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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____

Commission file number 001-04321



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.)

150 Baytech Drive **San Jose, CA**	**95134**
(Address of Principal Executive Offices)	(Zip Code)

(650) 232-7200
Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.00001 par value per share	PRCT	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2024, the aggregate market value of shares held by non-affiliates of the Registrant (based upon the closing sale prices of such shares on the Nasdaq Global Market on June 30, 2024) was approximately $3.1 billion. Shares of common stock held by each executive officer, director, and their affiliated holders have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status for this purpose is not necessarily a conclusive determination for any other purpose.

The registrant had outstanding 54,818,700 shares of common stock as of February 20, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Stockholders' Meeting, to be filed within 120 days of the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K,

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Annual Report are only predictions and are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of known and

unknown risks, uncertainties, and assumptions, including those described under the sections in this Annual Report entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

SUMMARY RISK FACTORS

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

- We have 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 robotic systems and the accompanying single-use disposable handpieces, and we are therefore highly dependent on the success of those products.
- 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.
- The commercial success of our products and Aquablation therapy will depend upon the degree of market acceptance of our products among hospitals, surgeons and patients.
- We have limited experience in training and marketing and selling our products and we may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop and maintain broad brand awareness in a cost-effective manner.
- We may not be able to maintain adequate levels of third-party coverage and reimbursement, and third parties may rescind or modify their coverage or delay payments related to our products.
- We face competition from many sources, including larger companies, and we may be unable to compete successfully.
- We have limited experience manufacturing our products in large-scale commercial quantities, and we face a number of manufacturing risks that may adversely affect our manufacturing abilities which could delay, prevent or impair our growth.
- We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.
- Our information technology systems, or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations.

- Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.
- Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.
- We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.
- Changes to the reimbursement rates for BPH treatments and measures to reduce healthcare costs may adversely impact our business.
- Our robotic systems 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 robotic systems, or if approvals or clearances for future products or modifications to existing products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.
- Even though we have obtained marketing authorization for our AquaBeam Robotic System and HYDROS Robotic System, we are subject to ongoing regulatory review and scrutiny. Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.
- We have to obtain, maintain and protect our intellectual property and failure to do so may adversely impact our competitive position.
- We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time-consuming, unsuccessful, and could interfere with our ability to sell and market our products or services.
- 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 HYDROS Robotic System and our other current and future products.
- Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies globally.
- 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, and we may not be able to meet investor or analyst expectations.
- Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.
- If we are not able to maintain adequate internal control over financial reporting, or if we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the trading price of our common stock could decline.

Part I

Item 1. Business

Overview

We are a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. We develop, manufacture and sell the AquaBeam Robotic System and HYDROS Robotic System, which are advanced, image-guided, surgical robotic systems 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. Each of our robotic systems 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 robotic systems to enable consistent and reproducible BPH surgery outcomes. We believe that Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing compromises associated with alternative surgical interventions. We designed Aquablation therapy to deliver effective, safe and durable outcomes for males suffering from lower urinary tract symptoms, or LUTS, due to BPH that is independent of prostate size and shape, and delivers resection independent of surgeon experience. We have developed a significant and growing body of clinical evidence, which includes nine clinical studies and over 150 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy. As of December 31, 2024, we had an install base of 647 AquaBeam Robotic Systems and HYDROS Robotic Systems globally, including 505 in the United States.

BPH refers to the non-malignant enlargement of the prostate gland, a small gland in the male reproductive system. 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 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 BPH. 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 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. By 2060, 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. Based on the average selling price of our single-use disposable 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 under-penetrated. This is largely due to the compromise patients must make between the incidence of irreversible side effects associated with alternative resective surgical interventions, where obstructive tissue is removed at the time of intervention, or the lower rates of efficacy and durability associated with non-resective surgical interventions, where obstructive tissue is not removed, but rather the prostatic urethra is re-shaped. 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.

We began developing our proprietary AquaBeam Robotic System in 2009 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. We believe our Aquablation therapy provides 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 results 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 were only 5.2% at five years

and 3.0% at five years, respectively. In the OPEN WATER study, there were no surgical retreatments at one year. The retreatment rates in the WATER and WATER II studies compare favorably to surgical retreatment rates observed for alternative treatments for BPH. One study published in the BJU International Journal reported on 52,748 men undergoing TURP or photoselective vaporation of the prostate or PVP, with an approximated three-year freedom from surgical retreatment of 92% and 89%, respectively. A second study published in the Journal of Urology reported on 43,041 men undergoing TURP, PVP, enucleation, or open simple prostatectomy with an approximated three-year freedom from surgical retreatment of 93%, 89%, 94%, and 96%, respectively.

- ***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 significantly higher level of sexual function compared to those who underwent TURP.
- ***Resection independent of prostate size and shape and surgeon experience.*** We designed Aquablation therapy to deliver outcomes that are effective, safe and durable for males suffering from LUTS due to BPH across all prostate sizes and shapes. 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 user interface of the conformal planning unit, or CPU, and automated robotic resection, and delivers resection that is independent of surgeon experience.
- ***Personalized treatment planning and improved decision-making.*** Aquablation therapy combines cystoscopic visualization, which uses a camera attached to a hollow tube, along with ultrasound imaging and advanced planning software to provide the surgeon with a multidimensional view of the treatment area and enables 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, with resection that is independent of prostate size and shape and surgeon experience. Our robust body of clinical evidence includes nine clinical studies and over 150 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 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. We believe that 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, European Association of Urology, Canadian Urological Association, German Urology Society, and National Institute for Health and Care Excellence.

Currently, in the United States, we primarily sell our products to hospitals, or end customers, and to a lesser extent, distribution partners, ambulatory surgery centers and leasing companies. The end customers in turn bill various third-party payors, such as commercial payors and government agencies, for reimbursement for the procedures using our products. 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 so long as such beneficiaries meet certain clinical criteria set forth in the local coverage determination. We believe that 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 many large commercial payors, which we estimate allows access to Aquablation therapy to approximately 95% of all men in the United States. 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, which targets urologists across the United States, who we believe represent the primary physician specialty managing the care of patients with BPH. We target approximately 2,700 hospitals that perform resective BPH procedures in the United States. 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 about the clinical benefits of Aquablation therapy, provide comprehensive training programs and deepen our relationships with key urologists and various medical societies. 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 $224.5 million and $136.2 million for the years ended December 31, 2024 and 2023, respectively, and incurred a net loss of $91.4 million and $105.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $546.0 million.

Our Growth Strategies

Our mission is to revolutionize BPH treatment globally in partnership with urologists by delivering best-in-class robotic solutions that positively impact patients and drive value. The key elements of our growth strategy are:

- ***Grow our install base of robotic systems by driving adoption of Aquablation therapy among urologists.*** In the United States, we are 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. 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 have also established a strategic accounts team, to build relationships and sell to integrated delivery networks, or group purchasing organizations, among other strategic accounts. 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 workshops.

- ***Increase system utilization by establishing Aquablation therapy as the surgical treatment of choice for BPH.*** Once we place a system within a customer, our objective is to establish Aquablation therapy as the surgical treatment of choice for BPH. Within each customer site, 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.

- ***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 so long as such beneficiaries meet certain clinical criteria set forth in the local coverage determinations. We believe that these favorable coverage decisions have been a catalyst for adoption of our robotic systems. 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 most large private payors, which we estimate allows access to Aquablation therapy for approximately 95% of all men in the United States. We plan to leverage these successes in our active discussions with private 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 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. To further strengthen this base, we plan to support new clinical studies aimed at advancing our commercial, regulatory, and reimbursement efforts. For example, we are supporting an investigator-initiated clinical study, called WATER III, which is a randomized controlled trial evaluating Aquablation therapy against laser enucleation in treating BPH patients with large prostate sizes.

- ***Invest in high quality clinical research to support the use of Aquablation therapy for prostate cancer.*** Currently, we are investing in two single arm prostate cancer clinical trials (PRCT001 (BPH+PCa) and PRCT002 (feasibility IDE for PCa)) and one randomized FDA approved pivotal Investigational Device Exemption, or IDE, clinical trial. This pivotal IDE clinical trial, known as WATER IV PCa, is a global multi-center, prospective, randomized clinical study designed to assess the safety and efficacy of Aquablation therapy compared to radical prostatectomy in men with Grade Group 1 to 3 localized prostate cancer. We believe our investment in level one clinical research will support future commercial, regulatory and reimbursement efforts to drive growth.
- ***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 our products. We also plan to leverage our treatment data and software development capabilities to further integrate and advance artificial intelligence and machine learning.
- ***Drive increased awareness of Aquablation therapy beyond the urology community.*** As we expand our network of urologists and grow our install 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 directed at primary care physicians in order to expand networks for BPH patients to visit a urologist. Once we have established a broader install 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 other 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. 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. By 2060, 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 disposable 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 prostate sits underneath the bladder and surrounds the top part of the urethra, which carries urine from the bladder.

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.

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 eighth decade of life, which we believe are predominantly caused by BPH. Furthermore, 50% of men between the ages of 51-60 have BPH pathology. 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. LUTS are classified as either mild, moderate or severe. 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. 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. Patients 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. Without surgical intervention, most men with BPH who start drug therapy will need to continue it indefinitely in order to relieve symptoms. While drug therapy can provide relief for some men, two out of three patients are not satisfied with the effectiveness of their medication. Drug therapy is also often associated with negative side effects, including headaches, dizziness, nausea, erectile dysfunction, ejaculatory dysfunction, loss of libido, cardiac failure and dementia. These side effects often contribute to poor treatment compliance, with drug therapy failing in up to 30% of men within two years. Furthermore, drug therapy may be costly, particularly in light of limited 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 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 as an effective way to manage BPH symptoms compared to drug therapy.

There are two categories of surgical intervention, resective, where obstructive tissue is removed at the time of intervention, and non-resective, where obstructive tissue is not removed, but rather the prostatic urethra is re-shaped.

Resective Procedures

Resective prostate 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 surgeries may be performed endoscopically, allowing the procedure to be completed through a tubular instrument, 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. 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 almost 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.
- *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.
- *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, training and experience required.

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.

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 are generally approved for small- to average-sized prostates.

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 the degree and durability of symptom 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. 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%, ejaculatory dysfunction as high as 89%, 50% and 77%, and incontinence as high as 2%, 2%, and 33% 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. This results in highly variable depth of tissue penetration, damage to tissue which may extend deeper than cavity created, a potential for unintended prostate capsule perforation, potential damage to nerve bundle responsible for erectile function, and delayed healing of prostatic urethra.

- *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 resective procedures, open procedures commonly result in high rates of irreversible complications, with studies showing erectile, ejaculatory dysfunction and incontinence rates as high as 2-3%, 90% and 8%, respectively.
- *Long hospital stays 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.

Our Solution

Our first generation AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive urologic surgery, received De Novo FDA approval in December 2017. In August 2024, we received FDA 510(k) clearance of our next-generation platform – the HYDROS Robotic System. Our proprietary AquaBeam Robotic System and HYDROS Robotic System each deliver our Aquablation therapy, the first and only image-guided robotic therapy for the treatment of BPH. In August 2023, we received 510(k) clearance from FDA to remove the contraindication from our labeling that restricted Aquablation therapy from treating BPH in patients that also have an active diagnosis of prostate cancer. The most common side effects observed for Aquablation therapy are mild and transient and may include mild pain or difficulty when urinating, discomfort in the pelvis, blood in the urine, inability to empty the bladder or a frequent or urgent need to urinate, and bladder or urinary tract infection. During our clinical studies, we documented a rate of incontinence between 0%-2%, ejaculatory dysfunction between 6.9%-24.6%, and a peri-operative transfusion rate between 0.9%-5.9%. 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%.

Robotic Systems



We design and market two robotic systems: the next-generation HYDROS Robotic System where cleared, and the first-generation AquaBeam Robotic System. Both systems leverage a heat-free waterjet for automatic robotic execution, reducing the risk of complications associated with prolonged thermal injury. They also feature real-time image guidance that integrates intraoperative ultrasound imaging with cystoscopic visualization, offering a multidimensional view of the treatment area to enhance decision-making and enable real-time monitoring during procedures.

The robotic systems support personalized treatment planning through advanced software and ultrasound imaging, allowing surgeons to map the treatment contour to precisely target the resection area and optimize tissue removal based on each patient's unique anatomy. With the introduction of the HYDROS Robotic System in August 2024, we unveiled the FirstAssist AI feature. This innovation combines ultrasound imaging with advanced planning software to assist urologists in identifying key anatomical landmarks, enabling precise targeting of the resection area using the waterjet. By tailoring the tissue removal plan to individual anatomy, the FirstAssist AI feature aims to enhance procedural accuracy and outcomes.

Structurally, the HYDROS Robotic System fully integrates an advanced ultrasound system and a digital cystoscope providing the ability to improve visualization and streamline the operating room setup process. Additionally, the HYDROS Handpiece comes pre-assembled with a single-use digital scope eliminating the need for reprocessing the cystoscope between procedures.

These advanced features are designed to further deliver safe, effective, and durable outcomes for men suffering from lower urinary tract symptoms (LUTS) caused by BPH, regardless of prostate size and shapes and resection independent of surgeon experience.

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;
- favorable safety profile compared to other BPH resective procedures;
- outcomes consistent across all prostate sizes and shapes and resection independent of surgeon experience;
- personalized treatment planning and improved decision-making; and
- targeted and controlled resection with consistent resection times.

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 150 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.

Prostate Therapy

- ***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 study was designed with 80% power to show superiority in safety and more than 80% power to show non-inferiority in efficacy. The results of our WATER study served as the basis for FDA grant of our De Novo request and were first published in the Journal of Urology in 2018. The study has concluded with five-year data.

- ***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 study was designed with 80% power for safety and 99% power for efficacy against an objective performance criteria, or OPC, based upon TURP data, even though TURP procedures are typically performed in smaller prostates. 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. The study has concluded with five-year data.

- ***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. Due to the size of this study, it was sufficiently powered to statistical conclusions with the data. There was no OPC established for this study. The results of the OPEN WATER study were first published in Journal of Clinical Medicine in 2020. The study has concluded with one-year data.

Cancer Therapy

- ***PRCT001***. The PRCT001 study is a global, prospective, post-market, multi-center study of Aquablation therapy in patients with BPH and localized prostate cancer. The study is designed to assess safety in this population. The samples size of the study is 125 and is planned to be conducted in the United States, Hong Kong, Lebanon, Canada, and Portugal.

- ***PRCT002***. The PRCT002 study is an investigational device exemption, or IDE (G230155), prospective, post-market, multi-center study of Aquablation therapy in patients with localized prostate cancer. The study has completed enrollment across three centers in the United States.

- ***WATER IV PCa.*** WATER IV PCa is a global multicenter, prospective, randomized clinical study designed to assess the safety and efficacy of Aquablation therapy compared to radical prostatectomy in men with Grade Group 1 to 3 localized prostate cancer. There is a co-primary endpoint based on morbidity evaluated at the six-month follow-up. A key secondary endpoint is to measure the rate of Grade Group progression in the Aquablation therapy arm, which will be evaluated at the twelve-month follow-up. The study is planned to enroll up to 280 patients at up to 50 centers and follow them for 10 years. The patients will be randomized on a 3:1 basis, with 210 patients receiving Aquablation therapy and 70 patients receiving radical prostatectomy. Longer-term follow-up focuses on both the reduction in treatment related harm and oncologic events.

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 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 target the 2,700 hospitals where we estimate approximately 290,000 respective BPH surgeries of the 400,000 BPH surgeries are performed annually. Within each 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.

Our direct sales organization actively engages with providers to drive awareness, adoption and utilization of our Aquablation therapy. This team is supported by clinical specialists who are responsible for training and supporting surgeons, reimbursement specialists, who are responsible for customer and physician education on coding, coverage and payment, and field support employees, who provide preventative maintenance and technical 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 workshops. 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 install 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 expand networks for BPH patients to visit a urologist. Once we have established a broader install 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

Outside the United States, we utilize both a direct sales organization and, in certain regions, a network of distribution partners. In the United Kingdom and Japan specifically, we have increased the size of our direct sales force following recent reimbursement decisions specific to Aquablation therapy in those countries. In markets where our coverage is limited, we collaborate with distribution partners to support market development and sales efforts. We strategically select partners with clinical and marketing expertise to help us enter new markets. Our focus is on partners who can assist with surgeon training and, when necessary, securing regulatory approvals.

Third-Party Reimbursement

In the United States, the primary end users of our products are hospitals. These end users in turn bill various third-party payors, such as commercial payors and government agencies, for reimbursement for the procedures using our products. Our market access team includes professionals who are focused on all key aspects of reimbursement, which include securing appropriate coding, payment and coverage policies for our products and procedures using 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 May 2024, the AMA established a new CPT Category I code for Aquablation therapy to treat BPH. The Category I code will replace the existing Category III CPT code starting January 1, 2026.

Physician reimbursement under Medicare generally is based on a defined fee schedule, the Medicare Physician Fee Schedule, through which payment amounts are determined by a calculation of various inputs related to 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 physician using CPT code 0421T is currently similar to that for a TURP procedure.

In addition to payment to the physician 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. Medicare also provides reimbursement for procedures performed in ambulatory surgery centers. Reimbursement rates from commercial payors vary depending on the commercial payor, contract terms, and other factors.

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. We believe that 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 many large commercial payors – which we estimate allows access to Aquablation therapy to approximately 95% of all men in the United States.

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

Prior Authorization Approval Process

For certain customers, 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 education 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.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement. The Health Technology Assessment, or HTA, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic, impact and the economic and societal impact related to the use of a health technology. The outcome of the HTA will often influence the pricing and reimbursement status granted to the product under review by the competent authorities of individual EU Member States. On January 31, 2018, the

European Commission adopted a proposal for a regulation on HTA, or HTA Regulation. The HTA Regulation aims to boost cooperation among EU Member States in assessing health technologies and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation entered into force on January 11, 2022 and started to apply from January 12, 2025. Under the HTA Regulation, EU Member States are required to use common HTA tools, methodologies, and procedures across the EU. Among others, the HTA Regulation establishes an HTA coordination group, composed of national HTA bodies, which jointly conduct Joint Clinical Assessments, or JCA of new medicines and certain high-risk medical devices and introduces a single EU-level submission file for JCAs. However, the HTA Regulation focuses on the clinical aspects of HTA, i.e. the relative clinical effectiveness and relative clinical safety of a new health technology as compared with existing technologies, and, as such, individual EU Member States remain responsible for determining the overall value of a new health technology within their healthcare systems, as well as making pricing and reimbursement decisions.

Research and Development

We have established a dedicated research and development team with strong 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 our robotic systems. We also plan to leverage our treatment data and software development capabilities to enable artificial intelligence assisted anatomy recognition and improved treatment planning and personalization. We are also evaluating the application of our robotic systems in prostate cancer.

Manufacturing and Supply

We directly manufacture our robotic systems, the handpiece and other accessories at our facility in San Jose, 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 or HYDROS Robotic System is shipped to our customers with a third-party manufactured ultrasound system and probes. We utilize a well-known third-party logistics providers located in United States, United Kingdom, and the Netherlands to ship our products to our customers globally. We rely on third-party suppliers, almost all of whom are single source suppliers, to provide us with certain components, sub-assemblies and materials for our products. Our suppliers manufacture the components they produce for us and test our components and devices to our specifications. We have entered into manufacturing and supply agreements with several of our single-source suppliers pursuant to which they supply the components we need. In addition, we intend to maintain sufficient levels of inventory to enable us to continue our operations while we obtain another supplier in the event that one or more of our single-source suppliers were to encounter a delay in supply or end supply.

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 delivered through our robotic systems provides 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. Additionally, many of these companies have overcome reimbursement barriers and their procedures are covered by nearly all major insurance carriers. 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 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.

We believe that the primary basis 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

Our success depends in part on our ability to obtain, maintain, protect and enforce our proprietary technology and intellectual property rights, in particular, defend our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. 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 December 31, 2024, we had rights to 60 issued U.S. patents, expiring between 2028 and 2042, 133 issued foreign patents, expiring between 2028 and 2041, 38 pending U.S. patent applications, six pending PCT applications, and 55 foreign patent applications.

As of December 31, 2024, our rights to foreign issued patents included 21 granted Chinese patents, 30 granted Japanese patents, seven Brazilian patents, six Indian patents, and 17 granted European patents, of which 12 have been validated in Germany, 10 in Spain, 11 in France, 17 in the United Kingdom, six in Ireland, nine in Italy, one in Switzerland, and three European patents with unitary effect. As of December 31, 2024, our rights to foreign patent applications include 18 pending European applications, 17 pending Chinese applications, 14 pending Japanese applications, two pending Brazilian applications, one pending Indian application and three pending Hong Kong applications.

As of December 31, 2024, we had 44 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 material 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 Our Intellectual Property" for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

License Agreement with AquaBeam LLC

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 granted 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, 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 granted AquaBeam a worldwide, exclusive (even as to us), sublicensable, royalty-free license under certain of our patents rights until October 2021, that claim certain technology related to delivering energy to tissues by directing a liquid fluid stream, or PROCEPT Patents, outside the Field. No payments (except for patent prosecution and maintenance costs) have been made or are otherwise required under the AquaBeam License Agreement.

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 expiration date of the last-to-expire of the Licensed Patents and PROCEPT Patents will not be earlier than 2037. 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.

License Agreement with HydroCision

We are party to a Confidential Exclusive Patent License and Covenant Not To Sue, or the HydroCision License Agreement, with HydroCision, Inc., or HydroCision. Pursuant to the HydroCision License Agreement, HydroCision granted us a worldwide, exclusive, sublicensable, royalty-free license to certain patents related to fluid jet technology in the field of urology, or the Fluid Jet Technology Patents and related know-how and documentation. HydroCision also granted us a non-exclusive license to patents allowing us to make, sell, import, export, or otherwise dispose of products made using the Fluid Jet Technology Patents.

In exchange for the license from HyrdoCision, we paid HydroCision $2.5 million in 2019. No further payments have been made or are otherwise required under the HydroCision License Agreement. HydroCision is responsible for all patent prosecution and maintenance costs related to the Fluid Jet Technology Patents.

The HydoCision License Agreement will remain in full force and effect until the last to expire of the Fluid Jet Technology Patents. The expiration date of the last-to-expire of the Fluid Jet Technology Patents will not be earlier than 2039.

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 outside the United States. 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 United States regulations, we are subject to a variety of regulations outside the United States 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, De Novo authorization, 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 FDA's Quality System Regulation, or 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 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 request. 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. The de novo authorization establishes a new device class II product code. De novo authorized devices can then serve as predicate device for a 510(k). In addition, the FDA may reject the de novo request 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 robotic systems are Class II devices, 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 our robotic systems where we used the initially authorized device as the predicate device for our more recent 510(k) clearance.

510(k) Clearance Process

Our HYDROS Robotic System is a class II device that was cleared under the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent," as defined in the FDC Act, to a legally marketed predicate device.

A predicate device is a medical device that was legally marketed before May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. A device is considered to be substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics; or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise different questions of safety or effectiveness than the predicate device.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA determines that the device is substantially equivalent to a predicate device, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous requirements of the PMA approval process, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo classification or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance, approval of a PMA, or issuance of a de novo classification. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

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 QSR.

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 or de novo request 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;
- 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.

California Regulation

The State of California requires that we obtain a license to manufacture medical devices. In accordance with the State of California regulations, our license to manufacture is renewed annually with any updated manufacturing information. Although the State of California has announced the suspension of routine periodic inspections, there can be no assurance that the State of California will not resume such inspections or conduct such inspections under specific circumstances that are not yet known.

Regulation of Medical Devices Outside the United States

In order for us to market our products in countries outside the United States, we must obtain regulatory approvals and comply with extensive product and quality system regulations in other countries. These regulations, such as requirements for approvals or clearance and the time required for regulatory review, will vary from country to country. Some countries have regulatory review processes that are significantly longer than United States regulatory approval. Failure to obtain regulatory approval in a timely manner and meet all the local requirements (including language and specific safety standards) in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject us to fines.

Regulation of Medical Devices, European Economic Area, or EEA

The European Union, or EU, has adopted specific directives and regulations regulating among other things, the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

On May 26, 2021, the Regulation (EU) 2017/745 on Medical Devices, or the MDR, entered into application, repealing and replacing both the Medical Devices Directive 93/42/EEC, or the MDD, and the Active Implantable Medical Devices Directive 90/385/EEC, or the AIMDD. The MDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical requirements, premarket conformity assessment and post-market surveillance, vigilance, and market surveillance.

In order to avoid shortages of medical devices needed for the smooth functioning of healthcare services, the MDR was amended to provide extended transitional periods for devices which were CE marked under the MDD or the AIMDD and fulfill certain conditions outlined in the MDR. Pursuing marketing of medical devices in the EU will notably require that all our devices be certified under the MDR. Regardless of whether we have already obtained certification under the MDD, since May 26, 2021, the MDR requirements apply in place of the corresponding requirements of the MDD and the AIMDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements.

In the EU, unlike the US, there is no regulatory approval process prior to marketing of medical devices. However, the EU requires that all medical devices, including medical device software, or MDSW, placed on the market in the EU must comply with the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the MDR, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to devices, including MDSW, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the MDR and obtain the right to affix the CE Mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low-risk medical devices (Class I with no measuring function, not reusable and which are not sterile), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the involvement of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality management system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE Mark to its medical devices after having drawn up and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being

assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. Manufacturers are required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant GSPR. This level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose. The conduct of clinical studies in the EU is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the EU member state in which the investigation takes place and the requirement to obtain a positive opinion from a competent ethics committee. This process can be expensive and time-consuming.

To demonstrate compliance with certain GSPRs relating to the design and manufacture of medical devices, manufacturers may rely on compliance with the list of EU harmonized standards relating to medical devices. While not mandatory, compliance with these standards creates a presumption of conformity with the related GSPRs. Throughout the term of the Certificate, the manufacturer will be subject to periodic surveillance audits by the notified body to verify continued compliance with the applicable requirements. The notified body will also conduct an audit before renewing a Certificate. The quality management system and technical documentation of manufacturers will be required to be recertified periodically, as CE Certificates of Conformity issued by a notified body remain valid only for the period indicated in them and in no case exceed five years.

After a device is placed on the market, it remains subject to significant regulatory requirements. The MDR imposes post-marketing surveillance requirements which requires manufacturers to continuously and proactively monitor the performance and safety of their devices through implementation of a post-market surveillance system, in a manner that is proportionate to the risk class and appropriate for the type of their device. Once a device is on the EU market, manufacturers must comply with certain vigilance requirements, such as the reporting of serious incidents and field safety corrective actions (even those occurring outside the EU) to the relevant Competent Authorities. The Competent Authorities of each EU Member State oversee the implementation of the MDR within their jurisdiction.

Other Regions

Most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory approval to be sold in Japan.

Regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. These countries typically require regulatory approvals and compliance with extensive safety and quality system regulations.

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 referral of an individual or the 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, and can include 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 of our products 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 and may result in increased scrutiny by government enforcement authorities. 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.

The majority of states, as well as many of the non-U.S. jurisdictions where we operate, 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. 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. 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.

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), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) 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. 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.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. The advertising and promotion of medical devices are also subject to EU and EU Member States' laws governing promotion of medical devices, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. 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.

Violations of any of these laws or any other governmental regulations that apply may result in significant penalties including administrative, civil, and criminal damages, disgorgement, fines, additional reporting requirements and compliance oversight obligations in the event that a corporate integrity agreement or other agreement is required to resolve allegations of noncompliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and/or individual imprisonment.

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.

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 which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Subsequent amendments to this law provide for 1% Medicare sequestration through the second quarter of 2022 and the full 2% sequestration thereafter until 2032. This sequestration is currently set at 2% and will continue through the first 8 months of fiscal year 2032. 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, and consumer protection laws and regulations 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. In addition, certain foreign laws govern the privacy and security of personal information, including health-related information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. 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.

Employees and Human Capital Resources

Our growing and skilled employee base drives our success and helps us progress towards our vision of restoring patient lives by delivering the BPH treatment of choice. As of December 31, 2024, we had 756 employees.

Our future success depends on our ability to attract, retain, engage and further develop top talent. To facilitate talent attraction, retention, engagement and development, we strive for a diverse workplace with a superior employee experience that provides opportunities for our employees to grow within the organization, supported by strong compensation, benefits, and health and wellness programs and an inclusive environment.

Beginning in 2022 and updated annually since then, we have published our Environmental, Social, and Governance or ESG Report, which is available on our website and includes more detailed information on our human capital programs and initiatives. Nothing contained on or accessible through our website, including our ESG Report or sections thereof, shall be deemed incorporated by reference into this Annual Report.

Human Capital and Inclusiveness

Inclusiveness is valued in our organization because we strongly believe that it drives superior results – and truly reflects the communities we serve and in which we work. We believe that everyone should feel included and fairly treated, and we embrace the unique qualities of our employees including all genders and gender identities, races, ethnicities, ages,

national origins, disabilities, sexual orientations, military and socioeconomic backgrounds, and religions, as well as any other protected characteristics.

Additionally, from a governance perspective, we maintain a mix of skills, backgrounds and experience on our executive team and on our board to serve the needs of our diverse stakeholders.

Health, Safety and Wellness

The health, safety and wellness of our employees is an area where we continued to invest and expand throughout 2024. We provide our employees and their families with access to a variety of comprehensive health, wellness and time off programs that support physical, mental, emotional and financial well-being. We have a zero-tolerance policy concerning workplace violence including any threatening behavior on our premises or during any work-related activities.

Compensation and Benefits

Our compensation programs are designed to align the compensation of our employees with our Company's performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. We believe compensation and rewards should be fair and merit based and free from discrimination on the basis of race, gender or any other protected characteristics. We provide a comprehensive suite of compensation and benefits programs including annual bonuses, equity awards, an Employee Stock Purchase Plan, retirement savings plans with a company match, healthcare, income protection benefits, paid time off, leave of absence benefits, flexible work arrangements, and numerous well-being benefits.

Talent Development

Professional growth is a key indicator of employee satisfaction and helping our employees reach and exceed their goals helps us retain and engage our outstanding talent. We foster professional growth by providing stretch assignments, projects and manager-led coaching and mentoring to help employees meet their career goals. We continuously work on improving manager effectiveness by providing training on people processes and a program that focuses on building connection and trust, high performing teams, and fostering a growth mindset.

We have an annual global performance review process for reviewing all employees' performance and encourage ongoing conversations and a mid-year review as well. We also have an annual compensation process to review pay. To support our managers, we train them on topics such as conducting effective performance reflections and making equitable compensation recommendations, considering market pay data, experience in role and performance.

Engagement

We strive to continuously improve our employee experience to impact employee retention and engagement, and we periodically conduct an engagement survey and take actions to address areas of employee concern.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC. Our website address is www.procept-biorobotics.com. Information on our website is not part of this report. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

Item 1A. Risk Factors

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

Risks Related to Our Business

We have 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, 2024 and 2023, we had a net loss of $91.4 million and $105.9 million, respectively. We expect to continue to incur additional losses in the future. As of December 31, 2024, we had an accumulated deficit of $546.0 million. To date, we have financed our operations primarily through net proceeds from sales of our equity securities, indebtedness, including our loan and security agreement, and, to a lesser extent, product revenue from sales of our robotic systems and disposables. 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 continue to incur significant legal, accounting and other expenses. 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 robotic systems 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 robotic systems and our accompanying single-use disposable handpieces and other disposables. Our robotic systems deliver Aquablation therapy, using a heat-free robotically controlled waterjet to remove prostate tissue. 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 may have limited product and brand recognition within the medical industry. 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;

- 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 in which our products are used;
- 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 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 December 31, 2024, we had $52.0 million outstanding in the form of a term loan under our loan and security agreement with Canadian Imperial Bank of Commerce, which was entered into in October 2022 and amended in June 2023. 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 Annual Report on Form 10-K 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 for us to maintain in deposit accounts held at CIBC the lesser of (i) $90.0 million or (ii) all of our non-operating cash or require us to, among other things, either meet certain revenue targets detailed in an approved forecast or maintain a minimum amount of unrestricted cash. The loan and security agreement also contains customary events of default. If we fail to comply with such covenants, payments or other terms of the agreement, our lender could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our lender would have the right to proceed against the assets we provided as collateral pursuant to the loan and security agreement. If the debt under the loan and security agreement were accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition.

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

Since our inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily by net proceeds from sales of our equity securities, indebtedness and, to a lesser extent, product revenue from sales of our robotic systems and single-use disposable handpieces. As of December 31, 2024, we had $333.7 million in cash and cash equivalents, and an accumulated deficit of $546.0 million. Based on our current operating plan, we currently believe that our cash and cash equivalents and anticipated revenue will be sufficient to meet our capital requirements and fund our operations through at least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Changing circumstances could result in lower revenues or cause us to consume capital significantly faster than we currently anticipate, and we may need to raise capital sooner or in greater amounts than currently expected because of circumstances beyond our control.

We may require additional capital in the future as we expect to continue to expand our sales and marketing organization, invest in clinical trials and registries that are designed to provide clinical evidence of the safety and efficacy of our products and research and development of product improvements and future products. Moreover, we expect to continue to incur significant 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;
- the scope and timing of investment in our sales force and expansion of our commercial organization;
- the scope, rate of progress and cost of our current or future clinical trials and registries;
- the cost of our research and development activities;
- the cost and timing of additional regulatory clearances or approvals;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels;
- the costs of attaining, defending and enforcing our intellectual property rights;
- whether we acquire third-party companies, products or technologies;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the emergence of competing technologies or other adverse market developments; and
- the rate at which we expand internationally.

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

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. For example, our current loan and security agreement prohibits us from incurring additional indebtedness without the prior written consent of our lender. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

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

The commercial success of our products 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 products as safe, effective, reliable and durable and, with respect to hospitals, healthcare providers and patients, as cost-effective. Our products employ a computer-assisted patient-specific visualization system, a heat-free waterjet and an 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 treatment utilizing our products 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 treatment utilizing our products 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;
- concerns over the capital investment required to purchase our robotic systems and perform procedures utilizing our products;
- 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 robotic systems 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 products achieve widespread market acceptance, they 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 products, 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 direct 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 our procedures, 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 products 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 our products 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 rely on third-party distributors to effectively distribute our products in certain markets.

We depend, or expect to depend in the future, on qualified distributors for the marketing and selling of our products in certain markets. If our distributors fail to effectively market and sell our products in full compliance with applicable laws, our operating results and business may suffer. Screening, recruiting and retaining qualified third-party distributors and training them in our technology and product offering and business practices requires significant time and resources. To develop and expand our distribution, we may be required to scale and improve our processes and procedures that support

our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to develop or maintain positive relationships with our distributors, including in new markets, fail to manage, train or incentivize these distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, we may not achieve expected revenues or may have a reduction in revenue and our operating results, reputation and business would be harmed.

We may not be able to 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 robotic systems and single-use disposable handpieces to our customers. 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, maintaining 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 end user customers typically bill third-party payors for the costs and fees associated with the procedures in which our products are used. Any decline in the amount payors are willing to reimburse, could make it difficult for customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which 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 or maintain coverage for procedures in which our products are used. 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 revise existing local coverage determination decisions 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 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, and with medical device companies that manufacture resective or non-resective surgical alternatives for treating to our products. Resective alternatives for treating BPH include devices for the TURP procedure, laser-based therapies and simple prostatectomy, each of which is intended to remove the prostate tissue, and non-resective alternatives such as UroLift marketed by Teleflex Incorporated and Rezum marketed by Boston Scientific Corporation, which are intended to reshape the prostate and widen the cavity. Our primary medical device competitors for treating BPH 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. . If we are successful in obtaining regulatory clearance for the use of our products and Aquablation therapy for patients with prostate cancer, we expect we will be competing with additional companies.

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;
- established relationships with hospitals and physicians who are familiar with other surgical alternatives;
- 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 as well as the treatment of prostate cancer, 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 research and technological progress that exist within the market.

If we are unable to continue to innovate and improve our products, 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 products' functionality and efficiency. If we fail to make improvements to our robotic systems' functionality over time, our competitors may develop products that offer features and functionality similar or superior to those of our products. If we fail to make improvements to our products' efficiency, our competitors may develop products that are more cost-effective than ours. Our failure to make continuous improvements to our products 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. Currently, we have a sole manufacturing facility located in San Jose, California, where we manufacture, assemble, inspect, test, package and ship our products. We currently assemble all of our robotic systems and single-use disposable handpieces at this one facility. If this facility, or any of our future manufacturing facilities, suffers damage, or a force majeure event were to occur, 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 geopolitical or 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. As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although some future products may share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the

development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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 products require significant amounts of service after sale, our operating expenses may substantially increase, and our business and financial results will be adversely affected.

We typically warrant our robotic systems against defects in materials and workmanship for a period of approximately 12 months from the installation of our products at a customer location or in some cases from the delivery of our products. We also expect to continue to provide technical and other services to customers beyond the warranty period pursuant to a supplemental service plan that we sell for our robotic systems. Additionally, we warrant our disposable products against defects in materials and workmanship for a period of approximately 12 months from delivery. 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 products 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 robotic systems 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.

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

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our current or any new products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, or if we add more components to our systems, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, including during any international expansion, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm negatively affect our business, financial condition and results of operations.

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

We have experienced substantial growth in our operations, and we expect to experience continued substantial growth in our business. Over the next several years, we expect to increase significantly the scope of our operations, particularly in the areas of manufacturing, sales and support, research and development, product development, regulatory affairs, marketing and other functional areas, including finance, accounting, quality control, and legal. 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 products and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our robotic systems console and the single-use disposable handpieces based on our estimates of future demand for, and utilization of, our robotic systems. 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 information technology systems, or those used by third party service providers, partners, 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 information technology systems as well as those of our third-party partners, consultants, contractors, suppliers, and service providers, may be vulnerable to attack, damage and interruption 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, malicious code, phishing attacks and other social engineering schemes, denial or degradation of service attacks, attacks by sophisticated nation-state and nation-state-supported actors, 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 health-related and other personal information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage.

We and certain of our partners or service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. 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 partners, 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 health-related or other personal 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.

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. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Actual or perceived failure to comply with data protection, privacy and security laws, regulations, standards and other requirements could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

The global data protection landscape is rapidly evolving, and we are, or we may, become subject to federal, state, and foreign data protection laws, regulations and requirements governing the collection, use, disclosure, retention and security of personal information. 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, as amended by the Health Information Technology for Economic and Clinical Health Act of

2009, and regulations promulgated thereunder, or collectively, HIPAA, imposes 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 protected health information for or on behalf of a covered entity. 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 Section 5 of the Federal Trade Commission Act. The FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. 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.

In addition, certain state laws govern the privacy and security of health-related and other personal information, many of which may differ from each other, thus, complicating compliance efforts. For example, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. It created 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 for certain data breaches that has increased the likelihood of, and risks associated with, breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023, and amends the CCPA. The CPRA imposes 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 creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Following the lead of California, several other states, including Virginia, Colorado, Connecticut and Utah, have each enacted laws similar to the CCPA/CPRA and other states are considering enacting privacy laws as well. Health-specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. The multiple layers of privacy law within the United States could increase our potential liability, increase our compliance costs, and adversely affect our financial condition.

Foreign data protection laws, including the General Data Protection Regulation, including as implemented in the United Kingdom, or collectively or GDPR, 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 EEA and UK, including obligations to having a lawful basis for processing personal data (which may in certain situations require explicit consent of the individuals to whom the personal data relates), providing detailed information about the processing activities, dealing with restrictions on sharing of personal data with third parties, and the transferring 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 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. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by former President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines,

and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Moreover, as a result of the broad scale release and availability of Artificial Intelligence (AI) technologies such as generative AI, there is a global trend towards more regulation (e.g., the EU AI Act and AI laws passed in U.S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.

Further, from January 1, 2021, companies have had 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. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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

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

Natural or man-made disasters, including earthquakes, wildfires, floods, hurricanes, nuclear disasters, riots, acts of terrorism or other criminal activities, public health emergencies such as infectious disease outbreaks, power outages and other infrastructure failures may impact our facilities or operations or the facilities or operations of our suppliers, customers, and other business partners (including their suppliers and business partners), which could the result in a disruption in our business and operations or increase costs to operate our business. For example, following a natural disaster, and during the related recovery, our customers may limit the number of surgical procedures or elective procedures performed at their facilities due to disruptions to hospital operations or supply constraints, or patients may choose to cancel or delay such procedures even if the hospital is able to perform it. As a result, customers may reduce the number of products ordered during the disruption, including disposable handpieces, and we may experience material and adverse impacts to our business, financial condition and results of operations, even if such supply constraints would not directly impact our procedure.

Furthermore, 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 any such natural or catastrophic disasters, 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 business continuity or repair 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 products 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 products are based on a number of internal and third-party estimates, including, without limitation, the assumed prices at which we can sell our robotic systems 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 products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, or the total addressable market for our products 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 products, we may face risks associated with a more concentrated customer base.

Until we are able to achieve broader market acceptance of our products, 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 disposables, 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 robotic systems, the single-use disposable handpiece or any of their component parts, or any of our products, 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 products 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 products, 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 products. 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 countries outside of the United States. 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;

- to the extent we utilize third-party distributors in foreign markets, our ability to effectively screen, recruit and retain qualified third-party distributors and training them in our technology and product offering and business;
- 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, such as the conflicts between Russia and Ukraine, tensions across the Taiwan Strait, the Israel-Hamas conflict and other hostilities in the Middle East;
- fluctuations in foreign currency exchange rates;
- an inability, or reduced ability, to protect our intellectual property in various countries around the world, 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.

Changes in United States trade policy, including the imposition of tariffs and the resulting consequences, may have a material adverse impact on our business and results of operations.

As a result of new administration and associated policy changes or shifting proposals by the U.S. government, there may be greater restrictions and economic disincentives on international trade. For example, the U.S. government has pursued a new approach to trade policy, including renegotiating or terminating certain existing bilateral or multi-lateral trade agreements. It has also imposed tariffs on certain foreign goods and has raised the possibility of imposing significant, additional tariff increases or expanding the tariffs to capture other types of goods. These tariffs and other changes in U.S. trade policy have in the past and could continue to trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Foreign governments may also adopt other protectionist measures that could limit our ability to offer our products and services outside of the U.S. The ultimate impact of any tariffs or restrictions on international trade will depend on various factors, including if any tariffs are ultimately implemented, the timing of implementation, and the amount, scope, nature of the tariffs, and corresponding actions by foreign governments. We, our suppliers and our customers import certain raw materials, components and other products from foreign suppliers. Therefore, increased tariffs could increase the cost of our products and the components and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products, which could make our products less competitive and reduce consumer demand. As such, the increase of tariffs, the adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the United States economy, which in turn could have an adverse effect on our business, financial condition and results of operations.

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 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, 2024, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately $391.9 million and $242.2 million, respectively, and U.S. federal and state research and development credit carryforwards of $10.6 million and $8.3 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.

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

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

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

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

Also, the anticipated benefit of any acquisition may not materialize, or such acquisition may be prohibited. Our loan and security agreement 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 our products and procedures utilizing our products, as well as 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 eligible for procedures in which our products are used are covered by Medicare, the Medicare coverage policy and reimbursement rate are important factors in a physician's decision to use our products and limits the prices we may charge for our products.

Many patients have Medicaid coverage that is supplemental to Medicare coverage, and some 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 our products and procedures utilizing our products 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 products.

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 products. 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 products. 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 products.

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, an executive order was issued that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, from February 15, 2021 to 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.

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 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, 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 prices that we believe is fair for our products;
- 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 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), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; 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 physician consultants or our equipment placement practice, 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 robotic systems 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 robotic systems, 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 robotic systems are medical devices 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 products;
- 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 that received De Novo approval, and our HYDROS 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.

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 or de novo request 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 first generation AquaBeam Robotic System and have subsequently obtained 510(k) clearances for modifications to the system. In August 2024, we obtained FDA 501(k) clearance for our next-generation platform, the HYDROS Robotic System. Any future modifications to these robotic 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 robotic systems, 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 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 robotic systems.

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.

We believe some of our future products will require FDA clearance of a 510(k). Other future products may require the approval of a PMA. In addition, some of our future products may require clinical trials to support marketing authorization 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 approval 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 may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Modifications to our robotic systems and associated consumables may require new regulatory approvals or clearances, including 510(k) clearances, 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 products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products 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 apply for a new 510(k) clearance or possibly a PMA approval. If we determine that modifications to our products 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 products, 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 robotic systems, 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 equivalent 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 and/or equivalent foreign regulatory bodies 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 2021 we initiated a voluntary recall for a limited number of lots of our handpiece due to certain issues related to our supply chain. 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 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 corrections and removals be reported to the FDA within 10 working days after such correction or removal 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 current or future products, in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. 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 products.

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 products 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 products, 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.

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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.

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. For example, on February 22, 2024, the FDA finalized a rule amending the Quality System Regulation, or QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization, or ISO, standards. The rule, called the Quality Management System Regulation, or QSMR, becomes effective in February 2026.

Moreover, a new President of the United States, as well as many members of the U.S. Congress were elected on November 5, 2024. The policies of the new administration and their impact on the regulation of our products in the United States are uncertain. The outcome of this election could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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.

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 or de novo requests, or to provide additional safety and efficacy data beyond those 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 equivalent foreign regulatory authorities 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 in accordance with 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, 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, 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.

If a prolonged government shutdown occurs, or if any global health concerns hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 robotic systems 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 others from duplicating our robotic systems or its disposable components, and our other current and future products;
- prevent others 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.

The requirements for patentability may differ in certain countries, particularly in developing countries. The laws of some foreign countries may not protect our patent rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained sufficient patent protection to develop their own products or may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents rights may not be effective or sufficient to prevent them from competing. 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. Third parties may also challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. 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 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 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 robotic systems 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 robotic systems, 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 robotic systems 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 robotic systems 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 robotic systems 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, or challenging the validity, enforceability or scope of our patents, 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 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 robotic systems 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 robotic systems 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 robotic systems 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 robotic systems 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.

Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies globally.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices globally. We may become involved in opposition, derivation, revocation, reexamination, post-grant review, inter partes review ("IPR") or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology or products. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of 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 the USPTO or made a misleading statement during prosecution. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies globally, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation

proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. 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,

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 robotic systems 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. 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 robotic systems 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.

Proceedings to enforce our patent and trademark rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents and trademarks or applications in those

jurisdictions, as well as elsewhere, at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any proceedings that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- variations between our actual operating results, or those of companies that are perceived to be similar to us, and the expectations of securities analysts, investors and the financial community;
- any forward-looking financial or operating information we may provide to the public or securities analysts, any changes in this information or our failure to meet expectations based on this information;
- actions of securities analysts who initiate or maintain coverage of us, changes in financial estimates by any securities analysts who follow our Company or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders, or the anticipation of such sales;
- 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;
- 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.

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 Canadian Imperial Bank of Commerce 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.

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

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

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

Our amended and restated certificate of incorporation and bylaws currently in effect contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our

company or changes in our management that the stockholders of our company may deem advantageous. These provisions include the following:

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

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

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

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

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

will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. These provisions may also result in increased costs for investors seeking to bring a claim against us or any of our directors, officers or other employees.

Risks Related to Being a Public Company

If we are not able to maintain adequate internal control over financial reporting, or if we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the trading price of our common stock could decline.

We are subject to the periodic reporting requirements of the Exchange Act. As a result, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. As a result of becoming a public company, we will be required, in order to comply with the SEC's rules and regulations, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We designed our disclosure controls and procedures to provide reasonable assurance 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.

If we are not able to maintain adequate internal control over financial reporting, or if we identify material weaknesses in future periods, we may not be able to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the trading price of our common stock could decline.

If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information.

Section 404 of the Sarbanes-Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations, document our controls and perform testing of our key controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. We have incurred significant expense and devoted substantial management effort to complying with the requirements of Section 404 of the Sarbanes-Oxley Act, which we expect will continue. We anticipate hiring additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to support future growth. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or if we encounter difficulties in the timely and accurate reporting of our financial results, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our investors could lose confidence in our reported financial information, the market price of our stock may decline and we could be subject to lawsuits, sanctions or investigations by regulatory authorities, which would require additional financial and management resources.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

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

By disclosing information in this Annual Report on Form 10-K 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 robotic systems, 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, including from inflation and central bank policies among other sources. Such stresses may result 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.

Ongoing and potential conflicts could adversely affect our business, financial condition, or results of operations.

The length, impact, and outcome of ongoing military conflicts is highly unpredictable and could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, social and political, trade barriers or disputes, changes in consumer preferences, as well as an increase in espionage and cyberattacks. The extent and duration of the military action, sanctions, other consequences could be significant and could potentially have substantial impact on the global economy and our business for an unknown period of time. Impacts to our business may include, but are not limited to, procedures performed, demand for our products, and ability to spend on capital equipment and healthcare in general. A broadening of this conflict, or the initiation of other conflicts globally may heighten these risks. Any such disruption may also amplify the impact of other risks described.

We are actively monitoring the ongoing conflict between Israel and Hamas and assessing the impacts on our business, including our business partners and customers. To date, we have not experienced any material interruptions in our operations. We have no way to predict the progress, outcome, or consequences of the military conflict in the Israel-Gaza regions and any potential increases in hostilities in the Middle East.

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.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, customers, environmental activists, the media, and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on, or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

Our information technology team conducts monthly security assessments to identify cybersecurity threats utilizing third-party experts retained by us, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. Our research and development team utilizes third-party experts to evaluate cybersecurity risks during our product development process. These risk assessments generally include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we reasonably address any identified gaps in existing safeguards and regularly monitor the effectiveness of our safeguards. Our head of information technology periodically makes reports to the Company's Chief Financial Officer on the results of our risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train all of our employees on cybersecurity safeguards related to our information technology systems. Personnel at all levels and departments are made

aware of our cybersecurity policies through random cybersecurity testing and remedial trainings. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls, and procedures, will be fully implemented, complied with or effective in protecting our systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

See the section titled "Risk Factors" in this Annual Report for additional information.

Cybersecurity Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through delegation of primary responsibility to the audit committee. The audit committee receives periodic reports, at least annually, on our cybersecurity program, industry best practices, and any incidents or trends.

Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. The audit committee receives annual reports from management personnel responsible for enterprise risk management, which also evaluates cybersecurity among other enterprise level risks on an annual basis.

Our security officer, our Chief Financial Officer, and our head of information technology are primarily responsible to assess and manage our material risks from cybersecurity threats. Our incident response plan designates our head of information technology as primarily responsible for identifying and evaluating any cybersecurity incident or suspected incident, and reporting any such incidents to management (including the security officer, Chief Financial Officer, and Chief Legal Officer) in order for management to evaluate materiality, and to report to our audit committee, our board of directors and make public disclosures as applicable.

Item 2. Properties

Our principal office is located at 150 Baytech Drive, San Jose, California, where we lease approximately 163,221 square feet of office space, inclusive of approximately 5,000 square feet of temporary storage space on a month-to-month lease. The principal office lease commenced in July 2022, and will continue for 122 months following thereafter, with two five year options to extend the term of the lease.

Item 3. Legal Matters

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

Item 4. Mine Safety Disclosures

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issue Purchases of Equity Securities

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "PRCT" since September 14, 2021. Prior to that date, there was no public trading market for our common stock.

Holders of Common Stock

As of February 20, 2025, there were 212 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

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 Canadian Imperial Bank of Commerce. 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.

Recent Sales of Unregistered Securities

None.

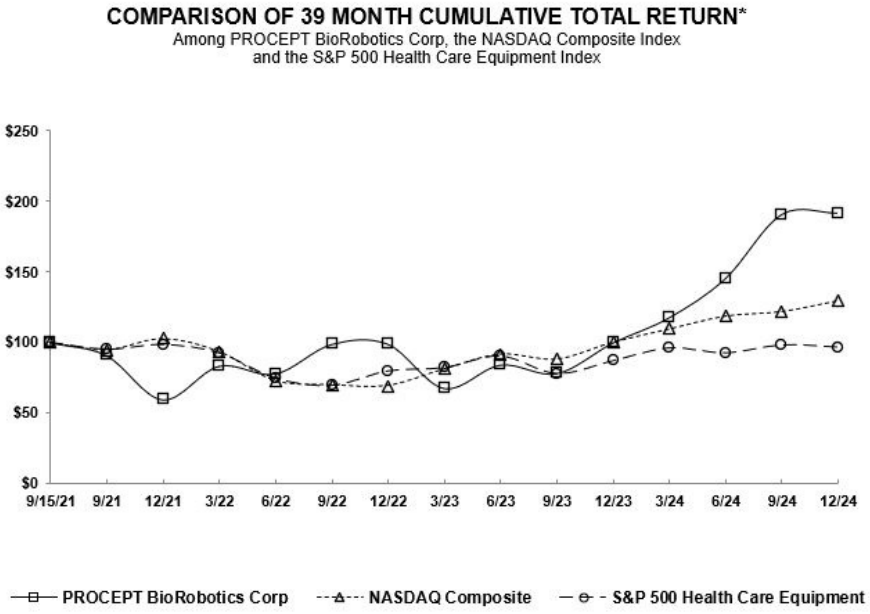
Issuer Purchases of Equity Securities

None.

Stock Performance Graph

The following shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

This chart compares the cumulative total return on our common stock with that of the NASDAQ Composite Index and the S&P Health Care Equipment Index. The graph assumes $100 was invested in each of the Company's common stock, the NASDAQ Composite Index and the S&P Health Care Equipment Index, and assumes reinvestment of any dividends. Note that historic stock price performance is not necessarily indicative of future stock price performance.



*$100 invested on 9/15/21 in stock or 8/31/21 in index, including reinvestment of dividends.
Fiscal year ending December 31.

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Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

The following generally compares our results of operations for the years ended December 31, 2024 and 2023. A detailed discussion comparing our results of operations for the years ended December 31, 2023 and 2022 can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2023.

Overview

We are a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. We develop, manufacture and sell the AquaBeam Robotic System and HYDROS Robotic System, which are advanced, image-guided, surgical robotic systems 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. Each of our robotic systems 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 robotic systems to enable consistent and reproducible BPH surgery outcomes. We believe that Aquablation therapy represents a paradigm shift in the surgical treatment of BPH by addressing compromises associated with alternative surgical interventions. We designed Aquablation therapy to deliver effective, safe and durable outcomes for males suffering from lower urinary tract symptoms, or LUTS, due to BPH that is independent of prostate size and shape, and delivers resection independent of surgeon experience. We have developed a significant and growing body of clinical evidence, which includes nine clinical studies and over 150 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy. As of December 31, 2024, we had an install base of 647 AquaBeam Robotic Systems and HYDROS Robotic Systems globally, including 505 in the United States.

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

In the United States, we sell our products to hospitals. We target approximately 2,700 hospitals that perform resective BPH procedures in the United States. Over time, we expect to 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 many large commercial payors. We plan to leverage these successes in our active discussions with all commercial payors to establish additional positive national and regional coverage policies. Outside of the United States, we have ongoing efforts in key markets to expand established coverage and improve payment which we believe will expand patient access to Aquablation therapy.

We manufacture the robotic systems, the single-use disposable handpiece, integrated scope and other accessories at our facility in San Jose, 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 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 $224.5 million and $136.2 million, for the years ended December 31, 2024 and 2023, respectively, and incurred a net loss of $91.4 million and $105.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $546.0 million.

Factors Affecting Our Performance

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

- *Grow our install base of robotic systems:* As of December 31, 2024, we had an install base of 647 robotic systems globally, including 505 in the United States. In the United States, we are initially focused on driving adoption of Aquablation therapy among urologists that perform hospital-based resective BPH surgery. We target approximately 2,700 hospitals that perform resective BPH procedures in the United States. To penetrate these hospitals, we expect to continue to increase our direct team of capital sales representatives, who are focused on driving system placement within hospitals by engaging with key surgeons and decision makers to educate them about the compelling value proposition of Aquablation therapy. As we increase our install base of robotic systems, we expect our revenue to increase as a result of the system sale and resulting utilization.

- *Increase system utilization:* Our revenue is significantly impacted by the utilization of our robotic systems. 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 expect to 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 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 robotic systems. We believe 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 many large commercial payors. We plan to leverage these 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 robotic Systems 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 our robotic systems. 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.

Components of Our Results of Operations

Revenue

We generate our revenue primarily from the sales and rentals of our robotic systems, sales of our single-use disposable handpieces that are used during each surgery performed with our system, and related accessories. Additionally, we also derive revenue from service and repair and extended service contracts with our existing customers. We expect our revenue to increase in absolute dollars for the foreseeable future as we continue to focus on driving adoption of Aquablation therapy, and increased system utilization, though it may fluctuate from quarter to quarter.

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

	Year Ended December 31,	
	2024	2023
United States	89 %	91 %
Outside the United States	11 %	9 %

We expect that both our United States and international revenue will increase in the near term as we continue to expand the install base of our robotic systems and increase the related single-use disposable handpieces sold. We expect our increase in revenues in absolute dollars to be larger in the United States.

Cost of Sales and Gross Margin

Cost of sales consists primarily of manufacturing overhead costs, material costs, warranty and service costs, direct labor, scrap 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 period to period.

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, clinical trial expenses, 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 include 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. 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 long-term debt.

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 loan facility derivative liability.

Loss on loan extinguishment

Loss on loan extinguishment was a result of our acquisition price of our new debt exceeded the carrying amount of our existing debt during the fiscal year ended December 31, 2022.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

The following table shows our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands, except percentages)			
Revenue	$ 224,498	$ 136,191	88,307	65
Cost of sales	87,399	65,142	22,257	34
Gross profit	137,099	71,049	66,050	93
Gross margin	*61 %*	*52 %*		
Operating expenses:				
Research and development	62,298	48,446	13,852	29
Selling, general and administrative	171,415	131,773	39,642	30
Total operating expenses	233,713	180,219	53,494	30
Loss from operations	(96,614)	(109,170)	12,556	12
Interest expense	(4,184)	(3,995)	(189)	(5)
Interest and other income, net	9,385	7,268	2,117	29
Net loss	$ (91,413)	$ (105,897)	14,484	14

Revenue

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands, except percentages)			
System sales and rentals	$ 90,299	$ 58,920	31,379	53
Hand pieces and other consumables	121,456	69,522	51,934	75
Service	12,743	7,749	4,994	64
Total revenue	$ 224,498	$ 136,191	88,307	65

Revenue increased $88.3 million, or 65%, to $224.5 million during the year ended December 31, 2024, compared to $136.2 million during the year ended December 31, 2023. The growth in revenue was primarily attributable to an increase

of $31.4 million and $51.9 million in revenues from higher sales volumes of both our robotic systems and our single-use disposable handpieces.

Cost of Sales and Gross Margin

Cost of sales increased $22.3 million, or 34%, to $87.4 million during the year ended December 31, 2024, compared to $65.1 million during the year ended December 31, 2023. The increase in cost of sales was primarily attributable to the growth in the number of units sold.

Gross margin increased to 61% during the year ended December 31, 2024, compared to 52% for the year ended December 31, 2023. 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 decreases in scrap and warranty costs.

Research and Development Expenses

R&D expenses increased $13.9 million, or 29%, to $62.3 million during the year ended December 31, 2024, compared to $48.4 million during the year ended December 31, 2023. The increase in R&D expenses was primarily due to employee-related expenses from increased headcount of our R&D organization, as well as increases in third-party product development costs. These expenses support ongoing product improvements and the development of additional and next generation technologies.

Selling, General and Administrative Expenses

SG&A expenses increased $39.6 million, or 30%, to $171.4 million during the year ended December 31, 2024, compared to $131.8 million during the year ended December 31, 2023. The increase in SG&A expenses was primarily due to employee-related expenses of our sales and marketing organization and administrative organizations as we expanded our infrastructure to drive and support our growth in revenue.

Interest Expense

Interest expense of $4.2 million during the year ended December 31, 2024 remained relatively flat compared to fiscal 2023.

Interest and other income, net, increased $2.1 million to $9.4 million during the year ended December 31, 2024 compared to $7.3 million during the year ended December 31, 2023. The increase in interest and other income, net was primarily due to higher interest rates earned on our cash equivalents.

Liquidity and Capital Resources

Overview

We completed a follow-on offering of common stock in October 2024, which raised $164.5 million in proceeds to us, net of issuance costs. Previously, our primary sources of capital have been from our initial public offering, private placements of redeemable convertible preferred securities and debt financing agreements.

As of December 31, 2024, we had cash and cash equivalents of $333.7 million, an accumulated deficit of $546.0 million, and $52.0 million outstanding on our loan facility. We expect our expenses will increase for the foreseeable future, 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 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 and anticipated revenue will be sufficient to meet our capital requirements and fund our operations through at least the next twelve months from the issuance date of the financial statements. We have based this estimate on assumptions that may prove to be wrong, and we may need to utilize additional available capital resources. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional public equity or debt securities or obtain an additional credit facility. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products.

Indebtedness

In October 2022, we entered into a loan and security agreement with Canadian Imperial Bank of Commerce. The Agreement provides for a senior secured term loan facility in the aggregate principal amount of $52.0 million, which was borrowed in full. Proceeds from the term loan facility were used to repay and terminate our previous loan facility, transaction fees, and related expenses.

The term loan facility is scheduled to mature on October 6, 2027, the fifth anniversary of the Closing Date (the “Maturity Date”). The loan and security agreement provides for interest-only payments on the term loan facility for the first thirty-six months following the Closing Date (the “Initial Interest-Only Period”). The Initial Interest-Only Period will be extended to an additional twelve months if we achieve either (i) $200.0 million or greater in revenue in any twelve-month period or (ii) $0 or greater in EBITDA in any six-month period. Thereafter, amortization payments on the Term Loan Facility will be payable monthly until the Maturity Date in monthly installments equal to 20% of the then outstanding principal amount of the Term Loan Facility divided by 12 plus any accrued and unpaid interest. We have the option to prepay the Term Loan Facility without any prepayment charge or fee. We achieved the twelve-month revenue target as of December 31, 2024.

The loan borrowed under the Term Loan Facility bears interest at an annual rate equal to the secured overnight financing rate ("SOFR") (calculated based on an adjustment of 0.10%, 0.15% and 0.25%, respectively, for one-month, three-month or six-month term SOFR as of a specified date, subject to a floor of 1.5%) plus an applicable margin of 2.25%.

The obligations under the loan and security agreement are secured by substantially all of our assets, including its intellectual property and by a pledge all of our equity interests in its U.S. subsidiaries and 65% of our equity interests in its non-U.S. subsidiaries that are directly owned by us. We are obligated to maintain in deposit accounts held at the lender equal to at least the lesser of (i) $100.0 million or (ii) all of our non-operating cash.

The loan and security agreement contains certain customary representations and warranties, affirmative and negative covenants, and events of default. Under the loan and security agreement, if we maintain less than $100.0 million in available cash, then we are required to meet either one of two financial covenants: a minimum unrestricted cash covenant or a minimum revenue and growth covenant. The minimum unrestricted cash covenant requires that we to maintain cash reserve not less than the greater of (i) $20.0 million, (ii) the absolute value of EBITDA losses (if any) for the most recent consecutive four-month period then ended or (iii) the aggregate outstanding principal amount of $52.0 million. The minimum revenue and growth covenant requires our revenue, for the consecutive twelve-month period as of each measurement date, of not less than $50.0 million and of at least 115% as of the last day of the consecutive twelve-month

period of the immediately preceding year. If we maintain at least $100.0 million in available cash, then it is not required to meet such financial covenants.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2024, 2023, and 2022:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Net cash provided by (used in):			
Operating activities	$ (99,213)	$ (108,003)	$ (80,382)
Investing activities	(4,409)	(25,206)	(2,653)
Financing activities	180,125	167,795	3,612
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 76,503	$ 34,586	$ (79,423)

Net Cash Used in Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $99.2 million, consisting primarily of a net loss of $91.4 million and an increase in net operating assets of $47.3 million, partially offset by non-cash charges of $39.5 million. The cash used in operations was primarily due to our net loss due to the increase in operating expenses to support our commercialization and development activities. The expansion of our commercialization resulted in increases in inventory, accounts receivable, prepaid expenses and other current assets along with long-term assets, a decrease in accounts payable, partially offset by an increase in accrued compensation, deferred revenue, lease liabilities, and accrued interest expense. Non-cash charges consisted primarily of stock-based compensation, accruals for excess and obsolete inventory and depreciation.

During the year ended December 31, 2023, net cash used in operating activities was $108.0 million, consisting primarily of a net loss of $105.9 million and an increase in net operating assets of $26.2 million, partially offset by non-cash charges of $24.1 million. The cash used in operations was primarily due to our net loss due to the increase in operating expenses to support our commercialization and development activities. The expansion of our commercialization resulted in an increase in inventory, accounts receivable, and long-term assets, a decrease in other accrued liabilities, partially offset by a decrease in prepaid expenses and other current assets, and increases in accounts payable, deferred revenue, lease liabilities, accrued compensation and accrued interest expense. Non-cash charges consisted primarily of stock-based compensation, and depreciation.

Net Cash Used in Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was $4.4 million, consisting of purchases of property and equipment.

During the year ended December 31, 2023, net cash used in investing activities was $25.2 million, consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $180.1 million, consisting primarily of proceeds from the issuance of common stock of $164.5 million, net of issuance costs, and proceeds of $11.1 million from the exercise of stock options.

During the year ended December 31, 2023, net cash provided by financing activities was $167.8 million, consisting primarily of proceeds from the issuance of common stock of $161.7 million, net of issuance costs, and proceeds of $2.5 million from the exercise of stock options.

Contractual Commitments and Contingencies

The information included in Note 12 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K is incorporated herein by reference.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of the 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 Annual Report on Form 10-K, 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 HYDROS Robotic Systems, along with handpieces that are for one-time use during each surgery using our robotic systems. Each of our robotic systems 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 determine those that are performance obligations and assess whether each promised good or service is distinct based on the contract.

The contracts are typically in the form of an agreement and an ordering document from our customer. Sales generally contain multiple products and services and can include a combination of the following performance obligations: robotic system, handpieces and consumables, and service.

We determine the transaction price we expect to be entitled to in exchange for transferring the promised product to our customer, which is based on the invoiced price for the products. All prices are at fixed amounts per the contract with the customer. We have granted rebates on a limited basis and have been historically immaterial. Rebates are recorded as a reduction to revenue at time of sale.

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 update these estimates as necessary.

We recognize revenue as the performance obligations are satisfied by transferring control of the product or service to our customer. We generally recognize revenue for the performance obligations at the following points in time:

AquaBeam Robotic Systems and HYDROS Robotic Systems

End user sales - For systems (including system components and system accessories) sold directly to end user customers, revenue is recognized when we transfer control to our customer, in accordance with agreed upon shipping terms. We have determined in these type of arrangements the end user is our customer.

Intermediary sales - For systems sold to distributors or to leasing companies, revenue is recognized when we transfer control to our intermediary, in accordance with agreed upon shipping terms. We have determined in these type of arrangements the intermediary our customer.

Robotic system arrangements generally do not provide a right of return, however, we have granted a right of return on a case-by-case basis. We estimate returns at contract inception based on historical return amounts. Return estimates are recorded as a reduction to revenue. Historical returns have been immaterial.

Additionally, given the release of the HYDROS Robotic System, on a case-by-case basis, we have granted our customers a contractual right to exchange a previously purchased AquaBeam Robotic System for a HYDROS Robotic System where consideration exchanged for the AquaBeam Robotic System is recorded at fair value. The consideration is recognized when the exchange is considered probable. We estimate exchanges at contract inception, based on historical exchange amounts. The fair value of consideration for the AquaBeam Robotic System is recorded as a reduction to revenue. Historical exchanges have been immaterial. The robotic systems are generally covered by a one-year service agreement included in the warranty. The service agreements are typically recognized as deferred revenue and amortized over the one-year service period.

Hand pieces and other consumables - Revenue from sales of handpieces and other consumables is recognized when control is transferred to the customers, in accordance with agreed upon shipping terms.

Service - Service revenue, inclusive of the amounts associated with the robotic system warranties or extended service agreements, 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 do not represent separate performance obligations for which transaction price is allocated.

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.

Stock-Based Compensation

We account for stock options granted to employees and directors under the fair value recognition provision of ASC 718, Compensation - Stock Compensation. 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.

The valuation model used for calculating the fair value of awards for stock options 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:

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 limited public market for our common stock and limited 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 Annual Report Form 10-K 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, 2024 and 2023. 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.

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 current 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.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our financial statements contained in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures

Interest Rate Risk

Cash and cash equivalents of $333.7 million as of December 31, 2024, 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 bears interest at an annual rate equal to the secured overnight financing rate ("SOFR") (calculated based on an adjustment of .10%, .15% and .25%, respectively, for one-month, three-month or six-month term SOFR as of a specified date, subject to a floor of 1.5%) plus an applicable margin of 2.25%. 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 SOFR would have had a material impact on our financial statements included elsewhere in this Annual Report on Form 10-K.

Credit Risk

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

Our accounts receivable primarily relate to revenue from the sale or rental of our products. No customers accounted for greater than 10% of accounts receivable at December 31, 2024. We believe that credit risk in our accounts receivable is mitigated by our credit evaluation process, relatively short collection terms and diversity of our customer base.

Foreign Currency Risk

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

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 Annual Report on Form 10-K.

Item 8. Financial Statements - Audited Financial Statements

PROCEPT BioRobotics Corporation

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of PROCEPT BioRobotics Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of PROCEPT BioRobotics Corporation and its subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 in accordance with the standards of the PCAOB. 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, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Robotic Systems Revenue Recognition

As described in Notes 2 and 11 to the consolidated financial statements, for the year ended December 31, 2024, the Company recognized system sales and rentals revenue of $90.3 million, which the majority relates to Robotic Systems. The Company's Robotic Systems 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 recognizes revenue as the performance obligations are satisfied by transferring control of the product or service to a customer. For Robotic Systems (including system components and system accessories) sold directly to end users or intermediaries, revenue is recognized when the Company transfers control to the end users or intermediaries, in accordance with agreed upon shipping terms.

The principal considerations for our determination that performing procedures relating to the Robotic Systems revenue recognition is a critical audit matter are the high degree of effort in performing procedures and evaluating audit evidence related to the Robotic Systems revenue recognition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process. These procedures also included, among others, (i) evaluating revenue transactions by testing the issuance and settlement of invoices and credit memos, (ii) tracing transactions not settled to a detailed listing of accounts receivable, (iii) confirming a sample of outstanding customer invoice balances at year end and obtaining and inspecting source documents, including invoices, sales contracts, and shipping documents for unpaid invoices, and obtaining subsequent cash receipt for paid invoices, where applicable, for confirmations not returned, and (iv) testing the completeness and accuracy of data provided by management.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 27, 2025

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

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 333,725	$ 257,222
Accounts receivable, net,	83,496	48,376
Inventory	56,168	39,756
Prepaid expenses and other current assets	8,453	5,213
Total current assets	481,842	350,567
Restricted cash, non-current	3,038	3,038
Property and equipment, net	26,709	28,748
Operating lease right-of-use assets, net	18,941	20,241
Intangible assets, net	932	1,204
Other assets	2,555	919
Total assets	$ 534,017	$ 404,717
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,032	$ 13,499
Accrued compensation	21,537	16,885
Deferred revenue	9,565	5,656
Operating leases, current	1,910	1,683
Loan facility derivative liability	2,000	1,886
Other current liabilities	8,089	6,318
Total current liabilities	53,133	45,927
Long-term debt	51,472	51,339
Operating leases, non-current	26,868	26,182
Other non-current liabilities	324	517
Total liabilities	131,797	123,965
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.00001 par value;		
Authorized shares: 10,000 at December 31, 2024 and 2023, respectively		
Issued and outstanding shares: none at December 31, 2024 and 2023	—	—
Common stock, $0.00001 par value;		
Authorized shares: 300,000 at December 31, 2024 and 2023, respectively		
Issued and outstanding shares: 54,718 and 50,771 at December 31, 2024 and 2023	—	—
Additional paid-in capital	948,091	735,240
Accumulated other comprehensive gain	114	84
Accumulated deficit	(545,985)	(454,572)
Total stockholders' equity	402,220	280,752
Total liabilities and stockholders' equity	$ 534,017	$ 404,717

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,		
	2024	**2023**	**2022**
Revenue	$ 224,498	$ 136,191	$ 75,014
Cost of sales	87,399	65,142	37,929
Gross profit	137,099	71,049	37,085
Operating expenses:			
Research and development	62,298	48,446	28,981
Selling, general and administrative	171,415	131,773	88,828
Total operating expenses	233,713	180,219	117,809
Loss from operations	(96,614)	(109,170)	(80,724)
Interest expense	(4,184)	(3,995)	(5,183)
Interest and other income, net	9,385	7,268	2,011
Loss on loan extinguishment	—	—	(3,258)
Net loss	$ (91,413)	$ (105,897)	$ (87,154)
Net loss per share, basic and diluted	$ (1.75)	$ (2.24)	$ (1.96)
Weighted-average common shares used to compute net loss per share attributable to common shareholders, basic and diluted	52,125	47,255	44,400
Other comprehensive gain (loss):			
Unrealized gain on cash equivalents	30	90	48
Comprehensive loss	$ (91,383)	$ (105,807)	$ (87,106)

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

PROCEPT BioRobotics Corporation
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	43,676	$ —	$ 528,666	$ (54)	$ (261,521)	267,091
Issuance of common stock under stock plans	1,152	—	6,417	—	—	6,417
Stock-based compensation expense	—	—	10,670	—	—	10,670
Unrealized gain on cash equivalents	—	—	—	48	—	48
Net loss	—	—	—		(87,154)	(87,154)
Balance at December 31, 2022	44,828	—	545,753	(6)	(348,675)	197,072
Issuance of common stock under stock plans	858	—	6,090	—	—	6,090
Issuance of common stock, net of issuance costs of $10,795	5,085	—	161,705	—	—	161,705
Stock-based compensation expense	—	—	21,692	—	—	21,692
Unrealized gain on cash equivalents	—	—	—	90	—	90
Net loss	—	—	—	—	(105,897)	(105,897)
Balance at December 31, 2023	50,771	$ —	735,240	84	(454,572)	280,752
Issuance of common stock under stock plans	2,024	—	15,602	—	—	15,602
Issuance of common stock, net of issuance cost of $11,282	1,923	—	164,523	—	—	164,523
Stock-based compensation expense	—	—	32,726	—	—	32,726
Unrealized gain on cash equivalents	—	—	—	30	—	30
Net loss	—	—	—	—	(91,413)	(91,413)
Balance at December 31, 2024	54,718	$ —	$ 948,091	$ 114	$ (545,985)	$ 402,220

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,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net loss	$ (91,413)	$ (105,897)	$ (87,154)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	5,234	3,807	2,841
Stock-based compensation expense	31,840	19,134	10,337
Change in fair value in derivative liability	114	107	283
Non-cash lease adjustment	(383)	13	1,478
Provision for credit losses	840	—	—
Inventory write-down	1,881	995	62
Loss on loan extinguishment	—	—	3,258
Changes in operating assets and liabilities:			
Accounts receivable, net	(35,960)	(33,103)	(10,809)
Inventory	(17,235)	(9,751)	(15,251)
Prepaid expenses and other current assets	(3,211)	1,051	(1,880)
Other assets	(1,637)	(868)	(51)
Accounts payable	(2,152)	5,789	3,959
Accrued compensation	4,652	3,438	6,972
Accrued interest expense	134	125	757
Deferred revenue	3,716	3,317	1,830
Operating lease liabilities	2,596	4,989	327
Other liabilities	1,771	(1,149)	2,659
Net cash used in operating activities	(99,213)	(108,003)	(80,382)
Cash flows from investing activities:			
Purchases of property and equipment	(4,409)	(25,206)	(2,653)
Net cash used in investing activities	(4,409)	(25,206)	(2,653)
Cash flows from financing activities:			
Proceeds from issuance of common stock under employee stock purchase plan	4,527	3,610	2,409
Proceeds from issuance of common stock from the exercise of stock options, net	11,075	2,480	4,008
Proceeds from issuance of common stock, net of issuance costs	164,523	161,705	—
Proceeds from issuance of long-term debt, net of issuance costs	—	—	51,195
Payment of principal on long-term debt	—	—	(50,000)
Payment of final payment fee	—	—	(3,000)
Payment of prepayment fee	—	—	(1,000)
Net cash provided by financing activities	180,125	167,795	3,612
Net increase (decrease) in cash, cash equivalents and restricted cash	76,503	34,586	(79,423)
Cash, cash equivalents and restricted cash			
Beginning of the period	260,260	225,674	305,097
End of the period	$ 336,763	$ 260,260	$ 225,674
Reconciliation of cash, cash equivalents and restricted cash to balance sheets:			
Cash and cash equivalents	$ 333,725	$ 257,222	$ 221,859
Restricted cash	3,038	3,038	3,815
Cash, cash equivalents and restricted cash in balance sheets	$ 336,763	$ 260,260	$ 225,674
Supplemental cash flow information			
Interest paid	$ 3,970	$ 4,056	$ 4,291
Non-cash investing and financing activities			
Transfer of evaluation units from inventory to property and equipment, net	$ 106	$ 347	$ 124
Property and equipment included in accounts payable and accrued expenses	$ 348	$ 1,863	$ 3,544
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ —	$ 22,854

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 San Jose, 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. On August 20, 2024, the Company received 510(k) clearance from the FDA for its next generation robot system, HYDROS Robotic System.

Liquidity

As of December 31, 2024, the Company had cash and cash equivalents of $333.7 million and an accumulated deficit of $546.0 million. Since its inception, the Company has financed its operations with a combination of debt and equity financing arrangements. In October 2024, the Company completed a public offering of common stock, which raised $164.5 million, net of issuance costs. The Company expects its cash and cash equivalents, and revenue will be sufficient to fund its operations through at least the next twelve months from the issuance date of these consolidated financial statements. The Company has not achieved positive cash flow from operations to date and expects to continue incurring losses for the foreseeable future as it focuses on growing its business.

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 allowance for credit losses, excess and obsolete inventory reserves, stock-based compensation expense, right-of-use lease asset, lease liability, the valuations of the 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

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

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 gain (loss) and included as a separate component of stockholders' equity.

Restricted cash is related to the Company's letter of credit for the lease of its San Jose, CA location.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash and cash equivalents, and accounts receivable, accounts payable and accrued liabilities, which approximate fair value due to their relatively short maturities as well as the 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.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and, to a lesser extent, accounts receivable and leases receivable. The Company believes that credit risk in both accounts receivable and lease is mitigated by its credit evaluation process, relatively short collection terms and diversity of its customer base.

No customers accounted for more than 10% of revenue during the year ended December 31, 2024, 2023 and 2022. No customers accounted for more than 10% of accounts receivable at December 31, 2024 and 2023.

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.

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.

Allowance for Credit Losses

The Company's expected loss allowance methodology is developed using its historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of its customers. Specific allowance amounts are established to record the appropriate allowance for customers that have a known risk of default. Balances are written off when they are ultimately determined to be uncollectible. The Company has not experienced significant credit losses. Credit losses have not been material for periods presented.

Inventory

Inventory, which primarily consists of raw materials, labor and overhead related to work in process and sub-assemblies, 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 intangible assets are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization for property and equipment are determined using the straight-line method over the estimated useful lives of the respective assets, generally 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 operating expenses as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and intangible assets, net, and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated by the asset group to the carrying amount of the asset group. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. The Company determines fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. The Company's cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. No impairment losses were incurred in the periods presented.

Deferred Revenue

The timing of revenue recognition may differ from the timing of invoicing to customers. The Company records deferred revenue when revenue will be recognized subsequent to invoicing. Service agreements are generally invoiced annually at the beginning of each coverage period and recorded as deferred revenue and recognized as revenue ratably over the coverage period. Deferred revenue that will be recognized during the 12 months following the balance sheet date is recorded as the current portion of deferred revenue, and the remaining portion, if any, would be recorded as non-current.

During the year ended December 31, 2024, the Company recognized $5.9 million of revenue that was included in the deferred revenue balance as of December 31, 2023. During the year ended December 31, 2023, the Company recognized $2.9 million of revenue that was included in the deferred revenue balance as of December 31, 2022.

Loan Facility Derivative Liability

In connection with the Company's previous loan facility (Note 6), the Company is obligated to pay a fee upon the earlier occurrence of a defined liquidity event, including but not limited to, a merger or sale of our assets or voting stock, or achieving a $200.0 million trailing 12 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. At the time of extinguishment, the Company has drawn on the first two installments. The Company has determined this fee is a freestanding derivative instrument. The $2.0 million fair value of this loan facility derivative was initially recorded as a debt discount and a current 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. At December 31, 2024, the Company achieved the 12 month revenue target. As a result, the loan facility derivative became due and will no longer be revalued. The Company has recorded the amount due as a current liability in the Company's consolidated balance sheets.

Leases

The Company accounts for leases under the guidance of ASC 842, Leases.

Operating Leases-Lessee. For agreements with a term of more than 12 months, the Company determines if the 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.

The Company has not elected to separate lease and non-lease components for any leases within its existing classes of assets. The Company 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.

Lessor. For leases in which the Company is the lessor and classifies the lease as a sales-type lease, revenue is recognized at the commencement of the lease term. Leasing arrangements generally only include a robotic system. Customers are provided with the right to purchase the leased system at the end of the lease term. Lease terms are typically 48 months and are usually collateralized by a security interest in the underlying robotic system. Selling profit is recognized at the lease commencement date as the difference between the fair value of the leased asset and the carrying amount of the asset at the lease commencement date. Interest income is recognized over the lease term.

In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following terms at lease commencement: (1) whether title of the system transfers automatically or for a nominal fee by the end of the lease term; (2) whether the present value of the minimum lease payments equals or exceeds substantially all of the fair value of the leased system; (3) whether the lease term is for the major part of the remaining economic life of the leased system; (4) whether the lease grants the lessee an option to purchase the leased system that the lessee is reasonably certain to exercise; and (5) whether the underlying system is of such a specialized nature that it is expected to have no alternative use to the Company at the end of the lease term.

The Company invoices its leasing customers on a monthly basis. Leases receivable are reported in accounts receivable within the Company's consolidated balances sheets.

In addition, the Company evaluates each sales-type lease for whether the collectibility of lease payments is reasonably assured and whether there are any significant uncertainties related to the costs yet to be incurred. The Company also assesses whether the lease term includes any renewal or extension options that would impact the revenue recognition pattern.

Revenue Recognition

Revenue is derived primarily from the sales of the AquaBeam Robotic Systems and HYDROS Robotic Systems, along with handpieces that are for one-time use during each surgery using the Company's robotic systems. The Company's robotic systems contain 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 determined those that are performance obligations and assess whether each promised good or service is distinct based on the contract.

The contracts are typically in the form of an agreement and an ordering document from the customer. The Company's HYDROS Robotic System and 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 contract with the customer.

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

The Company's typical payment terms are between 30 to 90 days. All shipping and handling costs are expensed as incurred, and are recorded in cost of sales as a fulfillment activity. 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.

Robotic system arrangements generally do not provide a right of return, however, the Company has granted a right of return on a case-by-case basis. The Company estimates returns at contract inception based on historical return amounts. Return estimates are recorded as a reduction to revenue. Returns have not been material for periods presented.

The Company has granted rebates on a limited basis. Rebates are recorded as a reduction to revenue at time of sale. Rebates have not been material for periods presented.

Given the release of the next generation robotic system, HYDROS Robotic System, for a limited period and on a case by case basis, the Company has on a limited basis entered into arrangements with existing customers to sell a HYDROS Robotic System with an exchange of a previously purchased AquaBeam Robotic System for additional consideration. Exchanges have not been material for periods presented.

Sales commissions are considered incremental and recoverable costs of acquiring customer contracts. These costs are deferred and amortized over a straight-line basis when the estimated benefit period is greater than one year. The Company applies the practical expedient to expense costs to obtain a contract as incurred when the amortization period would have been one year or less. The amortization expense is reported in selling, general and administrative expense in the statements of operations and comprehensive loss.

The Company utilizes the practical expedient under ASC 606 and does not disclose unsatisfied performance obligations for service contracts as these contracts generally have an original duration of less than one year. For those contracts with an original duration exceeding one year, the aggregate amount of transaction price allocated to the performance obligations unsatisfied at December 31, 2024 was not material.

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 as follows:

AquaBeam Robotic Systems and HYDROS Robotic Systems

End user sales - For systems (including robotic system components and robotic system accessories) sold directly to end users, revenue is recognized when the Company transfers control to the end user, in accordance with agreed upon shipping terms. The Company has determined in these type of arrangements the end user is the Company's customer.

Intermediary sales - For systems sold to distributors or to leasing companies (intermediary), revenue is recognized when the Company transfers control to the intermediary, in accordance with agreed upon shipping terms. The Company has determined in these type of arrangements the intermediary is the Company's customer.

Hand pieces and other consumables

Revenue from sales of handpieces and other consumables is recognized when the Company transfers control to the customer, in accordance with agreed upon shipping terms.

Service

Service revenue, inclusive of the amounts associated with the AquaBeam Robotic System and HYDROS Robotic System warranties or extended service agreements, is recognized over the term of the service period, as the customer benefits from the services throughout the service period.

Cost of Sales

Cost of sales consists primarily of manufacturing overhead costs, material costs and direct labor, including stock-based compensation. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of sales also includes depreciation expense for

production equipment, warranty, and field service costs, and purchased intangibles and certain direct costs such as shipping costs.

Research and Development

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

Stock-Based Compensation

The Company accounts for stock options granted to employees and directors under the fair value recognition provision of ASC 718, Compensation - *Stock Compensation*. 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 Company estimates the fair value of stock options 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 limited 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. The Company has elected to account for forfeitures when they occur.

The Company accounts for the fair value of restricted stock units ("RSUs") using the closing market price of the Company's common stock on the date of the grant. Stock-based compensation cost for RSUs is measured at the grant date based on the estimated fair value of the award and is recognized as expense over the requisite service period (generally the vesting period), net of forfeitures.

The Company accounts for the fair value of performance stock units ("PSUs") using the closing market price of the Company's common stock on the date of the grant. include predefined performance and market conditions. The Company estimates the number of awards with performance conditions that will ultimately vest based on the probability of achievement each quarter to determine the amount of compensation expense to recognize each reporting period.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2024, 2023, and 2022 were $0.5 million, $0.3 million, and $0.1 million respectively.

Income Taxes

The Company accounts for income taxes under the asset and 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 related to uncertain tax positions as a component of income tax expense in the statement of operations. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Net Loss Per Share

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

Comprehensive Gain (Loss)

Comprehensive gain (loss) consists of unrealized gains and losses on cash equivalents and foreign currency translation adjustments.

Segment Information

The Company operates as a single operating segment. The Company's chief operating decision maker, or CODM, its Chief Executive Officer, reviews the Company's forecast, as well as budget to actual financial information, as key inputs to making decisions on resource allocation and assessing the performance of the business. The CODM monitors budget versus actual results using income (loss) from operations and net income (loss).

Significant expenses within income from operations, as well as within net income (loss), include cost of goods sold, research and development expenses, and selling, general and administrative expenses, which are each separately presented on the Company's consolidated statements of operations. Other segment items within net income (loss) include interest expense, and interest and other income, net on an aggregate basis for the purposes of allocating resources and evaluating financial performance.

For the year ended December 31, 2024 and 2023, substantially all of the Company's long-lived assets are held in the United States.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board or FASB, issued Accounting Standards Update, or ASU, 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, that requires disclosure of significant segment expenses that are regularly reviewed by the chief operating decision maker and included within each reported measure of segment profit or loss. The standard also requires disclosure of the composition of other segment items included in the measure of segment profit or loss that are not separately disclosed. The new standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 for the fiscal year ended December 31, 2024, for the fiscal year ending December 31, 2024, on a retrospective basis. The adoption did not have a material effect on the Company's consolidated financial statements.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for all public entities for fiscal years beginning after December 15, 2024. Early adoption is permitted and should be applied either prospectively or retrospectively. The Company plans to adopt the ASU and related updates with the year ending December 31, 2025. The adoption of this ASU is not expected to have a material impact on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, requiring public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is evaluating the impact of this ASU will have on its financial statement disclosures.

3. Fair Value Measurements

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

	December 31,							
	2024				2023			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:								
Cash	$ 10,961	$ —	$ —	$ 10,961	$ 6,609	$ —	$ —	$ 6,609
Cash equivalents	322,764	—	—	322,764	250,613	—	—	250,613
Total cash and cash equivalents	$ 333,725	$ —	$ —	$ 333,725	$ 257,222	$ —	$ —	$ 257,222
Loan facility derivative liability	$ —	$ —	$ —	$ —	$ —	$ —	$ 1,886	$ 1,886

The carrying amounts of the Company's cash, accounts receivable, accounts payable, and loan facility derivative liability approximate their fair values due to their short maturities. The carrying value of the Company's long-term debt approximates fair value, as the Company's variable rate is approximate to the stated rate.

There were no transfers in and out of Level 3 during the years ended December 31, 2024 and 2023.

Loan facility derivative liability

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 (for the year ended December 31, 2023) (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning of the period	$ 1,886	$ 1,779
Change in fair value	114	107
End of the period	$ 2,000	$ 1,886

The fair value of the loan facility derivative liability was determined using a discounted cash flow calculation discounted at 6%.

4. Composition of Certain Consolidated Financial Statement Items

Allowance for credit losses consisted of the following (in thousands):

	December 31,
	2024
Beginning balance	$ —
Net changes during the period	840
Ending balance	$ 840

For the years ended December 31, 2023 and 2022, the Company did not have an allowance for credit losses.

Inventory (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 18,189	$ 11,832
Work-in-process	11,452	6,047
Finished goods	26,527	21,877
Total inventory	$ 56,168	$ 39,756

The Company reclassified $4.9 million associated with sub-assemblies from raw materials to work-in process in the December 31, 2023 balances to conform with current year presentation.

Property and Equipment, Net (in thousands):

	December 31,	
	2024	2023
Manufacturing and computer equipment, and furniture and fixtures	$ 19,683	$ 14,379
Laboratory equipment	1,509	1,231
Rental equipment	597	897
Leasehold improvements	12,488	12,362
Construction in progress	262	3,548
Total property and equipment	34,539	32,417
Less: accumulated depreciation and amortization	(7,830)	(3,669)
Total property and equipment, net	$ 26,709	$ 28,748

Deferred Commission Costs (in thousands):

	December 31,	
	2024	2023
Reported as:		
Prepaid expenses and other current assets	$ 357	$ 60
Other assets	$ 840	$ 487

Other Current Liabilities (in thousands):

	December 31,	
	2024	2023
Accrued purchases	97	106
Professional services	1,704	1,558
Sales tax	2,068	1,725
Interest	310	333
Travel expenses	1,049	519
Asset retirement obligation	—	232
Clinical trial expenses	1,171	392
Other	1,690	1,453
Total other current liabilities	$ 8,089	$ 6,318

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

	Year Ended December 31,		
	2024	2023	2022
Interest income	$ 10,895	$ 7,551	$ 2,497
Change in fair value of loan facility derivative liability	(114)	(107)	(283)
Other	(1,396)	(176)	(203)
Total interest and other income, net	$ 9,385	$ 7,268	$ 2,011

5. 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, 2024 and 2023, accumulated amortization was $1.6 million and $1.3 million, respectively, and the net carrying amount is expected to be amortized at a rate of $0.3 million per year until fully amortized.

Amortization expense for intangible assets for each of the years ended December 31, 2024, 2023, and 2022 was $0.3 million.

6. Long-Term Debt

In October 2022, the Company entered into a loan and security agreement ("The Agreement") with Canadian Imperial Bank of Commerce, or CIBC. The Agreement provides for a senior secured term loan facility in the aggregate principal amount of $52.0 million (the "Term Loan Facility") which was borrowed in full.

The Term Loan Facility was used to repay and terminate the Company's previous loan facility, transaction fees, and related expenses.

The Term Loan Facility is scheduled to mature on the fifth anniversary of the Closing Date (the "Maturity Date"). The Agreement provides for interest-only payments on the Term Loan Facility for the first thirty-six months following the Closing Date (the "Initial Interest-Only Period"). The Initial Interest-Only Period will be extended to an additional twelve months if the Company achieves either (i) $200.0 million or greater in revenue in any twelve-month period or (ii) $0 or greater in EBITDA in any six-month period. Thereafter, amortization payments on the Term Loan Facility will be payable monthly until the Maturity Date in monthly installments equal to 20% of the then outstanding principal amount of the Term Loan Facility divided by 12 plus any accrued and unpaid interest. The Company has the option to prepay the Term Loan Facility without any prepayment charge or fee. The Company achieved the twelve-month revenue target as of December 31, 2024.

The loan borrowed under the Term Loan Facility bears interest at an annual rate equal to the secured overnight financing rate ("SOFR") (calculated based on an adjustment of .10%, .15% and .25%, respectively, for one-month, three-month or six-month term SOFR as of a specified date, subject to a floor of 1.5%) plus an applicable margin of 2.25%. The weighted-average interest rate for the periods ending December 31, 2024, 2023, and 2022 were 7.60%, 7.32%, and 6.12%, respectively.

The obligations under the Loan Agreement are secured by substantially all of the Company's assets, including its intellectual property and by a pledge all of the Company's equity interests in its U.S. subsidiaries and 65% of the Company's equity interests in its non-U.S. subsidiaries that are directly owned by the Company. In June 2023, the Term Loan Facility was amended to lower the amount the Company is obligated to maintain in deposit accounts held at the lender to the lesser of (i) $90.0 million or (ii) all of its non-operating cash and allow the Company to maintain cash or cash equivalents in excess of that amount with other financial institutions. The Agreement also contains a minimum unrestricted cash requirement and minimum revenue growth financial covenants, along with other covenants customary for loan facilities. As of December 31, 2024, the Company was in compliance with all debt covenants.

The Company recorded a loss on loan extinguishment in the amount of $3.3 million in its consolidated statements of operations and comprehensive loss for the period ended December 31, 2022. The loss was attributed to the acquisition price of the CIBC debt exceeded the carrying amount of the Company's previous loan facility.

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

Fiscal Year	Amount
2025	$ —
2026	8,667
2027	43,333
Total minimum payments	52,000
Less: amount representing unamortized debt discount	(528)
Present value of future payments	$ 51,472

7. Leases

Facility Leases

The Company previously leased a facility located in Redwood City, California. In September 2023, the Company exited the facility. In October 2023, the lease expired and was not renewed.

In December 2021, the Company entered into a lease for two existing buildings, comprising approximately 158,221 square feet of space, located in San Jose, California. The lease commenced in July 2022, and will continue for 122 months following thereafter, with two five year options to extend the term of the lease.

The Company began operations at this facility in September 2023. The lease provides for annual base rent of $4.3 million for the first year, which increases on a yearly basis up to $5.5 million for the tenth year, for an aggregate of $49.2 million. Under the terms of the lease, the Company received an allowance of up to $7.9 million from the landlord to be applied to the Company's construction of tenant improvements following the landlord's delivery of the two buildings to the Company. During the year ended December 31, 2022, the Company recorded both a right-of-use asset and liability of $22.7 million related to the lease. 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. Rent expense recognized under the leases, includes additional rent charges for utilities, parking, maintenance and real estate taxes.

The following table presents supplemental lease information (in thousands, except for weighted-average amounts):

	Year Ended December 31,		
	2024	2023	2022
Operating lease expense	$ 5,284	$ 7,118	$ 4,725
Variable lease expense	1,804	1,282	375
Total lease expense	$ 7,088	$ 8,400	$ 5,100
Cash paid for amounts included in the measurement of operating lease liabilities	$ 4,172	$ 5,610	$ 2,505
Weighted-average lease term	8.2 years	9.2 years	9.4 years
Weighted-average discount rate	8.6%	8.5%	8.7%

Future minimum annual operating lease payments are as follows (in thousands):

Fiscal Year	Amount
2025	$ 4,297
2026	4,426
2027	4,808
2028	4,952
2029	5,101
Thereafter	17,196
Total minimum payments	40,780
Less: amount representing interest/tenant improvement allowance	(12,002)
Present value of future payments	$ 28,778

As of December 31, 2024 and 2023, the Company's security deposit is in the form of, and recorded as, restricted cash.

Lessor Information for Robotic Systems

Contractual maturities of gross lease receivables as of December 31, 2024 are as follows (in thousands):

Fiscal Year	Amount
2025	$ 394
2026	513
2027	357
2028	357
2029 and thereafter	476
Total	$ 2,097

Leases receivable relating to sales-type lease arrangements are presented on the Company's consolidated balance sheets as follows (in thousands):

	December 31,	
	2024	2023
Reported as:		
Accounts receivable	$ 157	$ 157
Other assets	1,514	260
Net investment in sales-type leases	$ 1,671	$ 417

	December 31,	
	2024	2023
Gross receivables	$ 2,097	$ 470
Unearned interest income	(426)	(53)
Net investment in sales-type leases	$ 1,671	$ 417

The components of income from sales-type leases are as follows:

	December 31,		
	2024	2023	2022
Sales-type lease revenue	$ 1,357	$ 417	$ —
Interest income	$ 28	$ —	$ —

8. Stock-Based Compensation

2021 Equity Incentive Award Plan

In September 2021, the Company adopted the 2021 Equity Incentive Award Plan (the "2021 Plan"), which allows for the granting of stock options and stock purchase rights to the employees, members of the board of directors, and consultants of the Company. A total of 10,267,301 shares of common stock were reserved for issuance under the 2021 Plan. Options granted under the 2021 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to the Company's employees, including officers and directors who are also employees. NSOs may be granted to employees and consultants.

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

Granted options for newly hired employees usually vest over four years monthly with a one-year cliff vesting, and follow-on options vest monthly over four years with no cliff vesting. Options granted to consultants have various vesting schedules depending on the underlying consulting arrangement and anticipated period of service. Granted restricted stock units usually vest over four years annually. As of December 31, 2024, there were 6.8 million shares available for grant and 2.7 million awards outstanding under the 2021 Plan.

2008 Stock Plan

The Company ceased making awards under the 2008 Stock Plan upon the effective date of the Company's IPO. In 2008, the Company adopted the 2008 Stock Plan (the "2008 Plan"), which allows for the granting of stock options and stock purchase rights to the employees, members of the board of directors, and consultants of the Company. Options granted under the 2008 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to the Company's employees, including officers and directors who are also employees. NSOs may be granted to employees and consultants. Options granted under the 2008 Plan started expiring in August 2021. Options outstanding under the 2008 Plan will expire upon forfeiture. As of December 31, 2024, 3.1 million options were outstanding under the 2008 Plan.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan (the "2021 ESPP"). The 2021 ESPP became effective on the effective date of the IPO. A total of 412,988 shares were initially reserved for issuance under the 2021 ESPP. Additionally, the number of shares of common stock reserved for issuance under the 2021 ESPP will increase automatically each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; or (2) such lesser number as determined by the Company's board of directors. The number of shares that may be issued under the 2021 ESPP shall not exceed a total of 10,526,315 shares. As of December 31, 2024, approximately 400,000 shares have been issued under the 2021 ESPP. As of December 31, 2024, there were 1.4 million shares available for grant under the 2021 ESPP.

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

	Year Ended December 31,		
	2024	2023	2022
Cost of sales	$ 6,913	$ 2,493	$ 1,053
Research and development	8,018	4,798	2,230
Sales, general and administrative	20,819	14,401	7,387
Stock-based compensation capitalized in inventory	(3,910)	(2,558)	(333)
Total stock-based compensation	$ 31,840	$ 19,134	$ 10,337

Stock Options

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

	Year Ended December 31, 2024	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	5,215	$ 9.42
Granted	173	50.13
Exercised	(1,456)	7.61
Forfeited	(137)	20.67
Outstanding, end of period	3,795	11.56
Vested and expected to vest	3,795	11.56
Exercisable	3,305	8.18

The weighted-average grant date fair value of options granted during the years of December 31, 2024 and 2023 was $28.52 and $21.02, respectively. As of December 31, 2024, the aggregate pre-tax intrinsic value of options outstanding and exercisable was $239.7 million and options outstanding were $261.7 million. The aggregate pre-tax intrinsic value of options exercised was $92.1 million and $15.4 million during the years ended December 31, 2024 and 2023, 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 $5.6 million and $5.8 million during the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, total unrecognized stock-based compensation related to unvested stock options was $8.5 million, which the Company expects to recognize over a remaining weighted-average period of 2.2 years.

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

	Year Ended December 31,		
	2024	2023	2022
Expected life (years)	6.0	6.0	5.9
Expected volatility	57%	57%	55%
Risk-free interest rate	4.1%	4.0%	2.5%
Expected dividend rate	—%	—%	—%
Weighted-average fair value	$ 28.52	$ 21.02	$ 19.15

Restricted Stock Units

A summary of the Company's restricted stock unit or RSU activity and related information are as follows (RSUs in thousands):

	Year Ended December 31, 2024	
	Restricted Stock Units	Weighted-Average Fair Value
Unvested, beginning of period	1,565	$ 36.27
Granted	1,063	53.31
Vested	(449)	36.36
Cancelled forfeited	(285)	39.30
Unvested, end of period	1,894	45.36

The weighted-average grant date fair value of RSUs granted during the years of December 31, 2024 and 2023 was $53.31 and $36.16, respectively.

As of December 31, 2024, the aggregate pre-tax intrinsic value of RSUs outstanding was $152.5 million, calculated based on the closing price of the Company's common stock at the end of the period.

As of December 31, 2024, total unrecognized stock-based compensation related to unvested RSUs was $67.7 million, which the Company expects to recognize over a remaining weighted-average period of 2.8 years.

Performance Stock Units

A summary of the Company's restricted stock unit or PSU activity and related information are as follows (PSUs in thousands):

	Year Ended December 31, 2024	
	Performance Stock Units	Weighted-Average Fair Value
Unvested, beginning of period	—	$ —
Granted	81	73.20
Canceled/forfeited	—	—
Vested	—	—
Unvested, end of period	81	73.20

As of December 31, 2024, the aggregate pre-tax intrinsic value of PSUs outstanding was $6.5 million, calculated based on the closing price of the Company's common stock at the end of the period.

As of December 31, 2024, total unrecognized stock-based compensation related to unvested RSUs was $5.5 million, which the Company expects to recognize over a remaining weighted-average period of 1.3 years.

Employee Stock Purchase Plan

As of December 31, 2024, there was approximately $1.1 million of unrecognized cost related to employee stock purchases under the 2021 ESPP. This cost is expected to be recognized over a weighted average period of 0.5 years. As of December 31, 2024, a total of 1.4 million shares were available for issuance under the 2021 ESPP.

The fair value of the options granted under the 2021 ESPP to employees 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,		
	2024	2023	2022
Expected life (years)	0.8	0.7	0.7
Expected volatility	55 %	53 %	56 %
Risk-free interest rate	5.0 %	5.1 %	4.2 %
Expected dividend rate	— %	— %	— %
Weighted-average fair value	$ 26.20	$ 11.20	$ 15.11

9. Income Taxes

The Company did not record an income tax provision for the periods presented.

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,		
	2024	2023	2022
Federal statutory tax rate	21 %	21 %	21 %
R&D tax credit	2	1	2
Stock-based compensation	9	(1)	2
Other permanent differences	(1)	—	—
Change in valuation allowance	(31)	(21)	(25)
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,	
	2024	2023
Deferred tax assets:		
Net operating losses	$ 96,477	$ 80,273
Property and equipment	583	203
R&D tax credit	12,849	9,224
Stock-based compensation	5,041	3,829
Capitalized R&D expenses	32,306	20,644
Inventory	2,747	2,708
Lease liability	7,059	6,824
Accruals and reserves	3,738	2,713
Total deferred tax assets	160,800	126,418
Valuation allowance	(156,145)	(121,461)
Net deferred tax assets	4,655	4,957
Deferred tax liabilities:		
Right-of-use assets	(4,655)	(4,957)
Total deferred tax liabilities	(4,655)	(4,957)
Net deferred tax assets	$ —	$ —

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 $34.7 million during the year ended December 31, 2024, and increased by $27.4 million during the ended December 31, 2023. The valuation allowance increased by $16.0 million during the year ended December 31, 2022.

As of December 31, 2024 and 2023, the Company has U.S. federal net operating loss ("NOL") carryforwards of approximately $391.9 million and $326.3 million, respectively, expiring beginning 2028. As of December 31, 2024 and 2023, the Company has U.S. state and local NOL carryforwards of approximately $242.2 million and $194.0 million, respectively, expiring beginning 2028.

As of December 31, 2024 and 2023, the Company has federal research and development credit carryforwards of approximately $10.6 million and $7.5 million, respectively, available to reduce future taxable income, if any. As of December 31, 2024 and 2023, the Company has California research and development credit carryforwards of approximately $8.3 million and $6.0 million, respectively, available to reduce future taxable income, if any.

The federal research and development credit carryforwards expire beginning 2028 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 un-utilized.

The Company files federal, state, and foreign income tax returns. The tax periods 2008 through 2024 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.

On August 16, 2022, former President Biden signed the Inflation Reduction Act of 2022 (the Inflation Act) into law. The Inflation Act contains certain tax measures, including a corporate alternative minimum tax of 15% on some large corporations and an excise tax of 1% on corporate stock buy-backs. The various provisions of the Inflation Act did not have an impact on the Company's consolidated financial statements and related notes.

A reconciliation of the change in the unrecognized tax benefit during the year is as follows (in thousands):

	December 31,		
	2024	2023	2022
Beginning of year	$ 3,392	$ 2,700	$ 1,917
Additions for tax positions related to:			
Current year	1,327	842	783
Prior years	—	(150)	—
End of year	$ 4,719	$ 3,392	$ 2,700

As of December 31, 2024, the Company had a total of $4.7 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 12 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, 2024, the Company has not accrued interest or penalties related to uncertain tax positions.

10. Net Loss Per Share

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

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (91,413)	$ (105,897)	$ (87,154)
Weighted-average common stock outstanding	52,125	47,255	44,400
Net loss per share, basic and diluted	$ (1.75)	$ (2.24)	$ (1.96)

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,		
	2024	2023	2022
Common stock options	3,795	5,215	5,353
Restricted and performance stock units	1,975	1,565	742
Employee stock purchase plan	56	80	110
Total	5,826	6,860	6,205

11. Geographical Information

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

	Year Ended December 31,		
	2024	2023	2022
U.S.			
System sales and rentals	$ 78,614	$ 53,626	$ 36,527
Handpieces and other consumables	110,542	64,051	28,543
Service	11,316	6,620	2,698
Total U.S. revenue	200,472	124,297	67,768
Outside of U.S.			
System sales and rentals	11,685	5,294	3,201
Handpieces and other consumables	10,914	5,471	3,273
Service	1,427	1,129	772
Total outside of U.S. revenue	24,026	11,894	7,246
Total revenue	$ 224,498	$ 136,191	$ 75,014

12. 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, 2024, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

13. 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. Employer contributions were $2.4 million, $1.5 million, and $0 for the year ended December 31, 2024, 2023, and 2022, respectively.

Item 9. Changes in and Disagreements with Accountants

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. These disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our CEO and our CFO, to allow timely decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Company's CEO and CFO and effected by our Board of Directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management, with the participation of our CEO and our CFO, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024.

Management assessed our internal control over financial reporting as of December 31, 2024 using the criteria in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective, based on these criteria. PricewaterhouseCoopers LLP, an independent registered public accounting firm, audited the effectiveness of our internal control over financial reporting as of December 31, 2024, as stated within their report which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Disclosure Controls and Procedures

A system of internal control over financial reporting is intended to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP and no control system, no matter how well designed and operated, can provide absolute assurance. The design of any control system is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of its inherent limitations, internal control over financial reporting may not prevent or detect financial statement errors and misstatements. Also, projection of any evaluation of effectiveness to future periods is subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

During the quarter ended December 31, 2024, no director or officer of the Company informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408 of Regulation S-K), except as follows: On November 21, 2024, Antal Desai, a member of the Company's Board of Directors, adopted a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "Desai Rule 10b5-1 Plan") under the Exchange Act, for the sale of shares of the Company's common stock held by the 2:22 DNA Trust. The Desai Rule 10b5-1 Plan was entered into during an open trading window in accordance with the Company's policies regarding transactions in the Company's securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c)

under the Exchange Act. The Desai Rule 10b5-1 Plan provides for the potential sale of up to 150,000 shares of the Company's common stock during various specified trading periods through June 13, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Proxy Statement under the headings "Proposal 1 — Election of Directors," "Board Committees and Meetings," "Stockholder Communications with the Board of Directors," "Management" and if applicable, "Delinquent Section 16(a) Reports."

Our written Code of Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at procept-biorobotics.com in the Investors section under "Corporate Governance." Changes to or waivers of the Code of Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Ethics by disclosing such information on the same website.

We have adopted an insider trading policy governing the purchase, sale and other dispositions of our securities by our directors, officers and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Executive Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation of Non-Employee Board Members."

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

Item 13. Certain Relationships and Related Party Transactions

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Proposal 1 — Election of Directors" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the heading "Principal Accountant Fees and Services."

With the exception of the information specifically incorporated by reference in Part III to this Annual Report from our Proxy Statement, our Proxy Statement shall not be deemed to be filed as part of this report.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a) Exhibits.

Exhibit No.	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (File No. 001-40797) filed on September 21, 2021)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K (File No. 001-40797) filed on September 21, 2021)
4.1	Description of PROCEPT BioRobotics Corporation's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.1 to the registrant's annual report on Form 10-K for the year ended December 31, 2021 (File No. 001-40797))
10.1+	Offer Letter, by and between the Registrant and Reza Zadno, Ph.D., dated as of January 31, 2020 (incorporated by reference to Exhibit 10.1 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.2+	Offer Letter, by and between the Registrant and Kevin Waters, dated as of August 7, 2018 (incorporated by reference to Exhibit 10.2 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.3+	Offer Letter, by and between the Registrant and Hisham Shiblaq, dated as of March 21, 2019 (incorporated by reference to Exhibit 10.3 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.4+	Offer Letter, by and between the Registrant and Alaleh Nouri, dated as of May 15, 2018 (incorporated by reference to Exhibit 10.18 to the registrant's quarterly report on Form 10-Q for the period ended March 31, 2023 (File No. 001-40797))
10.5+	Amended and Restated 2008 Stock Plan (incorporated by reference to Exhibit 10.4 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.5(a)+	Form of Stock Option Agreement under the Amended and Restated 2008 Stock Plan (incorporated by reference to Exhibit 10.4(a) to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.6	Form of Indemnification and Advancement Agreement (incorporated by reference to Exhibit 10.5 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.7	Amended and Restated Exclusive License Agreement, by and between the Registrant and AquaBeam LLC, dated as of September 13, 2019 (incorporated by reference to Exhibit 10.6 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.8	Not used.
10.9	Lease, by and between the Registrant and 150-180 Baytech Drive CA Owner, LLC, dated December 31, 2021 (incorporated by reference to Exhibit 10.9 to the registrant's annual report on Form 10-K for the year ended December 31, 2021 (File No. 001-40797))
10.10+	Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the period ended March 31, 2024 (File No. 001-40797))
10.11+	2021 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.11 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.11(a)+	Form of Stock Option Agreement under the 2021 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.11(a) to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.11(b)+	Form of Restricted Stock Unit Agreement under the 2021 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.11(b) to the registrant's registration statement on Form S-1 (File No. 333-258898))

10.11(c)+	Form of Performance Stock Unit Agreement under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the period ending March 31, 2024 (File No. 001-40797))
10.12+	Amended and Restated 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the period ending September 30, 2023 (File No. 001-40797))
10.13+	Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Reza Zadno, Ph.D., dated September 17, 2021 (incorporated by reference to Exhibit 10.13 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.14+	Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Kevin Waters, dated September 17, 2021 (incorporated by reference to Exhibit 10.14 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.15+	Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Hisham Shiblaq, dated September 17, 2021 (incorporated by reference to Exhibit 10.15 to the registrant's registration statement on Form S-1 (File No. 333-258898))
10.16+	Amended and Restated Change of Control Severance Agreement, by and between the Registrant and Alaleh Nouri, dated September 17, 2021 (incorporated by reference to Exhibit 10.19 to the registrant's quarterly report of Form 10-Q for the period ended March 31, 2023 (File No. 001-40797))
10.17	Loan and Security Agreement, by and among Canadian Imperial Bank of Commerce, the Registration, and each Borrower and Guarantor from time to time, dated as of October 6, 2022 (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on October 10, 2022 (File No. 001-40797))
10.17(a)	First Amendment to Loan and Security Agreement, by and between Canadian Imperial Bank of Commerce and the Registrant, dated June 1, 2023 (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on June 2, 2023 (File No. 001-40797))
10.18#	Confidential Exclusive Patent License and Covenant Not to Sue, by and between the Registrant and HydroCision, Inc., dated March 14, 2019 (incorporated by reference to Exhibit 10.7(d) to the registrant's annual report on Form 10-K for the year ended December 31, 2022 (File No. 001-40797))
21.1*	List of subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the registrant's annual report on Form 10-K for the year ended December 31, 2023 (File No. 001-40797))
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.

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

_____
* Filed herewith.
** Furnished herewith.
+ Indicates management contract or compensatory plan.
# Certain portions of this Exhibit (indicated by "[***]") have been omitted pursuant to Regulation S-K, Item (601)(b)(10)

(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 16. Form 10-K Summary

None.

Signatures

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

PROCEPT BIOROBOTICS CORPORATION

Date: February 27, 2025

By: /s/ Reza Zadno
Name: Reza Zadno, Ph.D.
Title: Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Reza Zadno and Kevin Waters, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report 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
/s/ Reza Zadno Reza Zadno, Ph.D.	President, Chief Executive Officer and Director (principal executive officer)	February 27, 2025
/s/ Kevin Waters Kevin Waters	EVP, Chief Financial Officer (principal financial and accounting officer)	February 27, 2025
/s/ Thomas M. Prescott Thomas M. Prescott	Director and Chair of the Board	February 27, 2025
/s/ Antal Desai Antal Desai	Director	February 27, 2025
/s/ Amy Dodrill Amy Dodrill	Director	February 27, 2025
/s/ Mary Garrett Mary Garrett	Director	February 27, 2025
/s/ Taylor Harris Taylor Harris	Director	February 27, 2025
/s/ Elisabeth Little Elisabeth Little	Director	February 27, 2025
/s/ Frederic Moll, M.D. Frederic Moll, M.D.	Director	February 27, 2025
/s/ Larry Wood Larry Wood	Director	February 27, 2025