan Therapeutics, Inc. from June 2013 to November 2016, where he was a member of the audit committee, in addition to a number of private companies. Dr. Zadno received both a Ph.D. and an M.Sc. in Mechanical Properties of Materials from Ecole Nationale Superieure des Mines de Paris.

We believe that Dr. Zadno is qualified to serve on our board of directors based on his understanding of our business and operations and perspective as our Chief Executive Officer and President.

***Kevin Waters.*** Mr. Waters has served as our SVP, Chief Financial Officer since October 2018. He previously served as Chief Financial Officer at Accuray Incorporated, a radiation oncology company, from September 2015 to October 2018, and as its SVP, Finance from October 2013 to August 2015. Mr. Waters received a B.S. in Business Administration, with a double concentration in Accounting and Finance from Cal Poly San Luis Obispo.

***Alaleh Nouri.*** Ms. Nouri has served as our SVP, General Counsel & Corporate Secretary since July 2018. She previously served as Senior Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer at Accuray Incorporated, a radiation oncology company, from February 2014 to July 2018. Ms. Nouri received a J.D.

from U.C. Hastings College of Law and a Bachelor of Commerce in International Business and also completed the requirements for a Finance specialization from the University of British Columbia.

***Hisham Shiblaq.*** Mr. Shiblaq has served as our SVP, Global Commercialization since March 2019. He previously served as Vice President of Commercial Operations at Invuity, Inc., a medical device company, from January 2017 to January 2019 and as Vice President of Sales at Analogic Corporation from June 2016 to January 2017. Mr. Shiblaq received a B.A. in Psychology from Ohio State University.

***Non-Employee Directors***

***Frederic Moll, M.D.*** Dr. Moll has served as a member of our board of directors since August 2011 and has served as Chair since March 2021. Since April 2019, Dr. Moll has served as Chief Development Officer for Johnson & Johnson Medical Devices Companies. Dr. Moll was also a co-founder, and, from September 2012 to 2019, was the Chairman and Chief Executive Officer of Auris Health, Inc. Dr. Moll previously served as member and as Chairman of the board of Restoration Robotics, Inc., from November 2002 until its merger with Venus Concept in November 2019. He has also served on the boards of Shockwave Medical, Inc., since March 2011, where he is a member of the nominating and corporate governance committee, INSIGHTEC Ltd., since June 2020, where he is a member of the audit committee, and Lux Health Tech Acquisition Corp., since June 2020, where he is a member of the audit committee, and he previously served on the board of directors at IntersectENT, Inc. from March 2010 to February 2021, where he was a member of the nominating and corporate governance committee. Dr. Moll received a B.A. in economics from the University of California at Berkeley, an M.S. in management from Stanford University and an M.D. from the University of Washington.

We believe Dr. Moll’s deep experience in the healthcare sector and his medical background and experience provide him with the qualifications and skills to serve on our board of directors.

***Antal Desai***. Mr. Desai has served as a member of our board of directors since June 2015. Mr. Desai joined Cardinal Investment Company, Inc. in September 2004, the predecessor firm to CPMG, Inc., an investment firm that invests in publicly-traded and private companies globally, were he currently serves as a Partner. Mr. Desai is a director at several private companies. Mr. Desai received both a B.S. in Economics and an M.B.A. from the Wharton School at the University of Pennsylvania.

We believe Mr. Desai is qualified to serve on our board of directors due to his experience as a director of several companies and his experience investing in publicly-traded companies in the healthcare industry.

***Amy Dodrill***. Ms. Dodrill has served as a member of our board of directors since June 2021. Ms. Dodrill has worked at Hillrom Holdings, Inc., a company specializing in medical device innovation, since October 2012. During her time at Hillrom, Ms. Dodrill has held various positions including President of Global Surgical, Vice President and General Manager of the US Surgical Division and Vice President and General Manager of Trumpf Medical Surgical Solutions NA. Ms. Dodrill holds a B.S. from Johns Hopkins University.

We believe Ms. Dodrill is qualified to serve on our board of directors because of her expertise in managing medical device companies.

***Taylor Harris***. Mr. Harris has served as a member of our board of directors since December 2020. Mr. Harris served as the Chief Financial Officer for MyoKardia, Inc., a clinical-stage biopharmaceutical company, from April 2018 until that company's acquisition by Bristol Myers Squibb in November 2020. Previously, Mr. Harris served as Senior Vice President and Chief Financial Officer of Zeltiq Aesthetics, Inc., a company that markets and licenses devices used for cryolipolysis procedures, from March 2016 until that company’s acquisition by Allergan plc. in April 2017. Mr. Harris has served as a member of the board of directors of HealthCor Catalio Acquisition Company, where he is also a member of the audit committee, since January 2021. Mr. Harris holds a B.A. in Physics and Economics from the University of North Carolina at Chapel Hill.

We believe that Mr. Harris is qualified to serve on our board of directors because of his extensive finance, accounting and operations experience and experience in managing medical device companies.

***Thomas Krummel M.D***. Dr. Krummel has served as a member of our board of directors since December 2010. Since October 1998, Dr. Krummel has been a professor at Stanford University and has served as Venture Partner at Santé Ventures, an early stage medical technology investment firm, since March 2021. He has been a member of the board of directors of California Water Service Group since July 2010, where he serves as a member of the Nominating Corporate Governance committee and serves as Chair of the Compensation committee, in addition to a number of private companies. Dr. Krummel received a B.S. in Chemistry from University of Wisconsin at Parkside and an M.D. from the Medical College of Wisconsin.

We believe Dr. Krummel is qualified to serve on our board of directors due to his expertise with medical, public health and science issues.

***Rodney Perkins, M.D.*** Dr. Perkins is our Founder and will be resigning from our board of directors immediately upon effectiveness of the registration statement of which this prospectus forms a part after having served as a member of our board of directors since April 2007. Dr. Perkins previously served as our Chairman of the Board from May 2007 to March 2021. Dr. Perkins is an internationally known surgeon who has participated actively in the development of multiple successful medical device companies. Dr. Perkins holds an M.D. from The Indiana University and completed his surgical residency at The Stanford University School of Medicine.

We believe that Dr. Perkins is qualified to serve on our board of directors because of his extensive experience with medical technology companies and the historical knowledge and continuity he brings to our board of directors.

***Eric Reuter***. Mr. Reuter has served as a member of our board of directors since December 2014. Mr. Reuter previously acted as CEO of Laserscope Inc. from June 1999 until its acquisition by Boston Scientific in August 2006. Mr. Reuter received his B.S. in Mechanical Engineering from the University of California, Davis.

We believe Mr. Reuter is qualified to serve on our board of directors because of his past experience with medical technology companies.

***Lisa Skeete Tatum***. Ms. Tatum has served as a member of our board of directors since June 2021. Ms. Tatum has been the Chief Executive Officer of Landit, Inc., a technology platform created to increase the success and engagement of women and diverse groups in the workplace, since she founded the company in October 2014. Previously, Ms. Tatum was a General Partner at Cardinal Partners, an early-stage healthcare venture capital firm, from 2004 to 2014. Since May 2020, Ms. Tatum has served on the board of directors and as a member of the audit committee of Stryker Corporation. Ms. Tatum received her B.S. in Chemical Engineering from Cornell University and her M.B.A. from Harvard Business School. Ms. Tatum has served on the board of directors for several medical technology companies.

We believe Ms. Tatum is qualified to serve on our board of directors because of her deep experience with medical technology companies.

***Colby Wood***. Mr. Wood has served as a member of our board of directors since February 2014. Since March 2018, Mr. Wood has been a Managing Partner at Sonder Capital Management, LLC, a healthcare venture capital investment firm. Prior to this, Mr. Wood was a Portfolio Manager and Equity Analyst at Oechsle International Advisors, Ltd., an international investment advisors, from December 2011 to December 2017. Mr. Wood currently serves on the board of directors for two private companies. Mr. Wood received his B.A. in English from University of Delaware and M.B.A. from F.W. Olin Graduate School of Business at Babson College.

We believe Mr. Wood is qualified to serve on our board of directors because of his financial expertise and deep knowledge of the healthcare industry.

**Family Relationships**

There are no family relationships among any of our executive officers or directors.

**Composition of the Board of Directors after This Offering**

Our business and affairs are managed under the direction of the board of directors. Our board of directors will consist of directors.

In accordance with our amended and restated certificate of incorporation, each of which will be in effect upon the closing of this offering, our board of directors will be divided into three classes with staggered three year terms. At each annual meeting of stockholders after the initial classification, the successors to the directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. Our directors will be divided among three classes as follows:

- the Class I directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2024.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our Company.

**Director Independence**

We intend to apply to have our common stock listed on the Nasdaq Global Market. Under the rules of the Nasdaq Global Market, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of this offering. In addition, rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under these rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the closing of this offering.

In connection with this offering, our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that are "independent directors" as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the Nasdaq Global Market, representing of our directors. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and current and prior relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and any transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

**Committees of the Board of Directors**

Upon consummation of this offering, our board of directors will have the following committees: the audit committee, the compensation committee and the nominating and corporate governance committee. From time to time, our board of directors may also establish any other committees that it deems necessary or desirable.

***Audit Committee.*** Upon consummation of this offering, we expect to have an audit committee consisting of , as chair and . Rule 10A-3 of the Exchange Act requires us to have one independent audit committee member upon the listing of our common stock, a majority of independent directors on our audit committee within 90 days of the effective date of this registration statement and an audit committee composed entirely of independent directors within one year of the effective date of this registration statement. qualifies as our "audit committee financial expert" within the meaning of regulations adopted by the SEC. The audit committee appoints and reviews the qualifications and independence of our independent registered public accounting firm, prepares compensation committee reports to be included in proxy statements filed under SEC rules and reviews the scope of audit and non-audit assignments and related fees, the results of the annual audit, accounting principles used in financial reporting, internal auditing procedures, the adequacy of our internal control procedures, the quality and integrity of our financial statements and investigations into matters related to audit functions. The audit committee is also responsible for overseeing risk management on behalf of our board of directors. See "—Risk Oversight."

***Compensation Committee.*** Upon consummation of this offering, we expect to have a compensation committee consisting of , as chair and . The principal responsibilities of the compensation committee are to review and set or make recommendations to our board of directors regarding executive and director compensation, review and approve or make recommendations to our board of directors regarding our incentive compensation and equity-based plans and arrangements, and appoint and oversee any compensation consultants.

***Nominating and Corporate Governance Committee.*** Upon the consummation of this offering, we expect to have a nominating and corporate governance committee consisting of , as chair and . The nominating and corporate governance committee assists our board of directors in identifying individuals qualified to become board members, consistent with criteria approved by our board of directors, makes recommendations for nominees for committees, oversees the evaluation of the board of directors and management and develops, recommends to the board of directors and reviews our corporate governance principles.

**Risk Oversight**

Our board of directors has extensive involvement in the oversight of risk management related to us and our business and accomplishes this oversight primarily through the audit committee. To that end, our audit committee will meet quarterly with our Chief Financial Officer and our independent auditors where it will receive regular updates regarding our management's assessment of risk exposures including liquidity, credit and operational risks and the process in place to monitor such risks and review results of operations, financial reporting and assessments of internal controls over financial reporting.

**Code of Ethics**

Prior to the consummation of this offering, we intend to adopt a code of ethics applicable to all of our directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees. Our code of ethics will be available on our website at www.procept-biorobotics.com under Investor Relations. Our code of ethics will be a "code of ethics" as defined in Item 406(b) of Regulation S-K. In the event that we amend or waive certain provisions of our code of ethics applicable to our principal executive officer, principal financial officer or principal accounting officer that requires disclosure under applicable SEC rules, we intend to disclose the same on our website. The information contained on, or that can be accessed through, our website is not incorporated by reference into, and is not a part of, this prospectus or the registration statement of which this prospectus forms a part. We have included our website in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves, or in the past year has served, as a member of the board of directors or compensation committee (or other committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors or compensation committee. No interlocking relationship exists between any member of our compensation committee (or other committee performing equivalent functions) and any executive, member of the board of directors or member of the compensation committee (or other committee performing equivalent functions) and of any other company.

## EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2020 Summary Compensation Table" below. In 2020, our "named executive officers" and their positions were as follows:

- Reza Zadno, Ph.D., President and Chief Executive Officer;
- Kevin Waters, Senior Vice President, Chief Financial Officer;
- Hisham Shiblaq, Senior Vice President, Commercial Operations; and
- Eric Reuter, Advisor.

Following the departure of our prior chief executive officer in 2019, Mr. Reuter served as our principal executive officer from September 2019 until February 2020, when Dr. Zadno joined our company.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

### 2020 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2020.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Option Awards ($)[2] | Non-Equity Incentive Plan Compensation ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Reza Zadno, Ph.D.[1]<br>President and Chief Executive Officer | 2020 | 437,768 | — | 2,902,634 | 217,384 | — | 3,557,786 |
| Kevin Waters<br>Senior Vice President, Chief Financial Officer | 2020 | 388,130 | 22,000[3] | 169,626 | 155,252 | — | 735,008 |
| Hisham Shiblaq<br>Senior Vice President, Commercial Operations | 2020 | 310,500 | — | 131,770 | 139,725 | — | 581,995 |
| Eric Reuter<br>Advisor | 2020 | 30,000[4] | — | — | — | 42,500[5] | 72,500 |

(1) Dr. Zadno's employment commenced with us in February 2020; therefore, certain amounts for Dr. Zadno, such as base salary, reflect a partial year of service.
(2) Represents the grant date fair value of stock options to purchase shares of our common stock during the year ended December 31,2020 computed in accordance with Financial Accounting Standards Board, or FASB, ASC 718. See Note 8 to our consolidated financial statements for the year ended December 31, 2020 included elsewhere in this prospectus for a description of the assumptions used in valuing our stock options.
(3) Amount represents additional bonus payments to Mr. Waters in August 2020 and December 2020.
(4) Amount represents consulting fees received by Mr. Reuter for his services as our principal executive officer in 2020.
(5) Amount represents fees received by Mr. Reuter for services performed as a member of our board of directors.

### Narrative to Summary Compensation Table

***2020 Salaries***

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

The annual base salaries for Dr. Zadno and Messrs. Waters and Shiblaq for 2020 were $475,000, $388,130 and $310,500, respectively. Mr. Reuter received a consulting fee of $30,000 for consulting services as our principal executive officer in 2020. The actual base salaries earned by our named executive officers for services in 2020 are set forth above in the Summary Compensation Table in the column entitled "Salary."

The 2021 annual base salaries for Dr. Zadno and Messrs. Waters and Shiblaq are $490,000, $388,130 and $350,000, respectively.

***2020 Bonuses***

Our named executive officers are eligible to earn cash bonuses based on the achievement of corporate performance measures for the applicable year. For 2020, Dr. Zadno and Messrs. Waters, and Shiblaq were eligible to receive a target bonus of up to 50%, 40% and 45%, respectively, of their base salaries.

For 2020, annual bonus payments were based in part on the achievement of pre-established objective performance goals, including operational goals, product development and strategy goals, production and innovation goals, and reimbursement, weighted 15%, 30%, 25% and 30%, respectively, of each executive's bonus opportunity. In 2020, we achieved all of the goals. Therefore, our board of directors determined that the corporate performance goals were attained at a level of 100%. The annual cash bonuses actually earned by each named executive officer for 2020 performance are set forth above in the Summary Compensation Table above in the column entitled "Non-Equity Incentive Plan Compensation.

We paid Mr. Waters additional $10,000 and $12,000 bonuses in August 2020 and December 2020, respectively.

***Equity Compensation***

We historically have used stock options as the primary incentive for long-term compensation to our employees (including our named executive officers) because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which generally is set at or above the fair market value of our common stock as of the applicable grant date. Generally, the stock options we grant vest in equal monthly installments over four years following a one-year cliff, subject to the employee's continued service with us as of the vesting date. The equity awards granted to our named executive officers in 2020 are described below.

We currently maintain the Amended and Restated 2008 Stock Plan, or the 2008 Plan, in order to help us attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees and consultants and to promote the success of our company's business. As noted above, we generally offer stock options to certain of our employees, including our named executive officers, and consultants as the long-term incentive component of our compensation program. For additional information about the 2008 Plan, please see the section titled "2008 Stock Plan" below. As mentioned below, in connection with the completion of this offering, no further awards will be granted under the 2008 Plan.

In connection with this offering, our board of directors will adopt, and our stockholders will approve, the 2021 Incentive Award Plan, or the 2021 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and our affiliates, and to enable us to obtain and retain services of these individuals, which we believe is essential to our long-term success. For additional information about the 2021 Plan, please see the section titled "2021 Incentive Award Plan" below.

*2020 Stock Option Awards*

The following table sets forth the stock options granted to our named executive officers in 2020:

| Named Executive Officer | Options Granted |
|---|---|
| Reza Zadno, Ph.D. | 6,370,425 (1) |
| Reza Zadno, Ph.D. | 1,350,071 (2) |
| Kevin Waters | 333,547 (2) |
| Hisham Shiblaq | 300,000 (3) |

(1) This option was granted in February 2020 and vests and becomes exercisable as to 25% of the shares subject to the option on the first anniversary of Dr. Zadno's start date with our company and as to the remaining shares in substantially equal monthly installments thereafter.

(2) These options were granted in August 2020 and each vests and becomes exercisable as to 6/48$^{th}$ of the shares underlying the options on the six month anniversary of the August 1, 2020 vesting commencement date and 1/48$^{th}$ each month thereafter.

(3) This option was granted in December 2020 and vests and becomes exercisable (i) as to 150,000 of the shares underlying the option, monthly over four years and (ii) as to the remaining 150,000 shares, over four years, with 25% of such shares vesting on the first anniversary of the grant date and the remaining shares vesting in substantially equal installments thereafter.

***Other Elements of Compensation***

*Retirement Plans*

We currently maintain a 401(k) retirement savings plan, or the 401(k) plan, for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Internal Revenue Code of 1986, as amended, or the Code, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. We do not provide for matching contributions under the 401(k) plan.

*Employee Benefits*

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

*No Tax Gross-Ups*

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or benefits paid or provided by our company.

**Outstanding Equity Awards at Fiscal Year-End**

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2020. Each equity award listed in the following table was granted under the 2008 Plan and, with respect to Dr. Zadno and Messrs. Waters and Shiblaq, will vest in

full upon a termination of employment either without cause or for good reason, in either case, within 12 months following a change in control.

| | | Option Awards | | | |
|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options Exercisable (#) | Number of Securities Underlying Unexercised Options Unexercisable (#) | Option Exercise Price ($) | Option Expiration Date |
| Reza Zadno, Ph.D. | 2/20/2020[1] | — | 6,370,425 | 0.92 | 2/19/2030 |
| | 8/10/2020[2] | — | 1,350,071 | 1.09 | 8/9/2030 |
| Kevin Waters | 10/23/2018[1] | 669,859 | 566,804 | 0.95 | 10/22/2028 |
| | 12/12/2019[3] | 84,301 | 252,906 | 0.96 | 12/11/2029 |
| | 8/10/2020[2] | — | 333,547 | 1.09 | 8/9/2030 |
| Hisham Shiblaq | 4/5/2019[4] | 410,614 | 488,828 | 0.96 | 4/4/2029 |
| | 12/16/2020[5] | — | 300,000 | 1.09 | 12/15/2030 |
| Eric Reuter | 9/18/2015 | 127,061 | — | 0.28 | 9/17/2025 |
| | 4/26/2018[3] | 83,333 | 41,667 | 0.95 | 4/25/2028 |

_____

(1) These options vest and become exercisable as to 25% of the shares subject to the option on the first anniversary of the vesting commencement date and as to 1/48$^{th}$ of the shares each month thereafter.
(2) These options vest and becomes exercisable as to 6/48$^{th}$ of the shares subject to the option on the six month anniversary of the vesting commencement date and as to 1/48$^{th}$ each month thereafter.
(3) These options vest and become exercisable with respect to 1/48$^{th}$ of the shares subject to the option on each monthly anniversary of the vesting commencement date.
(4) This option vests and becomes exercisable as to 10/46$^{th}$ of the shares subject to the option on the ten-month anniversary of the vesting commencement date and as to 1/46$^{th}$ each month thereafter.
(5) 150,000 shares underlying this option vest and become exercisable as to 25% of such shares subject to the option on the first anniversary of the vesting commencement date and as to 1/48$^{th}$ of the remainder of such shares each month thereafter. The remaining 150,000 shares subject to this option vest and become exercisable with respect to 1/48$^{th}$ of such shares on each monthly anniversary of the vesting commencement date.

**Executive Compensation Arrangements**

***Offer Letters with Reza Zadno, Kevin Waters, and Hisham Shiblaq***

We have entered into employment offer letters with Reza Zadno, Ph. D., Kevin Waters, and Hisham Shiblaq, which were entered into in January 2020, August 2018, and March 2019, respectively.

Pursuant to the offer letters, each of Dr. Zadno and Messrs. Waters, and Shiblaq is entitled to receive a base salary of $475,000, $375,000, and $300,000, respectively and is eligible to receive an annual discretionary bonus, expressed as a target percentage of their base salary (as determined by our board of directors in its sole discretion), subject to the executive's continued employment through the bonus payment date. The 2021 annual base salaries for Dr. Zadno and Messrs. Waters and Shiblaq are $490,000, $388,130 and $350,000, respectively. Pursuant to the offer letters, the target bonuses for Dr. Zadno and Messrs. Waters and Shiblaq are 50%, 35% and 45%, respectively. In addition, each is eligible to participate in the health, welfare, retirement, vacation and other employee benefit plans, practices, policies and programs generally available to similarly situated employees.

Pursuant to the terms of the applicable executive's employment agreement, we granted each executive an option to purchase shares of our common stock (6,370,425 shares for Dr. Zadno, 1,236,663 shares for Mr. Waters, and 899,442 shares for Mr. Shiblaq) in January 2020, August 2018, and March 2019. Further, the offer letters with Mr. Waters and Mr. Shiblaq provide for the opportunity to earn an option to purchase up to an additional 206,111 and 149,907 shares of our common stock by the end of years 2019 and 2020 and 2020 and 2021, respectively, each of which has been granted.

Mr. Waters's offer letter also provides for a severance protection, which was superseded by his Change of Control and Severance Agreement described below.

Each of Dr. Zadno and Messrs. Waters and Shiblaq entered into our standard employee confidential information and assignment agreement as a condition of employment.

*Change of Control and Severance Agreement with Reza Zadno, Ph. D.* We are party to a change of control and severance agreement with Dr. Zadno entered into in February 2020.

Pursuant to the change in control and severance agreement, if Dr. Zadno's employment is terminated by us without "cause" or by the executive for "good reason" within 12 months following a "change of control" (each, as defined in the executive's change of control and severance agreement), he will receive the following severance payments and benefits: (i) continued payments of base salary for 24 months; (ii) payment of 150% of his target annual cash bonus for the year in which his termination occurs; (iii) 100% accelerated vesting and exercisability of all outstanding unvested stock awards then held by him; and (iv) COBRA continuation payments for up to 18 months. If Dr. Zadno's employment is terminated by us without "cause" or by the executive for "good reason" not within the change in control period described above, he will receive the following severance payments and benefits: (a) continued payment of base salary for 12 months; and (b) COBRA continuation payments for up to 12 months.

The severance payments and benefits described above are subject to the executive's timely execution and non-revocation of a release of claims in our favor.

*Change of Control and Severance Agreement with Kevin Waters and Hisham Shiblaq*. We are party to change of control and severance agreement with Kevin Waters and Hisham Shiblaq, each of which was originally entered into in October 2018 and March 2019, respectively, and amended in January 2020.

These agreements provide for the same terms as Dr. Zadno's agreement described above, except if Messrs. Waters's or Shiblaq's employment is terminated by us without "cause" or by the executive for "good reason" within 12 months following a "change of control," the executive will receive the following severance payments and benefits: (i) continued payments of base salary for 18 months or 12 months, respectively; (ii) payment of 150% or 100% of the executive's target annual cash bonus for the year in which his termination occurs, respectively; (iii) 100% accelerated vesting and exercisability of all outstanding unvested stock awards then held by the applicable executive; and (iv) COBRA continuation payments for up to 18 months or 12 months, respectively. If Messrs. Waters's or Shiblaq's employment is terminated by us without "cause" or by the executive for "good reason" not within the change in control period described above, he will receive continued payment of base salary for 6 months.

***2008 Stock Plan***

We maintain the 2008 Plan. A total of 49,471,170 shares of our common stock are reserved for issuance under the 2008 Plan. The 2008 Plan will terminate on June 10, 2031, unless earlier terminated by our board of directors. Following the effectiveness of the 2021 Plan, the 2008 Plan will terminate, and we will not make any further awards under the 2008 Plan. However, any outstanding awards granted under the 2008 Plan will remain outstanding, subject to the terms of the 2008 Plan and applicable award agreements.

*Eligibility and Administration*. Employees and consultants employed or engaged by us or our affiliates are eligible to receive awards under the 2008 Plan. The 2008 Plan is administered by our board of directors, which may delegate its duties and responsibilities as it deems appropriate. The board of directors has the authority to determine who will be granted awards, what type of awards will be granted and in what amount, when and how awards will be granted, the provisions of each award, and the fair market value applicable to an award; to construe and interpret the 2008 Plan; to accelerate the vesting of any award or waive forfeiture restrictions of any award; to approve the form of agreements for use under the 2008 Plan; to modify grants of awards to non-U.S. participants as necessary to recognize differences in local law, tax policies or customs; and to make all other determinations and take all other actions it deems necessary or expedient to promote the best interests of our company and that are not in conflict with the terms of the 2008 Plan.

*Awards*. The 2008 Plan provides for the grant of nonqualified stock options, incentive stock options, and restricted stock awards. Each award under the 2008 Plan is evidenced by a separate agreement between our company and the participant, which details all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. The following types of awards have been granted under the 2008 Plan:

- **Nonqualified Stock Options**. Nonqualified stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. The exercise price of a stock option is fixed by the board of directors and may not be less than 100% of the fair market value of the underlying share on the date of grant. The term of a stock option is determined by our board of directors, but may not exceed ten years. Vesting conditions determined by our board of directors may apply to stock options and may include the occurrence of certain events, the passage of a specified period of time, achievement by us of certain performance goals, and/or other fulfillment of certain conditions.

- **Incentive Stock Options**. Incentive stock options are designed to comply with the provisions of the Code and are subject to specified restrictions contained in the Code applicable to incentive stock options. Among such restrictions, incentive stock options must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the participant's termination of employment, and must be exercised within ten years after the date of grant. In the case of an incentive stock option granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock on the date of grant, the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the incentive stock option must expire on the fifth anniversary of the date of its grant.

*Certain Transactions*. In the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, or a combination or other change in shares of our common stock, our board of directors shall make appropriate and proportionate adjustments to the number and type of shares subject to the 2008 Plan, the number and type of shares that may be issued pursuant to incentive stock options, and the number, type and price per share of stock subject to outstanding awards granted under the 2008 Plan. In the event of a dissolution or liquidation, all outstanding awards will terminate, unless otherwise determined by the board of directors. In the event of a corporate transaction, the board of directors may take one or more of the following actions: (i) arrange for the assumption or substitution of, or adjustment to, each outstanding award by the successor corporation; (ii) accelerate the vesting and exercisability of any award; and (iii) cancel any award to the extent not vested or exercised prior to the corporate transaction in exchange for cash consideration.

*Plan Amendment and Termination*. Our board of directors may suspend or terminate the 2008 Plan or any portion thereof at any time and may amend it from time to time in such respects as our board of directors may deem necessary or advisable, provided that no such amendment shall be made without stockholder approval to the extent such approval is required by applicable law. Further, no such amendment, suspension or termination shall impair the rights of participants under outstanding awards without the consent of the affected participants. As described above, the 2008 Plan will terminate as of the effective date of the 2021 Plan.

***2021 Incentive Award Plan***

In connection with this offering, our board of directors expects to adopt, subject to approval by our stockholders, the 2021 Plan, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2021 Plan, currently contemplated, are summarized below.

*Eligibility and Administration.* Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries, will be eligible to receive awards under the 2021 Plan. Following this offering, the 2021 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator

below), subject to certain limitations that may be imposed under Section 16 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2021 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2021 Plan, including any vesting and vesting acceleration conditions.

*Limitation on Awards and Shares Available*. An aggregate of shares of our common stock are available for issuance under awards granted pursuant to the 2021 Plan, which shares may be authorized but unissued shares, treasury shares or shares purchased in the open market. Notwithstanding anything to the contrary in the 2021 Plan, no more than shares of our common stock may be issued pursuant to the exercise of incentive stock options under the 2021 Plan.

The number of shares available for issuance will be increased by an annual increase on the first day of each calendar year beginning January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) % of the aggregate number of shares of our common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors.

If an award under the 2021 Plan expires, lapses or is terminated, exchanged for or settled for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2021 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2021 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2021 Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2021 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2021 Plan will not reduce the shares available for grant under the 2021 Plan. However, the following shares may not be used again for grant under the 2021 Plan: (i) shares subject to stock appreciation rights, or SARs, that are not issued in connection with the stock settlement of the SAR on exercise, and (ii) shares purchased on the open market with the cash proceeds from the exercise of options.

Awards granted under the 2021 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2021 Plan. The 2021 Plan provides that, commencing with the calendar year following the calendar year in which the effective date of the 2021 Plan occurs, the sum of any cash compensation and the aggregate grant date fair value (determined as of the date of the grant under ASC Topic 718, or any successor thereto) of all awards granted to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed the amount equal to $ .

*Awards.* The 2021 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, RSUs, stock appreciation rights, or SARs, and other stock or cash awards. Certain awards under the 2021 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2021 Plan will be set forth in award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- **Stock Options**. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs

granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions.

- **SARs**. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR may not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction) and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

- **Restricted Stock and RSUs**. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met, and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Settlement of RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

- **Other Stock or Cash-Based Awards**. Other stock or cash-based awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock may be granted under the 2021 Plan. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards.

- **Dividend Equivalent**s. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

*Performance Awards.* Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include but are not limited to: (i) net earnings (either before or after one or more of the following: (a) interest, (b) taxes, (c) depreciation, (d) amortization and (e) non-cash equity-based compensation expense); (ii) gross or net sales or revenue; (iii) net income (either before or after taxes); (iv) adjusted net income; (v) operating earnings or profit; (vi) cash flow (including, but not limited to, operating cash flow and free cash flow); (vii) return on assets; (viii) return on capital; (ix) return on stockholders' equity; (x) total stockholder return; (xi) return on sales; (xii) gross or net profit or operating margin; (xiii) costs; (xiv) funds from operations; (xv) expenses; (xvi) working capital; (xvii) earnings per share; (xviii) adjusted earnings per share; (xix) price per share of our common stock; (xx) regulatory achievements or compliance; (xxi) implementation or completion of critical projects; (xxii) market share; (xxiii) economic value; (xxiv) debt levels or reduction; (xxv) sales-related goals; (xxvi) comparisons with other stock market indices; (xxvii) operating efficiency; (xxviii) employee satisfaction; (xxix) financing and other capital raising transactions; (xxx) recruiting and maintaining personnel; (xxxi) year-end cash; and (xxxii) human capital management goals or environmental, social and governance goals, any of which may be measured either in absolute terms for us or any operating unit of our company or as compared to any incremental increase or decrease or as compared to results of a peer group or to market performance indicators or indices.

*Certain Transactions.* The plan administrator has broad discretion to take action under the 2021 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events

affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2021 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2021 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards will become fully vested and exercisable in connection with the transaction. Upon or in anticipation of a change of control, the plan administrator may cause any outstanding awards to terminate at a specified time in the future and give the participant the right to exercise such awards during a period of time determined by the plan administrator in its sole discretion. Individual award agreements may provide for additional accelerated vesting and payment provisions.

*Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments.* The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw- back policy implemented by our company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2021 Plan are generally non-transferable prior to vesting, and are exercisable only by the participant. With regard to tax withholding, exercise price and purchase price obligations arising in connection with awards under the 2021 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable.

*Plan Amendment and Termination.* Our board of directors may amend or terminate the 2021 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2021 Plan. Stockholder approval is not required for any amendment that "reprices" any stock option or SAR, or cancels any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. No award may be granted pursuant to the 2021 Plan after the tenth anniversary of the earlier of the date on which our stockholders approved the 2021 Plan or the date on which our board of directors adopted the 2021 Plan.

***2021 Employee Stock Purchase Plan***

In connection with this offering, our board of directors expects to adopt, subject to stockholder approval, the 2021 Employee Stock Purchase Plan, or ESPP. The material terms of the ESPP, as currently contemplated, are summarized below.

*Shares Available; Administration.* We expect a total of shares of our common stock to be initially reserved for issuance under our ESPP. In addition, we expect that the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2022 and ending in 2031, by an amount equal to the lesser of: (i) % of the aggregate number of shares of our common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors. In no event will more than shares of our common stock be available for issuance under the ESPP.

Our board of directors or a committee designated by our board of directors will have authority to interpret the terms of the ESPP and determine eligibility of participants. The compensation committee will be the administrator of the ESPP.

*Eligibility*. The plan administrator may designate certain of our subsidiaries as participating "designated subsidiaries" in the ESPP and may change these designations from time to time. Employees of our company and our designated subsidiaries are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under the ESPP if such employee, immediately after the grant, would own (directly or through

attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

If the grant of a purchase right under the ESPP to any eligible employee who is a citizen or resident of a foreign jurisdiction would be prohibited under the laws of such foreign jurisdiction or the grant of a purchase right to such employee in compliance with the laws of such foreign jurisdiction would cause the ESPP to violate the requirements of Section 423 of the Code, as determined by the plan administrator in its sole discretion, such employee will not be permitted to participate in the ESPP.

Eligible employees become participants in the ESPP by enrolling and authorizing payroll deductions by the deadline established by the plan administrator prior to the relevant offering date. Directors who are not employees, as well as consultants, are not eligible to participate. Employees who choose to not participate, or are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

*Participation in an Offering*. We intend for the ESPP to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP will permit participants to purchase our common stock through payroll deductions of up to 15% of their eligible compensation, unless otherwise determined by the plan administrator, which will include a participant's gross base compensation for services to us, including overtime payments, periodic bonuses, and sales commissions, and excluding one-time bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be shares for an offering period and/or a purchase period. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant automatically will be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period.

Participants may voluntarily end their participation in the ESPP at any time at least two weeks prior to the end of the applicable offering period (or such longer or shorter period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

*Transferability*. A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided in the ESPP.

*Certain Transactions*. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, (iii) the adjustment in the number and type of

shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2021 Plan.

*Plan Amendment; Termination.* The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP must be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the ESPP in any manner that would be considered the adoption of a new plan within the meaning of Treasury regulation Section 1.423-2(c)(4), or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

**Non- Employee Director Compensation**

The following table summarizes compensation received by our non-employee directors during the year ended December 31, 2020. Dr. Zadno, our President and Chief Executive Officer, is also a member of our board of directors, but does not receive any additional compensation for his service as a director in addition to the compensation he receives as an employee. See the section titled "Executive Compensation" for more information. In addition to serving on our board of directors, Mr. Reuter served as our Advisor from September 2019 to February 2020 and received additional compensation for such service. See the section titled "Executive Compensation" for more information.

In 2020, each non-employee director received an annual cash retainer equal to $35,000. In addition, Dr. Perkins received an annual retainer of $12,500 for his services as Chairman of our board of directors, and Messrs. Reuter and Wood, Dr. Krummel received an annual retainer of $7,500 for their services as committee chairs. We have reimbursed, and will continue to reimburse, any non-employee director for his or her reasonable out-of-pocket expenses incurred in attending board of director and committee meetings.

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($)[5] | Total ($) |
|---|---|---|---|
| Rodney Perkins, M.D. | 47,500 | — | 47,500 |
| Antal Desai | — | — | — |
| Taylor Harris[1] | 1,848 | 199,146 | 200,994 |
| Thomas Krummel, M.D. | 42,500 | — | 42,500 |
| Fred Moll, M.D. | 35,000 | — | 35,000 |
| Eric Reuter[2] | — | — | — |
| Colby Wood | 42,500 | — | 42,500 |
| Noam Krantz(3) | — | — | — |
| William Facteau[4] | 41,666 | — | 41,666 |

(1) Mr. Harris was elected to our board of directors in December 2020. We paid Mr. Harris a pro-rata fee for his December 2020 board service.
(2) Compensation received by Mr. Reuter during the year ended December 31, 2020 is disclosed in the "Summary Compensation Table" above.
(3) Mr. Krantz resigned from our board of directors on June 25, 2021.
(4) Mr. Facteau resigned from our board of directors on October 30, 2020.
(5) Represents the grant date fair value of stock options to purchase shares of our common stock during the year ended December 31, 2020 computed in accordance with FASB ASC 718. See Note 8 to our consolidated financial statements for the year ended December 31, 2020 included elsewhere in this prospectus for a description of the assumptions used in valuing our stock options.

The table below shows the aggregate numbers of option awards (whether exercisable and unexercisable) held as of December 31, 2020 by each non-employee director who served in 2020.

| Name | Options Outstanding at Fiscal Year End |
|---|---|
| Rodney Perkins, M.D. | 689,150 |
| Antal Desai | 252,061 |
| Taylor Harris | 453,500 |
| Thomas Krummel, M.D. | 174,766 |
| Fred Moll, M.D. | 502,061 |
| Eric Reuter[(1)] | — |
| Colby Wood | 482,061 |
| Noam Krantz | — |
| William Facteau | 263,541 |

(1) The number of option awards held as of December 31, 2020 by Mr. Reuter is disclosed in the section titled "Outstanding Equity Awards at Fiscal Year End."

In connection with this offering, our board of directors expects to approve a non-employee director compensation policy, which will take effect following the completion of this offering.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of , 2021, and as adjusted to reflect the sale of the shares of common stock offered by us in this offering for:

- each person or entity who is known by us to beneficially own more than 5% of our common stock;
- each of our directors and named executive officers; and
- all of our directors and executive officers as a group.

Information with respect to beneficial ownership has been furnished to us by each director, executive officer or stockholder listed in the table below, as the case may be. The amounts and percentages of our common stock beneficially owned are reported on the basis of rules of the SEC governing the determination of beneficial ownership of securities. Under these rules, a person is deemed to be a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or direct the voting of such security, or "investment power," which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has a right to acquire beneficial ownership within 60 days after , 2021. More than one person may be deemed to be a beneficial owner of the same securities.

Percentage of beneficial ownership prior to this offering is based on shares of common stock outstanding as of , 2021. Percentage of beneficial ownership after this offering is based on shares of common stock outstanding after giving effect to the sale by us of the shares of common stock offered hereby. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable or will otherwise vest within 60 days of , 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under

applicable law. Unless otherwise indicated below, the address for each person or entity listed below is c/o PROCEPT BioRobotics Corporation, 900 Island Drive, Redwood City, California 94065.

| Name of Beneficial Owner | Total Shares Beneficially Owned | Percentage of Shares Beneficially Owned | |
|---|---|---|---|
| | | Before the Offering (%) | After the Offering (%) |
| **5% Stockholders** | | | |
| Viking Global Opportunities Illiquid Investments Sub-Master LP[1] | | | |
| Entity Associated with CPMG, Inc.[2] | | | |
| Entities Associated with Fidelity[3] | | | |
| Nikolai Aljuri, Ph.D.[4] | | | |
| **Named Executive Officers and Directors** | | | |
| Reza Zadno, Ph.D. | | | |
| Kevin Waters | | | |
| Alaleh Nouri | | | |
| Hisham Shiblaq | | | |
| Frederic Moll, M.D. | | | |
| Antal Desai | | | |
| Amy Dodrill | | | |
| Taylor Harris | | | |
| Thomas Krummel M.D. | | | |
| Rodney Perkins M.D. | | | |
| Eric Reuter | | | |
| Lisa Skeete Tatum | | | |
| Colby Wood | | | |
| **All Executive Officers and Directors as a Group (13 individuals)** | | | |

* Represents beneficial ownership of less than 1% of our outstanding common stock. Represents beneficial ownership of less than 1% of our outstanding common stock.

(1)

(2) Consists of (i) shares of common stock, (ii) shares of common stock issuable upon conversion of Series D redeemable convertible preferred stock, (iii) shares of common stock issuable upon conversion of Series E redeemable convertible preferred stock, (iv) shares of common stock issuable upon conversion of Series F redeemable convertible preferred stock and (v) shares of common stock issuable upon conversion of Series G redeemable convertible preferred stock held by White Tailed Ptarmigan, LP. CPMG, Inc. is the general partner of White Tailed Ptarmigan, LP and has voting and investment control over the shares beneficially owned by the White Tailed Ptarmigan, LP. Antal Desai, a member of our board of directors, is a Partner of CPMG, Inc. and may be deemed to share voting and investment power with respect to the shares beneficially owned by White Tailed Ptarmigan, LP. Mr. Desai disclaims beneficial ownership of the shares beneficially owned by White Tailed Ptarmigan, LP except to the extent of any pecuniary interest therein. The business address of the entities referenced in this footnote is 2000 McKinney Ave, Suite 2125, Dallas, Texas 75201.

(3)

(4)

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions to which we were a participant since January 1, 2018 in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our executive officers, directors or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

### Series G Financing

In June 2021, we completed the sale of an aggregate of 21,125,882 shares of our Series G redeemable convertible preferred stock at a purchase price of $4.0235 per share for an aggregate purchase price of $85.0 million. Each share of our Series G redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the closing of this offering in accordance with our certificate of incorporation.

The following table summarizes the Series G redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock, our board of directors and any entities affiliated with our executive officers or a member of our board of directors.

| Participants[1] | Shares of Series G Redeemable Convertible Preferred Stock | Aggregate Purchase Price |
|---|---|---|
| | | (in thousands) |
| Viking Global Opportunities Illiquid Investments Sub-Master LP | 540,252 | $ 2,174 |
| Entity Associated with CPMG, Inc. | 1,292,977 | $ 5,202 |
| Frederic Moll | 285,820 | $ 1,150 |
| Rodney Perkins M.D.[2] | 537,241 | $ 2,162 |
| Entities Associated with Fidelity[3] | 12,427,114 | $ 50,000 |
| Nikolai Aljuri, Ph.D.[4] | 372,809 | $ 1,500 |

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled “Principal Stockholders.”
(2) Shares of Series G redeemable convertible preferred stock are held by The Perkins Family Revocable Trust dated February 28, 1986.
(3) Consists of (i) 515,197 shares of Series G redeemable convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, (ii) 2,461,674 shares of Series G redeemable convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (iii) 2,715,902 shares of Series G redeemable convertible preferred stock held by Fidelity Growth Company Commingled Pool, (iv) 520,784 shares of Series G redeemable convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund and (v) 6,213,557 shares of Series G redeemable convertible preferred stock held by Fidelity Select Portfolios: Select Medical Technology and Devices Portfolio.
(4) Shares held by the Aljuri Family Trust u/a/d 8-22-2012.

### Series F Financing

Between July 2020 and August 2020, we completed the sale of an aggregate of 24,828,160 shares of our Series F redeemable convertible preferred stock at a purchase price of $3.1006 per share for an aggregate purchase price of $77.0 million. Each share of our Series F redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the closing of this offering in accordance with our certificate of incorporation.

The following table summarizes the Series F redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock, our board of directors and any entities affiliated with our executive officers or a member of our board of directors.

| | Initial Closing | | Second Closing | | | |
|---|---|---|---|---|---|---|
| Participants[1] | Shares of Series F Redeemable Convertible Preferred Stock | Aggregate Purchase Price | Shares of Series F Redeemable Convertible Preferred Stock | Aggregate Purchase Price | Total Shares Purchased | Aggregate Purchase Price |
| | | (in thousands) | | (in thousands) | | (in thousands) |
| Viking Global Opportunities Illiquid Investments Sub-Master LP | 3,225,182 | $ 10,000 | — | $ — | 3,225,182 | $ 10,000 |
| Entity Associated with CPMG, Inc. | 9,659,805 | $ 29,951 | 129,007 | $ 400 | 9,788,812 | $ 30,351 |
| Antal Desai[2] | 40,637 | $ 126 | — | $ — | 40,637 | $ 126 |
| Frederic Moll | 80,630 | $ 250 | — | $ — | 80,630 | $ 250 |

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled "Principal Stockholders."
(2) Includes 5,160 shares of Series F redeemable convertible preferred stock purchased by the Desai 2010 Children's trust.

**Series E Financing**

In February 2018, we completed the sale of an aggregate of 39,968,857 shares of our Series E redeemable convertible preferred stock at a purchase price of $2.89 per share for an aggregate purchase price of $115.5 million. Each share of our Series E redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the closing of this offering in accordance with our certificate of incorporation.

The following table summarizes the Series E redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock, our board of directors and any entities affiliated with our executive officers or a member of our board of directors.

| Participants[1] | Shares of Series E Redeemable Convertible Preferred Stock | Aggregate Purchase Price |
|---|---|---|
| | | (in thousands) |
| Viking Global Opportunities Illiquid Investments Sub-Master LP | 17,647,058 | $ 51,000 |
| Entity Associated with CPMG, Inc. | 14,258,827 | $ 41,208[3] |
| Taylor Harris[2] | 136,167 | $ 354[4] |
| Antal Desai | 77,375[5] | $ 211[6] |

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled "Principal Stockholders."
(2) Series E redeemable convertible preferred stock are held in the Harris Trust Dated 3/10/2016.
(3) Amount shown includes $5,089,632 related to the cancellation of debt.
(4) Amounts shown relate to the cancellation of debt.
(5) Includes (i) 2,984 shares of Series E redeemable convertible preferred stock held by the Desai 2010 Children's Trust and (ii) 39,789 shares of Series E redeemable convertible preferred stock held by The 2:22 DNA Trust.
(6) Amount shown includes $111,255 related to the cancellation of debt.

**Amended and Restated Investor Rights Agreement**

We are party to an amended and restated investor rights agreement with certain holders of our redeemable convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors. The amended and restated investor rights agreement grants rights to certain holders, including certain registration rights with respect to the registrable securities held by them,

and also imposes certain affirmative obligations on us, including with respect to the furnishing of financial statements and information to the holders. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

As a result of this offering, most of the covenants and restrictions set forth in the amended and restated investor rights agreement that apply to us will terminate and we will remain obligated to comply with reporting requirements under the Exchange Act. The provisions relating registration rights included in the amended and restated investor rights agreement will not terminate as a result of this offering.

**Voting Agreement**

We are party to the Series F voting agreement with certain holders of our redeemable convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors. Pursuant to the Series F voting agreement, these holders have agreed to vote in a certain way on certain matters, including with respect to the election of directors.

The Series F voting agreement will terminate by its terms in connection with the completion of this offering and none of our stockholders will have any continuing voting rights, including special rights regarding the election or designation of members of our board of directors, following this offering.

**Amended and Restated Right of First Refusal and Co-Sale Agreement**

We are party to an amended and restated first refusal and co-sale agreement with certain holders of our redeemable convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors, pursuant to which we have a right of first refusal and holders of our common stock that are party to the amended and restated first refusal and co-sale agreement have a right of first refusal and a co-sale right.

The amended and restated first refusal and co-sale agreement will terminate in connection with the completion of this offering.

**License Agreement with AquaBeam LLC**

In September 2019, we entered into the AquaBeam License Agreement, with AquaBeam, which is affiliated with our co-founders. Pursuant to the AquaBeam License Agreement, AquaBeam grants us a worldwide, exclusive (even as to AquaBeam), sublicensable, royalty-free license under the AquaBeam patents and to all other patent rights owned by AquaBeam, which are filed on or before the earlier of October 28, 2021 and the date on which we are acquired by a third party, that claim certain technology related to delivering energy to tissues by directing a liquid fluid stream, or together with AquaBeam Patents, Licensed Patents, in the field of urology, or Field. Pursuant to the AquaBeam License Agreement, and subject to the terms therein, we grant AquaBeam a worldwide, exclusive (even as to us), sublicensable, royalty-free license under certain of our patents rights, which are filed on or before the earlier of October 28, 2021 and the date on which AquaBeam is acquired by a third party, that claim certain technology related to delivering energy to tissues by directing a liquid fluid stream, or PROCEPT Patents, outside the Field.

If AquaBeam desires to grant a license under the Licensed Patents to any third party outside the Field on or before the earlier of October 28, 2021 or the date on which AquaBeam is acquired by a third party, we have the first right to negotiate such license grant pursuant to the terms of the AquaBeam License Agreement.

AquaBeam has the first right to prosecute and maintain the Licensed Patents and we have the right to step-in if AquaBeam declines or fails to prosecute or maintain any of the Licensed Patents. We have the first right to prosecute and maintain the PROCEPT Patents. We have the first right to enforce the Licensed Patents and the PROCEPT Patents if a third party infringes on any such patents in the Field, provided, if such third party infringes the Licensed Patents or the PROCEPT Patents both in and outside of the Field, or Cross-Field Infringement, and AquaBeam or any of its other licensees under the Licensed Patents or the PROCEPT Patents are developing or commercializing products that are covered by the infringed Licensed Patents or the PROCEPT Patents, then

AquaBeam and we will discuss which party will control the enforcement action with respect to such Cross-Field Infringement.

The AquaBeam License Agreement will remain in full force and effect on a country-by-country basis until the last to expire of the Licensed Patents and the PROCEPT Patents in such country. The AquaBeam Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 90 days (or 30 days for payment related breaches), or bankruptcy of the other party.

**Indemnification Agreements**

Our amended and restated bylaws, as will be in effect following this offering, provide that we will indemnify our directors and officers to the fullest extent permitted by the DGCL, subject to certain exceptions contained in our amended and restated bylaws. In addition, our amended and restated certificate of incorporation, as will be in effect following this offering, will provide that our directors will not be liable for monetary damages for breach of fiduciary duty.

Prior to the closing of this offering, we will enter into indemnification agreements with each of our executive officers and directors. The indemnification agreements will provide the indemnitees with contractual rights to indemnification, and expense advancement and reimbursement, to the fullest extent permitted under the DGCL, subject to certain exceptions contained in those agreements.

There is no pending litigation or proceeding naming any of our directors or officers for which indemnification is being sought, and we are not aware of any pending litigation that may result in claims for indemnification by any director or executive officer.

**Our Policy Regarding Related Party Transactions**

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interests or improper valuation (or the perception thereof). In connection with this offering, our board of directors intends to adopt a written policy on transactions with related persons that is in conformity with the requirements for issuers having publicly held common stock that is listed on the Nasdaq Global Market. Under such policy:

- any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by a committee of the board of directors composed solely of independent directors who are disinterested or by the disinterested members of the board of directors; and
- any employment relationship or transaction involving an executive officer and any related compensation must be approved by the compensation committee of the board of directors or recommended by the compensation committee to the board of directors for its approval.

In connection with the review and approval or ratification of a related person transaction:

- management must disclose to the committee or disinterested directors, as applicable, the name of the related person and the basis on which the person is a related person, the material terms of the related person transaction, including the approximate dollar value of the amount involved in the transaction and all the material facts as to the related person's direct or indirect interest in, or relationship to, the related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction complies with the terms of our agreements governing our material outstanding indebtedness that limit or restrict our ability to enter into a related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction will be required to be disclosed in our applicable filings under the Securities Act or the Exchange Act, and related rules, and, to the extent required to be disclosed, management must ensure that the related person transaction is disclosed in accordance with such Acts and related rules; and

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction constitutes a "personal loan" for purposes of Section 402 of the Sarbanes-Oxley Act.

In addition, the related person transaction policy will provide that the committee or disinterested directors, as applicable, in connection with any approval or ratification of a related person transaction involving a non-employee director or director nominee, should consider whether such transaction would compromise the director or director nominee's status as an "independent," or "outside" director, as applicable, under the rules and regulations of the SEC, the Nasdaq listing standards and the Code.

## DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part.

### General

Upon the closing of this offering, our authorized capital stock will consist of shares, all with a par value of $0.00001 per share, of which:

- shares are designated as common stock; and
- shares are designated as preferred stock.

### Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

### Preferred Stock

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

### Registration Rights

Our amended and restated investor rights agreement grants the parties thereto certain registration rights in respect of the “registrable securities” held by them, which securities include (i) the shares of our common stock issued upon the conversion of shares of our redeemable convertible preferred stock and warrants (ii) the common stock held by the founders and affiliates of the founders, (iii) any common stock of the company (issued or issuable upon the conversion or exercise of any warrant, right or other security which is issued as) a dividend 0r other distribution with respect to, or in exchange for or in replacement of, such above described securities. Notwithstanding the foregoing, registrable securities does not include any securities (a) sold by a person to the public either pursuant to a registration statement or Rule 144 or (b) sold in a private transaction in which the

transferor's rights are not assigned. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the amended and restated investor rights agreement, we will pay expenses relating to such registrations and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The amended and restated investor rights agreement also includes customary indemnification and procedural terms.

Holders of our outstanding shares of common and preferred stock, which represents approximately % of our outstanding shares before the offering, are entitled to registration rights pursuant to the amended and restated investor rights agreement. These registration rights will expire on the third anniversary of this offering or, with respect to each stockholder following the completion of this offering, at such time as such stockholder can sell all of its registrable securities pursuant to Rule 144(b)(1)(i) of the Securities Act or holds one percent or less of our outstanding common stock and all of such stockholder's registrable securities can be sold in any ninety day period without registration pursuant to Rule 144 of the Securities Act.

***Demand Registration Rights***

The amended and restated investor rights agreement provides that, at any time beginning on the 180th day after the closing of this offering, holders of not less than twenty five percent of the registrable securities then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement to register their registrable securities if the aggregate offering price to the public would exceed $7.5 million. Following such a request, we will as soon as practicable, but in any event no more than 100 days, use our best efforts to effect such registration. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the amended and restated investor rights agreement may request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated offering price would exceed $3.0 million.

***Piggyback Registration Rights***

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the amended and restated investor rights agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to (i) a registration relating solely to the employee benefits plans, (ii) a registration relating to the offer and sale of debt securities or (iii) a registration relating to a corporate reorganization transaction related to the issuance or resale of securities in such a transaction, the stockholders party to the amended and restated investor rights agreement will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

**Anti-Takeover Provisions**

***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws, which will be in effect upon the closing of this offering, will provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our board of directors, the chair of our board of directors, or our chief executive officer.

Our amended and restated certificate of incorporation will further provide that, immediately after this offering, the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and

two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Our amended and restated certificate of incorporation will further provide that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms, and will give our board of directors the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director.

Finally, our amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws; or as to which the Delaware General Corporation Law of the State of Delaware confers jurisdiction to the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim against us governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Under the Securities Act, federal and state 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. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a future court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

The foregoing provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

**Section 203 of the Delaware General Corporation Law**

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

before such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or on or after such date, the business combination is approved by our board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

**Limitations on Liability and Indemnification Matters**

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, will provide that we will indemnify each of our directors and executive officers to the fullest extent permitted by the DGCL. We have entered into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law. Further, pursuant to our indemnification agreements and directors’ and officers’ liability insurance, our directors and executive officers are indemnified and insured against the cost of defense, settlement or payment of a judgment under certain circumstances. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation will include provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be . The transfer agent and registrar’s address is .

**Stock Exchange Listing**

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “PRCT.”

## SHARES ELIGIBLE FOR FUTURE SALE

The sale of a substantial amount of our common stock in the public market after this offering could adversely affect the prevailing market price of our common stock. Furthermore, over % of our common stock outstanding prior to the consummation of this offering will be subject to the contractual and legal restrictions on resale described below. The sale of a substantial amount of common stock in the public market after these restrictions lapse, or the expectation that such a sale may occur, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Upon consummation of this offering, based on shares outstanding as of June 30, 2021, we expect to have outstanding an aggregate of shares of our common stock, assuming no exercise of outstanding options and assuming that the underwriters have not exercised their option to purchase additional shares. All of the shares of common stock sold in this offering will be freely transferable without restriction or further registration under the Securities Act by persons other than "affiliates," as that term is defined in Rule 144 under the Securities Act. Generally, the balance of our outstanding shares of common stock are "restricted securities" within the meaning of Rule 144 under the Securities Act, and the sale of those shares will be subject to the limitations and restrictions that are described below. Shares of our common stock that are not restricted securities and are purchased by our affiliates will be "control securities" under Rule 144. Restricted securities may be sold in the public market only if registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act. These rules are summarized below. Control securities may be sold in the public market subject to the restrictions set forth in Rule 144, other than the holding period requirement.

Upon the expiration of the lock-up agreements described below, 180 days after the date of this prospectus, and subject to the provisions of Rule 144, an additional shares will be available for sale in the public market. The sale of these restricted securities is subject, in the case of shares held by affiliates, to the volume restrictions contained in Rule 144.

### Lock-Up Agreements

In connection with this offering, we and our executive officers and directors and substantially all of our existing security holders have agreed with the underwriters not to, among other things and subject to certain exceptions, sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Goldman Sachs & Co. LLC, subject to certain limited exceptions. This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### Rule 144

In general, under Rule 144 as in effect on the date of this prospectus, beginning 90 days after the consummation of this offering, a person who is an affiliate, and who has beneficially owned our common stock for at least six months, is entitled to sell in any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately million shares immediately after consummation of this offering; or
- the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales by our affiliates under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. An "affiliate" is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with an issuer.

Under Rule 144, a person who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months, would be

entitled to sell those shares subject only to availability of current public information about us, and after beneficially owning such shares for at least twelve months, would be entitled to sell an unlimited number of shares without restriction. To the extent that our affiliates sell their common stock, other than pursuant to Rule 144 or a registration statement, the purchaser's holding period for the purpose of effecting a sale under Rule 144 commences on the date of transfer from the affiliate.

**Rule 701**

In general, under Rule 701 as in effect on the date of this prospectus, any of our employees, directors, officers, consultants or advisors who purchased shares from us in reliance on Rule 701 in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering, or who purchased shares from us after that date upon the exercise of options granted before that date, are eligible to resell such shares 90 days after the effective date of this offering in reliance upon Rule 144. If such person is not an affiliate, such sale may be made subject only to the manner of sale provisions of Rule 144. If such a person is an affiliate, such sale may be made under Rule 144 without compliance with the holding period requirement, but subject to the other Rule 144 restrictions described above. However, substantially all Rule 701 shares are subject to lock-up agreements as described above and will become eligible for sale in compliance with Rule 144 only upon the expiration of the restrictions set forth in those agreements.

**Stock Plans**

We intend to file a registration statement or statements on Form S-8 under the Securities Act covering shares of common stock reserved for issuance under our 2021 Plan and ESPP and pursuant to all outstanding option grants made prior to this offering under the 2008 Plan. These registration statements are expected to be filed as soon as practicable after the closing date of this offering. Shares issued upon the exercise of stock options after the effective date of the applicable Form S-8 registration statement will be eligible for resale in the public market without restriction, subject to Rule 144 limitations applicable to affiliates and the lock-up agreements described above.

**Registration Rights**

Following this offering, some of our stockholders will, under some circumstances, have the right to require us to register their shares for future sale. See the section titled "Certain Relationships and Related Party Transactions—Amended and Restated Investor Rights Agreement."

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS**

**ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

**Definition of a Non-U.S. Holder**

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

**Distributions**

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

**Sale or Other Taxable Disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

**Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

**Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## UNDERWRITING

BofA Securities, Inc. and Goldman Sachs & Co. LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

| Underwriter | Number of Shares |
|---|---|
| BofA Securities, Inc. | |
| Goldman Sachs & Co. LLC | |
| Cowen and Company, LLC | |
| Guggenheim Securities LLC | |
| SVB Leerink LLC | |
| Total | |

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

| | | Total | |
|---|---|---|---|
| | Per Share | Without Option | With Option |
| Public offering price | $ | $ | $ |
| Underwriting discounts and commissions | $ | $ | $ |
| Proceeds, before expenses, to us | $ | $ | $ |

The expenses of the offering, not including the underwriting discounts and commissions, payable by us are estimated to be approximately $ . We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $ .

**Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

**No Sales of Similar Securities**

We, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Goldman Sachs & Co. LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

**Listing**

We intend to apply to list the shares of our common stock on the Nasdaq Global Market under the symbol "PRCT."

**Determination of Offering Price**

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and

- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

**Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

**Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

**Other Relationships**

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**European Economic Area**

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

**Notice to Prospective Investors in the United Kingdom**

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

**Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

**Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

**Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

**Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

**Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

**Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA,
- where no consideration is or will be given for the transfer,

- where the transfer is by operation of law, or
- as specified in Section 276(7) of the SFA.

In connection with Section 309B of the SFA and the Capital Markets Products, or CMP, Regulations 2018, the shares are prescribed capital markets products (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in Monetary Authority of Singapore Notice SFA 04-N12: Notice on the Sale of Investment Products and Monetary Authority of Singapore Notice FAA-N16: Notice on Recommendations on Investment Products).

**Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. The validity of the shares of common stock offered hereby will be passed upon for the underwriters by Cooley LLP.

## EXPERTS

The financial statements as of December 31, 2019 and December 31, 2020 and for each of the two years in the period ended December 31, 2020 included in this Prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and its exhibits. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents. A copy of the registration statement and its exhibits may be obtained from the SEC upon the payment of fees prescribed by it. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding companies that file electronically with it.

We are not currently subject to the informational requirements of the Exchange Act. Upon completion of this offering, we will become subject to the information and periodic and current reporting requirements of the Exchange Act, and in accordance therewith, will file periodic and current reports, proxy statements and other information with the SEC. The registration statement, such periodic and current reports and other information can be obtained electronically by means of the SEC's website at *www.sec.gov*.

**PROCEPT BioRobotics Corporation**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2019 and 2020**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of PROCEPT BioRobotics Corporation

***Opinion on the Consolidated Financial Statements***

We have audited the accompanying consolidated balance sheets of PROCEPT BioRobotics Corporation and its subsidiaries (the "Company") as of December 31, 2019 and 2020, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Change in Accounting Principle*

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2020.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

June 25, 2021

We have served as the Company's auditor since 2020.

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

| | December 31, | |
|---|---|---|
| | **2019** | **2020** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 42,021 | $ 100,130 |
| Accounts receivable, net | 1,099 | 1,549 |
| Inventory | 6,284 | 6,924 |
| Prepaid expenses and other current assets | 1,332 | 1,653 |
| Total current assets | 50,736 | 110,256 |
| Restricted cash | 691 | 777 |
| Property and equipment, net | 8,273 | 8,274 |
| Operating lease right-of-use assets, net | — | 4,641 |
| Intangibles asset, net | 2,295 | 2,023 |
| Total assets | $ 61,995 | $ 125,971 |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,444 | $ 1,240 |
| Accrued compensation | 2,338 | 4,640 |
| Note payable – current portion | — | 4,551 |
| Operating lease – current portion | — | 1,708 |
| Convertible preferred stock warrant liability | 870 | 177 |
| Other current liabilities | 2,138 | 2,210 |
| Total current liabilities | 6,790 | 14,526 |
| Note payable – non-current portion | 23,224 | 44,407 |
| Operating lease – non-current portion | — | 4,096 |
| Loan facility derivative liability | 1,482 | 1,782 |
| Deferred rent – non-current portion | 1,068 | — |
| Other non-current liabilities | 200 | 200 |
| Total liabilities | 32,764 | 65,011 |
| Commitments and contingencies (see Note 9) | | |
| Redeemable convertible preferred stock issuable in series, $0.001 par value; | | |
| Authorized shares: 103,292 and 128,174, at December 31, 2019 and 2020, respectively | | |
| Issued and outstanding shares: 99,739 and 120,661 at December 31, 2019 and 2020, respectively | | |
| Aggregate liquidation preference: $174,994 and $245,768 at December 31, 2019 and 2020, respectively | 173,068 | 243,854 |
| Stockholders' deficit: | | |
| Common stock, $0.001 par value; | | |
| Authorized shares: 152,500 and 190,000 at December 31, 2019 and 2020, respectively | | |
| Issued and outstanding shares: 10,879 and 22,387 at December 31, 2019 and 2020, respectively | 11 | 22 |
| Additional paid-in capital | 4,797 | 18,766 |
| Accumulated other comprehensive income (loss) | 4 | (14) |
| Accumulated deficit | (148,649) | (201,668) |
| Total stockholders' deficit | (143,848) | (182,916) |
| Total liabilities, convertible redeemable preferred stock and stockholders' deficit | $ 61,995 | $ 125,971 |

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

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

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Revenue | $ 6,169 | $ 7,717 |
| Cost of sales | 8,054 | 8,972 |
| Gross profit | (1,885) | (1,255) |
| Operating expenses: | | |
| Research and development | 13,147 | 16,275 |
| Selling, general and administrative | 28,518 | 30,272 |
| Total operating expenses | 41,665 | 46,547 |
| Loss from operations | (43,550) | (47,802) |
| Interest expense | (724) | (5,261) |
| Interest and other income, net | 2,299 | 44 |
| Net loss | $ (41,975) | $ (53,019) |
| Net loss per share, basic and diluted | $ (4.00) | $ (3.05) |
| Weighted-average common shares used to compute net loss per share attributable to common shareholders, basic and diluted | 10,486 | 17,398 |
| Other comprehensive loss: | | |
| Unrealized loss on cash equivalents | (239) | (18) |
| Comprehensive loss | $ (42,214) | $ (53,037) |

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

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

| | 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, 2018 | 98,347 | $ 171,275 | 9,790 | $ 10 | $ 2,503 | $ 243 | $ (106,674) | $ (103,918) |
| Issuance upon exercise of warrants | 1,392 | 1,793 | — | — | — | — | — | — |
| Issuance upon exercise of options | — | — | 1,089 | 1 | 300 | — | — | 301 |
| Stock-based compensation expense | — | — | — | — | 1,994 | — | — | 1,994 |
| Unrealized loss on cash equivalents | — | — | — | — | — | (239) | — | (239) |
| Net loss | — | — | — | — | — | — | (41,975) | (41,975) |
| Balance at December 31, 2019 | 99,739 | 173,068 | 10,879 | 11 | 4,797 | 4 | (148,649) | (143,837) |
| Conversion of preferred stock to common stock | (7,000) | (9,520) | 7,000 | 7 | 9,513 | — | — | 9,520 |
| Issuance upon exercise of warrants | 3,094 | 3,818 | 58 | — | 11 | — | — | 11 |
| Issuance of preferred stock, net of issuance costs | 24,828 | 76,488 | — | — | — | — | — | — |
| Issuance upon exercise of options | — | — | 4,450 | 4 | 2,272 | — | — | 2,276 |
| Stock-based compensation expense | — | — | — | — | 2,173 | — | — | 2,173 |
| Unrealized loss on cash equivalents | — | — | — | — | — | (18) | — | (18) |
| Net loss | — | — | — | — | — | — | (53,019) | (53,019) |
| Balance at December 31, 2020 | 120,661 | $ 243,854 | 22,387 | $ 22 | $ 18,766 | $ (14) | $ (201,668) | $ (182,894) |

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

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

| | Year Ended December 31, | |
|---|---|---|
| | **2019** | **2020** |
| Cash flows from operating activities: | | |
| Net loss | $ (41,975) | $ (53,019) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 1,494 | 2,860 |
| Stock-based compensation expense | 1,994 | 2,173 |
| Change in fair value of preferred stock warrants and derivative liability | (1,196) | 114 |
| Non-cash lease expense | — | (157) |
| Amortization of net investment discount | (603) | — |
| Other non-cash expense | — | 169 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 522 | (511) |
| Inventory | (5,074) | (3,105) |
| Prepaid expenses and other current assets | 556 | (339) |
| Accounts payable | (260) | (205) |
| Accrued compensation | 459 | 2,302 |
| Accrued interest expense | 288 | 1,049 |
| Deferred revenue | (227) | 127 |
| Deferred rent | 885 | — |
| Other liabilities | (681) | 199 |
| Net cash used in operating activities | (43,818) | (48,343) |
| Cash flows from investing activities: | | |
| Sales of short-term investments | 23,830 | — |
| Maturities of short-term investments | 26,934 | — |
| Purchases of property and equipment | (7,611) | (233) |
| Net cash provided by (used in) investing activities | 43,153 | (233) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock from the exercise of stock options | 301 | 2,288 |
| Proceeds from issuance of note payable, net of issuance costs | 24,533 | 24,685 |
| Proceeds from the exercise of preferred stock warrants | 1,693 | 3,310 |
| Proceeds from issuance of Series F preferred stock, net of issuance costs | — | 76,488 |
| Net cash provided by financing activities | 26,527 | 106,771 |
| Net increase in cash, cash equivalents and restricted cash | 25,862 | 58,109 |
| **Cash, cash equivalents and restricted cash** | | |
| Beginning of the period | 16,850 | 42,712 |
| End of the period | $ 42,712 | $ 100,907 |
| Reconciliation of cash, cash equivalents and restricted cash to balance sheets: | | |
| Cash and cash equivalents | $ 42,021 | $ 100,130 |
| Restricted cash | 691 | 777 |
| Cash, cash equivalents and restricted cash in balance sheets | $ 42,712 | $ 100,907 |
| **Supplemental cash flow information** | | |
| Interest paid | $ 397 | $ 3,969 |
| **Non-cash investing and financing activities** | | |
| Embedded loan facility derivative liability in loan facility | $ 1,396 | $ — |
| Transfer of evaluation units from inventory to property and equipment, net | $ 2,560 | $ 2,822 |
| Property and equipment included in accounts payable and accrued expenses | $ 284 | $ 210 |

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

**PROCEPT BioRobotics Corporation**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 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® Robotic System, an automated surgical robot providing tissue removal for the treatment of benign prostatic hyperplasia, a prostate gland enlargement condition.

***Liquidity***

As of December 31, 2020, the Company had cash and cash equivalents of $100.1 million and an accumulated deficit of $201.0 million. 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 the consolidated financial statements. The Company has not achieved positive cashflow from operations to date and expects to continue incurring losses 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 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 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 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.

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

The Company considers all highly liquid securities, 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' 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, 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 cash and cash equivalents and other liabilities measured at fair value on a recurring basis (in thousands):

| | December 31, | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2019 | | | | 2020 | | | |
| | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents: | | | | | | | | |
| Cash | $ 8,499 | $ — | $ — | $ 8,499 | $ 1,502 | $ — | $ — | $ 1,502 |
| Cash equivalents | 33,522 | — | — | 33,522 | 98,628 | — | — | 98,628 |
| Total cash and cash equivalents | $ 42,021 | $ — | $ — | $ 42,021 | $ 100,130 | $ — | $ — | $ 100,130 |
| | | | | | | | | |
| Preferred stock warrant liability | $ — | $ — | $ 870 | $ 870 | $ — | $ — | $ 177 | $ 177 |
| Loan facility derivative liability | $ — | $ — | $ 1,482 | $ 1,482 | $ — | $ — | $ 1,782 | $ 1,782 |

Cash equivalents consist primarily of money market funds.

There were no transfers in and out of Level 3 during the years ended December 31, 2019 and 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):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Beginning of the period | $ 2,164 | $ 870 |
| Exercised | (98) | (508) |
| Change in fair value | (1,196) | (185) |
| End of the period | $ 870 | $ 177 |

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

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Expected life (years) | 0.9 | 1.7 |
| Expected volatility | 53 % | 68 % |
| Risk-free interest rate | 1.6 % | 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 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 million if only the first installment has been drawn, $2 million if the first two installments have been drawn, $2.4 million if the first three installments have been drawn, or $3 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):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Beginning of the period | $ 86 | $ 1,482 |
| Issued | 1,396 | — |
| Change in fair value | — | 300 |
| End of the period | $ 1,482 | $ 1,782 |

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

***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash equivalents and, to a lesser extent, accounts receivable. The Company believes that the 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.

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

Property and equipment and Purchased Intangibles 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 three to five 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 operations 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 planned initial public offering, until such financings are consummated. After consummation of the equity financing, these costs are recorded 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 December 31, 2020.

***Deferred Revenue and Cost of Sales***

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 12 months following the balance sheet date is recorded as the current portion of deferred revenue and the remaining portion is recorded as non-current.

Deferred cost of sales consists of cost for inventory items that have been shipped, but not all revenue recognition criteria has been met. Deferred cost of sales is included with prepaid expenses and other current assets in the consolidated balance sheets. Costs of sales under service agreements are recognized as incurred.

***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 has elected not to adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares 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 liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

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

The Company has issued freestanding warrants to purchase shares of 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 it creates a conditional obligation for the Company to repurchase its own shares for cash or other assets. The fair value of that warrant is recorded on the balance sheet at the inception of such classification and adjusted 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.

***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 liability in the consolidated balance sheets and is subject to remeasurement at each consolidated balance sheet date. Such instruments are outstanding and classified as long-term liabilities. Any change in fair value is recognized through other income (expense) in the 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 Accounding 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.

***Warranty***

Warranty costs are accrued based on the Company's best estimates when management determines that it is probable a charge or liability has been incurred and the amount of loss can be reasonably estimated. While the Company believes that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates.

***Revenue Recognition***

Revenue is derived primarily from the sales of the AquaBeam® 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. 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 warranty.

*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.

Revenue is recognized when the item is delivered, which is when control is transferred to the customer. For systems sold following an evaluation or lease period, revenue is recognized once the sales terms are mutually agreed (as the system is already installed at the customer site). 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):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| U.S. | | |
| System sales and rentals | $ 1,086 | $ 2,334 |

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Hand pieces and other consumables | 982 | 1,699 |
| Service | — | 67 |
| Total U.S. revenue | 2,068 | 4,100 |
| Outside of U.S. | | |
| System sales and rentals | 2,446 | 1,824 |
| Hand pieces and other consumables | 1,641 | 1,722 |
| Service | 14 | 71 |
| Total outside of U.S. revenue | 4,101 | 3,617 |
| Total revenue | $ 6,169 | $ 7,717 |

During the years ended December 31, 2019 and 2020, sales to customers in Germany accounted for $1.7 million and $2.4 million in revenue, respectively.

***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, warranty and field service, equipment and operations supervision and management. Cost of sales also includes depreciation expense for production equipment 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. These expenses include employee and non-employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses, consulting, 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 has been no public market for our common stock, the Board has 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 uses 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. 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 our stockholders to freely trade our common stock in the public markets, resulting in a discount to reflect the lack of marketability of our 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 grant dates through December 31, 2020, 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 derives the Company’s equity value of a company from the price of the securities issued by the Company in the equity financing. Following the closing of this offering, the fair value of the Company’s common stock will be 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 years ended December 31, 2019 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 as a component of income tax expense in the statement of operations.

***Net Loss***

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 participate in any dividends declared by the Company and are therefore considered to be participating securities.

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

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Net loss | $ (41,975) | $ (53,019) |
| Weighted-average common stock outstanding | 10,486 | 17,398 |
| Net loss per share, basic and diluted | $ (4.00) | $ (3.05) |

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):

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Preferred stock outstanding | 99,739 | 120,661 |
| Preferred stock warrants | 3,539 | 341 |
| Common stock warrants | 58 | — |

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Common stock options | 27,308 | 30,912 |
| Total | 130,644 | 151,914 |

***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.

One customer accounted for 19% of revenue during the year ended December 31, 2019. No customers accounted for more than 10% of revenue during the year ended December 31, 2020.

Three customers each accounted for 20%, 18%, and 11% of accounts receivable at December 31, 2019. 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. The Company is currently evaluating this standard and the impact it may have on its consolidated financial statements.

## 3. Composition of Certain Consolidated Financial Statement Items

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

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Raw materials | $ 2,244 | $ 2,647 |
| Work-in-process | 244 | 51 |
| Finished goods | 3,796 | 4,226 |
| Total inventory | $ 6,284 | $ 6,924 |

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

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Computer equipment | $ 116 | $ 203 |
| Laboratory and manufacturing equipment | 2,499 | 2,405 |
| Furniture and fixtures | 37 | 37 |
| Rental equipment | 468 | 1,247 |
| Leasehold improvements | 4,941 | 4,941 |
| Evaluation units | 2,454 | 4,229 |
| Total property and equipment | 10,515 | 13,062 |
| Less: accumulated depreciation and amortization | (2,242) | (4,788) |
| Total property and equipment, net | $ 8,273 | $ 8,274 |

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

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Inventory | $ 402 | $ 553 |
| Software | 240 | 375 |
| Rent | 209 | 245 |
| Insurance | 103 | 124 |
| Other | 378 | 356 |
| Total prepaid expenses and other current assets | $ 1,332 | $ 1,653 |

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

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Accrued purchases | $ — | $ 432 |
| Interest | 202 | 403 |
| Professional services | 502 | 339 |
| Sales tax | 90 | 302 |
| Deferred revenue | 106 | 233 |
| Clinical trial expenses | 477 | 47 |
| Deferred rent | 253 | — |
| Other | 508 | 454 |
| Total other current liabilities | $ 2,138 | $ 2,210 |

As of December 31, 2019 and 2020, other non-current liabilities consisted of an asset retirement obligation for the facility lease.

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

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Interest income | $ 1,149 | $ 184 |
| Decrease in fair value of preferred stock warrants | 1,196 | 185 |
| Increase in fair value of loan facility derivative liability | — | (300) |
| Other | (46) | (25) |
| | $ 2,299 | $ 44 |

## 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 December 31, 2020, accumulated amortization was $0.5 million 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 for the years ended December 31, 2019 and 2020, was $0.2 million and $0.3 million, respectively.

**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 for $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 comprised of 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. Upon drawing the final $15 million tranche, interest-only period is extended 12 months followed by 24 months amortization of principal and interest. If $50 million is raised in an IPO, interest-only payments are extended an additional 12 months followed by 24 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 resulting in a constant rate of interest 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 will 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 our assets or voting stock, or 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 million if only the first installment has been drawn, $2 million if the first two installments have been drawn, $2.4 million if the first three installments have been drawn, or $3 million if all four installments have been drawn, in each case, upon the occurrence of the liquidity event. The Company has determined that this obligation to pay success fees to the lender upon a successful liquidation event or achieving a revenue target represents freestanding financial instruments.

This amendment in January 2021 was determined to be a modification under ASC 470-50-40 as the carrying value of the loan changed less than 10%, thus non-substantial modification requiring prospective application of the new effective interest rate,

See Note 11, "Subsequent Events" to the Company's financial statements for additional information.

## 6. Redeemable Convertible Preferred Stock Warrant Liability

As of December 31, 2019 and 2020, the following warrants to purchase shares of redeemable convertible preferred stock were outstanding and exercisable (in thousands, except per share data):

| Dates | | | | | Shares Outstanding at December 31, | | | Fair Value at December 31, | |
|---|---|---|---|---|---|---|---|---|---|
| Issuance | Expiration | In Connection with | Series | Exercise Price | 2019 | 2020 | Initial Value | 2019 | 2020 |
| Jul 2015 | Jul 2020 | Convertible notes | D | $ 1.07 | 3,198 | — | $ 2,463 | $ 674 | $ — |
| Jun 2017 | Jun 2022 | Convertible notes | E | 2.89 | 341 | 341 | 763 | 196 | 177 |
| | | | | | 3,539 | 341 | | $ 870 | $ 177 |

In October 2011 and April 2012, in connection with the issuance of convertible notes, the Company issued 1,267,287 preferred stock warrants that were exercisable into Series B or the next round of preferred stock. During the year ended December 31, 2019, warrants for 284,318 shares were exercised and none were outstanding at December 31, 2019.

In July 2015, the Company issued 4,131,750 preferred stock warrants that were exercisable into Series D preferred stock immediately, with $1.07 exercise price and expiration in five years. During the years ended December 31, 2019 and 2020, warrants for 934,123 and 3,093,840 shares were exercised, respectively.

In June 2017, the Company issued 513,691 preferred stock warrants that were exercisable into Series E or the next round of preferred stock. During the years ended December 31, 2019 and 2020, warrants for 173,010 and zero shares were exercised, respectively.

## 7. Redeemable Convertible Preferred Stock

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

| | December 31, 2019 | | | December 31, 2020 | | |
|---|---|---|---|---|---|---|
| Series | Shares Authorized | Shares Issued and Outstanding | Carrying Value (in thousands) | Shares Authorized | Shares Issued and Outstanding | Carrying Value (in thousands) |
| A | 5,905,312 | 5,905,312 | $ 3,130 | 5,905,312 | 5,247,459 | $ 2,781 |
| B | 8,763,247 | 8,748,576 | 6,369 | 8,748,576 | 7,333,073 | 5,404 |
| C | 7,433,046 | 7,433,046 | 7,073 | 7,433,046 | 7,433,046 | 7,073 |
| D | 39,268,941 | 36,071,314 | 36,607 | 39,165,154 | 35,850,828 | 36,879 |
| E | 41,921,856 | 41,581,175 | 119,889 | 41,921,856 | 39,968,857 | 115,229 |
| F | — | — | — | 25,000,000 | 24,828,160 | 76,488 |
| Total | 103,292,402 | 99,739,423 | $ 173,068 | 128,173,944 | 120,661,423 | $ 243,854 |

In July 2020, an aggregate of 7.0 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.

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

| Series | Liquidation Preference Per Share | 8% Dividend Per Share |
|---|---|---|
| A | $ 0.5300 | $ 0.0424 |
| B | 0.6816 | 0.0545 |
| C | 0.9600 | 0.0768 |
| D | 1.0700 | 0.0856 |
| E | 2.8900 | 0.2312 |
| F | 3.1006 | 0.2480 |

The Company recorded its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. A redemption event will 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 is outside the control of the Company, all shares of redeemable convertible preferred stock have been presented outside of permanent equity. Further, the Company has also elected not to adjust the carrying values of the redeemable convertible preferred stock to the redemption value of such shares, since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying value to the redemption values will be made when it becomes probable that such redemption will occur. As of December 31, 2019 and 2020, it was not probable that such redemption would occur.

***Series F Redeemable Convertible Preferred Stock***

In July and August 2020, the Company issued 24,828,160 shares of Series F preferred stock for gross proceeds of $77.0 million. Issuance costs totaled $0.5 million and were recorded an offset to gross proceeds.

***Series G Redeemable Convertible Preferred Stock***

In June 2021, the Company issued 21,125,881 shares of Series G preferred stock for gross proceeds of $85.0 million. Issuance costs totaled $0.3 million and were recorded as an offset to gross proceeds. The liquidation preference per share is $4.0235 and all other preferences are pari-passu with Series D, E and F preferred stock.

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 articles of incorporation, each holder of Series G preferred stock is 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 preferred stock and common stock. If the assets of the Company are insufficient to make payment in full to all Series F preferred stockholders, then the assets or consideration will be distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise be entitled to.

See Note 11, "Subsequent Events" to the Company's financial statements for additional information.

***Dividends***

The holders of the Series D, E and F preferred stock, in preference to the holders of Series A, B and C preferred stock and common stock, are 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 and F preferred stock, and in preference to the holders of common stock, the holders of Series A, B, and C preferred stock shall be 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 years ended December 31, 2019 and 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 articles of incorporation, each holder of Series F preferred stock is entitled to receive

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

After the full payment of the liquidation preference to the holders of Series F preferred stock, each holder of Series E preferred stock shall be 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 preferred stock and common stock. If the assets of the Company are insufficient to make payment in full to all Series E preferred stockholders, then the assets or consideration will be distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise be entitled to.

After the full payment of the liquidation preference to the holders of Series E preferred stock, each holder of Series D preferred stock shall be 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 preferred stock and common stock. If the assets of the Company are insufficient to make payment in full to all Series D preferred stockholders, then the assets or consideration will be distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise be entitled to.

After the full payment of the liquidation preference to the holders of Series D preferred stock, each holder of Series A, B and C preferred stock shall be 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 are insufficient to make payment in full to all holders of Series A, B or C preferred stock, then the assets or consideration will be distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise be entitled to.

After the payment of the full liquidation preference to holders of preferred stock, the remaining assets of the Company legally available for distribution shall be distributed ratably to the holders of the common stock.

***Voting***

Each holder has the right to one vote for each share of common stock into which such preferred stock could be converted. So long as any shares of preferred stock are outstanding, the Company shall not, without first obtaining the approval of more than 50% of the holders of preferred stock then outstanding, be 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 and F preferred stock is 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 and F preferred stock, as applicable.

***Redemption***

The redeemable convertible preferred shares are not mandatorily redeemable.

***Conversion***

Each share of preferred stock is convertible at the option of the holder into shares of common stock (subject to adjustment for certain events, including dilutive issuances, stock splits, and reclassifications) at a conversion price originally equal to the original issue price. The preferred stock will also be converted automatically into shares of common stock (i) at any time upon the affirmative election of the holders of at least a majority of the outstanding shares of the preferred stock or (ii) immediately upon the closing of an initial public offering under the Securities Act of 1933, as amended, with a common stock price of at least $4.63 per share (as adjusted per the Company’s articles of incorporation) and at least $50.0 million in gross cash proceeds to the Company.

## 8. Stockholder's Equity

***2008 Stock Plan***

In 2008, the Company adopted the 2008 Stock Plan (the "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 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 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. Options granted under the Plan will expire starting August 2021. As of December 31, 2020, there were 7.1 million shares available for grant under the Plan.

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

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2019 | | 2020 | |
| | Options | Price | Options | Price |
| Outstanding, beginning of period | 24,477 | $ 0.63 | 27,308 | $ 0.71 |
| Granted | 5,286 | 0.96 | 12,476 | 0.99 |
| Exercised | (1,089) | 0.28 | (4,450) | 0.51 |
| Forfeited | (1,366) | 0.74 | (4,422) | 0.86 |
| Outstanding, end of period | 27,308 | 0.71 | 30,912 | 0.83 |
| Vested and expected to vest | 27,308 | 0.71 | 30,912 | 0.83 |
| Exercisable | 14,062 | 0.51 | 13,519 | 0.64 |

As of December 31, 2019 and 2020, the aggregate pre-tax intrinsic value of options outstanding and exercisable was $6.0 million and $6.9 million, respectively, and options outstanding were $6.4 million and $9.9 million, respectively. The aggregate pre-tax intrinsic value of options exercised was $0.7 million and $2.0 million during the years ended December 31, 2019 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 $1.9 million and $1.6 million during the years ended December 31, 2019 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, during the years ended December 31, 2019 and 2020, are as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Cost of sales | $ 106 | $ 80 |
| Research and development | 442 | 543 |
| Sales, general and administrative | 1,446 | 1,550 |
| Total stock-based compensation | $ 1,994 | $ 2,173 |

The amount of unearned stock-based compensation relate to unvested employee stock-based payment awards as of December 31, 2020 is $6.5 million. The weighted-average period over which the unearned stock-based compensation is expected to be recognized as of December 31, 2020 is 2.9 years.

The fair value of the options granted to employees or directors during the years ended December 31, 2019 and 2020, was estimated as of the grant date using the Black-Scholes model assuming the weighted-average assumptions listed in the following table:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Expected life (years) | 6.0 | 6.0 |
| Expected volatility | 37 % | 41 % |
| Risk-free interest rate | 1.9 % | 0.9 % |
| Expected dividend rate | — % | — % |
| Weighted-average fair value | 0.35 | 0.41 |

***Common Stock Warrants***

In May 2015, the Company issued warrants to purchase 58,466 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 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 December 31, 2020, the remaining future minimum lease payments under this lease is $6.7 million.

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 internal 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 are presented under Topic 842. The results for the years ended December 31, 2019, and other prior period amounts, were not adjusted and continue to be reported in accordance with our historical accounting under prior lease guidance, ASC Topic 840: Leases ("Topic 840").

Rent expense recognized under the lease, including additional rent charges for utilities, parking, maintenance, and real estate taxes, was $2.3 million and $2.9 million for the years ended December 31, 2019 and 2020, respectively.

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

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

| As of December 31, 2019 | Minimum Lease Payments | Debt Repayments | Total |
|---|---|---|---|
| 2020 | $ 2,211 | $ — | $ 2,211 |
| 2021 | 2,373 | 2,084 | 4,457 |
| 2022 | 2,444 | 8,333 | 10,777 |
| 2023 | 1,879 | 8,333 | 10,212 |
| 2024 | — | 6,250 | 6,250 |
| Total minimum payments | $ 8,907 | 25,000 | 33,907 |
| Less: amount representing interest/unamortized debt discount | | (1,776) | (1,776) |
| Present value of future payments | | 23,224 | 32,131 |
| Less: current portion | | — | — |
| Non-current portion | | $ 23,224 | $ 32,131 |

| As of December 31, 2020 | Minimum Lease Payments | Debt Repayments | Total |
|---|---|---|---|
| 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 December 31, 2019 and 2020, the Company's security deposit is recorded in other non-current assets and 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.

## 10. Income Taxes

The Company did not record an income tax provision for both periods.

Reconciliation between the tax provision computed at the federal statutory income tax rate and the Company's actual effective income tax rate are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Federal statutory tax rate | 21 % | 21 % |
| R&D tax credit | 1 | 1 |
| Stock-based compensation and other permanent differences | — | — |
| Change in valuation allowance | (22) | (22) |
| Total | — % | — % |

The Company’s income taxes are accounted for in accordance with authoritative guidance, which requires the use of the asset and liability method. Under this method, deferred income tax assets and liabilities are determined based upon the difference between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed.

Significant components of net deferred tax assets are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Deferred tax assets: | | |
| Net operating losses | $ 33,410 | $ 42,331 |
| Property and equipment | 144 | 303 |
| R&D tax credit | 2,695 | 3,830 |
| Stock-based compensation | 450 | 490 |
| Capitalized R&D expenses | — | 3,109 |
| Inventory | 464 | 511 |
| Lease liability | 316 | 1,461 |
| Accruals and reserves | 598 | 1,144 |
| Total deferred tax assets | 38,077 | 53,179 |
| Valuation allowance | (38,077) | (52,005) |
| Net deferred tax assets | — | 1,174 |
| Deferred tax liabilities: | | |
| Right-of-use assets | — | (1,174) |
| | — | (1,174) |
| Net deferred taxes | $ — | $ — |

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. The valuation allowance increased by $13.9 million during the year ended December 31, 2020.

As of December 31, 2019 and 2020, the Company has U.S. federal net operating loss (“NOL”) carryforwards of approximately $134.7 million and $170.8 million, respectively, expiring beginning 2029. As of December 31, 2019 and 2020, the Company has U.S. state and local NOL carryforwards of approximately $77.8 million and $100.7 million respectively, expiring beginning 2028.

As of December 31, 2019 and 2020, the Company has federal research and development credit carryforwards of approximately $2.2 million and $3.1 million, respectively, available to reduce future taxable income, if any. As of December 31, 2019 and 2020, the Company has California research and development credit carryforwards of approximately $1.7 million and $2.5 million, respectively, available to reduce future taxable income, if any.

The federal research and development credit carryforwards expire beginning 2029 and California research and development credit carryforwards are indefinite.

Internal Revenue Code section 382 places a limitation (the “Section 382 Limitation”) on the amount of taxable income that can be offset by net operating carryforwards after a change in control of a loss corporation. Generally, after a change in control, a loss corporation cannot deduct operating loss carryovers in excess of the Section 382 limitation. The Company has not performed an analysis to determine if a limitation applies and whether the limitation would cause the net operating losses to expire unutilized.

The Company files federal, state, and foreign income tax returns. The tax periods 2008 through 2020 remain open in most jurisdictions. In addition, any tax losses that were generated in prior years and carried forward may also be subject to examination by respective authorities. The Company is not currently under examination by federal, state or foreign income tax authorities.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was passed into law. The CARES Act includes several significant business tax provisions including modification to the taxable income limitation for utilization of NOLs incurred in 2018, 2019 and 2020 and the ability to carry back NOLs from those years for a period of up to five years, an increase to the limitation on deductibility of certain business interest expense, bonus depreciation for purchases of qualified improvement property and special deductions on certain corporate charitable contributions. The Company has analyzed the provision of the CARES Act and determined it did not have an impact on its consolidated financial statements due to the full valuation reserve.

A reconciliation of the change in the unrecognized tax benefit during the year is as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2020 |
| Beginning of year | $ 694 | $ 986 |
| Additions for tax positions related to: | | |
| Current year | 292 | 421 |
| Prior years | — | — |
| End of year | $ 986 | $ 1,407 |

As of December 31, 2020, the Company had a total of $1.4 million of gross unrecognized tax benefits, none of which would affect the effective tax rate upon realization. The Company currently has a full valuation allowance against its U.S. net deferred tax assets which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.

The Company does not expect the unrecognized tax benefits to change significantly over the next twelve months. The Company will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of December 31, 2020, the Company has not accrued interest or penalties related to uncertain tax positions.

**11. Subsequent Events**

In connection with the preparation of the financial statements, the Company evaluated events subsequent to the balance sheet date as of December 31, 2020 through June 25, 2021, the date the financial statements were available for issuance.

In January 2021, the Company amended its loan agreement with modified terms that include decreasing the revenue target for the $10.0 million third loan tranche from $20.0 million trailing 6 months revenue to $6.4 million. Since the Company met this revenue target, the interest-only period was modified from 24 months beginning October 1, 2021 to 36 months beginning October 1, 2022. In addition, the prepayment fee was eliminated.

This amendment was determined to be a modification under ASC 470-50-40 as the carrying value of the loan changed less than 10%, thus non-substantial modification requiring prospective application of the new effective interest rate.

In June 2021, the Company issued 21,125,881 shares of its Series G preferred stock for gross proceeds of $85.0 million. Issuance costs totaled $0.3 million and were recorded as an offset to gross proceeds. The liquidation preference per share is $4.0235 and all other preferences are pari-passu with the Company's Series D, E and F preferred stock.

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 articles of incorporation, each holder of Series G preferred stock is 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 preferred stock and common stock. If the assets of the Company are insufficient to make payment in full to all Series F preferred stockholders, then the assets or consideration will be distributed ratably among such holders in proportion to the full liquidation preference amounts to which the holders would otherwise be entitled to.

Subsequent to December 31, 2020, the Company granted options for 5,794,000 shares of common stock, subject to service-based vesting conditions, with a weighted-average price of $1.39 per share to employees.

Through and including , 2021 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

# Shares


## Common Stock

**P R O S P E C T U S**

## BofA Securities

## Goldman Sachs & Co. LLC

## Cowen

## Guggenheim Securities

## SVB Leerink

**, 2021**

## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all the costs and expenses, other than underwriting discounts, payable in connection with the sale of the shares of common stock being registered hereby. Except as otherwise noted, the Registrant will pay all of the costs and expenses set forth in the following table. All amounts shown below are estimates, except the SEC registration fee, the FINRA filing fee and the stock exchange listing fee:

| | Amount Paid or to Be Paid |
|---|---|
| SEC registration fee | $ * |
| FINRA filing fee | * |
| Stock exchange listing fee | * |
| Printing and engraving expenses | * |
| Legal fees and expenses | * |
| Accounting fees and expenses | * |
| Transfer agent and registrar fees | * |
| Miscellaneous expenses | * |
| **Total** | $ * |

* To be filed by amendment.

### Item 14. Indemnification of Directors and Officers

The Registrant is governed by the Delaware General Corporation Law, or DGCL. Section 145 of the DGCL provides that a corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was or is an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such officer, director, employee or agent acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the corporation's best interest and, for criminal proceedings, had no reasonable cause to believe that such person's conduct was unlawful. A Delaware corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or contemplated action or suit by or in the right of such corporation, under the same conditions, except that such indemnification is limited to expenses (including attorneys' fees) actually and reasonably incurred by such person, and except that no indemnification is permitted without judicial approval if such person is adjudged to be liable to such corporation. Where an officer or director of a corporation is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to above, or any claim, issue or matter therein, the corporation must indemnify that person against the expenses (including attorneys' fees) which such officer or director actually and reasonably incurred in connection therewith.

The Registrant's amended and restated certificate of incorporation and amended and restated bylaws will authorize the indemnification of its officers and directors, consistent with Section 145 of the DGCL.

Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing

violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities**

During the three years preceding the filing of this registration statement, we have issued the following securities which were not registered under the Securities Act of 1933, as amended:

1. In July 2020 and August 2020, we completed the sale of an aggregate of 24,828,160 shares of our Series F redeemable convertible preferred stock to certain investors at a purchase price of $3.1006 per share, for an aggregate purchase price of approximately $77.0 million. All of our shares of Series F redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the closing of our initial public offering.

2. In June 2021, we completed the sale of an aggregate of 21,125,882 shares of our Series G redeemable convertible preferred stock to certain investors at a purchase price of $4.0235 per share, for an aggregate purchase price of approximately $85.0 million. All of our shares of Series G redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the closing of our initial public offering.

3. Since January 1, 2018, we have granted stock options to employees, directors and consultants, covering an aggregate of 36,838,043 million shares of our common stock under our 2008 Stock Plan, at exercise prices ranging from $0.92 to $1.53 per share, and have issued 11,543,846 million shares of common stock upon exercise of stock options under our 2008 Stock Plan with an aggregate exercise price of $5.4 million.

The issuances of the securities in the transactions described above were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Rules 506 and 701 promulgated thereunder. The securities were issued directly by the registrant and did not involve a public offering or general solicitation. The recipients of such securities represented their intentions to acquire the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof.

**Item 16. Exhibits and Financial Statement Schedules**

*(a) Exhibits.*

| Exhibit No. | Exhibit Description |
|---|---|
| 1.1* | Form of Underwriting Agreement. |
| 3.2* | Form of Amended and Restated Certificate of Incorporation of the Registrant, to be effective upon the consummation of this offering. |
| 3.4* | Form of Amended and Restated Bylaws of the Registrant, to be effective upon the consummation of this offering. |
| 5.1* | Opinion of Latham & Watkins LLP. |

| | |
|---|---|
| 10.1*+ | Offer Letter, by and between the Registrant and Reza Zadno, Ph.D., dated as of January 31, 2020. |
| 10.2*+ | Offer Letter, by and between the Registrant and Kevin Waters, dated as of August 7, 2018. |
| 10.3*+ | Offer Letter, by and between the Registrant and Hisham Shiblaq, dated as of March 21, 2019. |
| 10.4*+ | Amended and Restated 2008 Stock Plan of the Registrant. |
| 10.4(a)*+ | Form of Stock Option Agreement under the Amended and Restated 2008 Stock Plan. |
| 10.5* | Form of Indemnification Agreement. |
| 10.6* | Amended and Restated Exclusive License Agreement, by and between the Registrant and AquaBeam LLC, dated as of September 13, 2019. |
| 10.7* | Loan and Security Agreement, by and between the Registrant and Oxford Finance LLC, dated as of September 25, 2019. |
| 10.7(a)* | First Amendment to Loan and Security Agreement, by and between the Registrant and Oxford Finance LLC, dated as of January 15, 2021. |
| 10.7(b)* | Second Amendment to Loan and Security Agreement, by and between the Registrant and Oxford Finance LLC, dated as of April 6, 2021. |
| 10.8* | Lease Agreement, by and between the Registrant and Westport Office Park LLC, dated as of July 15, 2013. |
| 10.8(a)* | First Amendment to Lease Agreement, by and between the Registrant and Westport Office Park LLC, dated as of March 2, 2016. |
| 10.8(b)* | Second Amendment to Lease Agreement, by and between the Registrant and Westport Office Park LLC, dated as of May 20, 2016. |
| 10.8(c)* | Third Amendment to Lease Agreement, by and between the Registrant and Westport Office Park LLC, dated as of April 4, 2018. |
| 10.9* | Form of Non-Employee Director Compensation Policy. |
| 10.10* | Form of 2021 Incentive Plan of the Registrant. |
| 21.1* | List of subsidiaries of the Registrant. |
| 23.1* | Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm. |
| 23.2* | Consent of Latham & Watkins LLP (included in Exhibit 5.1). |
| 24.1* | Power of Attorney (included on signature page). |

_____
* To be filed by amendment.
\+ Indicates management contract or compensatory plan.

*(b) Financial Statement Schedules.*

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

**Item 17. Undertakings**

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Redwood City, State of California on this day of , 2021.

**PROCEPT BIOROBOTICS CORPORATION**

By: _____

Name: Reza Zadno, Ph.D.
Title: Chief Executive Officer

## POWER OF ATTORNEY

We, the undersigned officers and directors of PROCEPT BioRobotics Corporation hereby severally constitute and appoint Reza Zadno and Kevin Waters, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| Reza Zadno, Ph.D. | President, Chief Executive Officer and Director (principal executive officer) | , 2021 |
| Kevin Waters | SVP, Chief Financial Officer (principal financial and accounting officer) | , 2021 |
| Frederic Moll, M.D. | Director and Chair of the Board | , 2021 |
| Antal Desai | Director | , 2021 |
| Amy Dodrill | Director | , 2021 |
| Taylor Harris | Director | , 2021 |
| Thomas Krummel, M.D. | Director | , 2021 |
| Rodney Perkins, M.D. | Director | , 2021 |
| Eric Reuter | Director | , 2021 |
| Lisa Skeete Tatum | Director | , 2021 |
| Colby Wood | Director | , 2021 |