2022
Annual Report

LENSAR

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Alan B. Connaughton – *Chief Operating Officer*
Thomas R. Staab, II – *Chief Financial Officer and Secretary*

HEADQUARTERS

LENSAR, Inc.
2800 Discovery Drive
Orlando, FL 32826
888-536-7271
www.lensar.com

STOCK TRANSFER AGENT

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP

AVAILABLE INFORMATION

We make available free of charge under the Investor Relations section of our website, https://ir.lensar.com, filings we make with the Securities and Exchange Commission and other information about the Company. Filings we make with the Securities and Exchange Commission may also be accessed free of charge on the Securities and Exchange Commission's publicly available website, www.sec.gov.

INVESTOR RELATIONS

Thomas R. Staab, II
888-536-7271
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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, 2022

or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from to

Commission File Number: 001-39473

LENSAR, INC.

(Exact name of registrant as specified in its charter)

Delaware	**32-0125724**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2800 Discovery Drive
Orlando, Florida 32826
(Address of principal executive offices and Zip Code)

(888) 536-7271
(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, par value $0.01 per share	LNSR	The Nasdaq Stock Market LLC

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	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 Exchange Act)Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second quarter, the approximate market value of the registrant's common stock held by non-affiliates was $59.4 million. As of February 28, 2023, there were 11,102,611 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements 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"). 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 operation from the global COVID-19 pandemic and related macroeconomic conditions; the timing of and our ability to obtain and maintain regulatory approvals and certifications; our expectations about our ability to successfully develop and commercialize our next generation system, the ALLY® Adaptive Cataract Treatment System ("ALLY System"), and the timing thereof; 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. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Without limiting the foregoing, in some cases, you can identify forward-looking statements by terms such as "aim", "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I. Item 1A. "Risk Factors" and Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report. These risks and uncertainties include, but are not limited to:

- our history of operating losses and ability to achieve or sustain profitability;
- our ability to develop, receive and maintain regulatory clearance or certification of and successfully commercialize the ALLY System and to maintain our LENSAR Laser System;
- the impact to our business, financial condition, results of operations and our suppliers and distributors as a result of the COVID-19 pandemic and global macroeconomic conditions;
- the willingness of patients to pay the price difference for our products compared to a standard cataract procedure covered by Medicare or other insurance;
- our ability to grow our U.S. sales and marketing organization or maintain or grow an effective network of international distributors;
- our future capital needs and our ability to raise additional funds on acceptable terms, or at all;
- the impact to our business, financial condition and results of operations as a result of a material disruption to the supply or manufacture of our systems or necessary component parts for such system or material inflationary pressures affecting pricing of component parts;
- our ability to compete against competitors that have longer operating histories, more established products and greater resources than we do;

- our ability to address the numerous risks associated with marketing, selling and leasing our products in markets outside the United States;
- the impact to our business, financial condition and results of operations as a result of exposure to the credit risk of our customers;
- our ability to accurately forecast customer demand and our inventory levels;
- the impact to our business, financial condition and results of operations if we are unable to secure adequate coverage or reimbursement by government or other third-party payors for procedures using our ALLY System or our other future products, or changes in such coverage or reimbursement;
- the impact to our business, financial condition and results of operations of product liability suits brought against us;
- risks related to government regulation applicable to our products and operations; and
- risks related to our intellectual property and other intellectual property matters.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we have no obligation 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.

Unless otherwise stated or the context requires otherwise, references to "LENSAR," the "Company," "we," "us," and "our," refer to LENSAR, Inc.

TRADEMARKS AND TRADE NAMES

We own or have rights to certain trademarks, trade names, copyrights and other intellectual property used in our business, including LENSAR, the LENSAR logo, LENSAR Cataract Laser with Augmented Reality logo, Streamline, IntelliAxis, IntelliAxis Refractive Capsulorhexis, and ALLY Adaptive Cataract Treatment System, each of which is considered a trademark. All other company names, product names, trade names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

MARKET AND INDUSTRY DATA AND FORECASTS

In this Annual Report, we present certain market and industry data and statistics. This information is based on third-party sources, which we believe to be reliable. We have not independently verified data from these sources and cannot guarantee their accuracy or completeness. While we are not aware of any misstatements regarding industry data provided herein, our estimates involve risks and uncertainties and are subject to change based upon various factors, including those discussed in this Annual Report under "Forward-Looking Statements" and Part I, Item 1A. "Risk Factors." Additionally, some data in this Annual Report is based on our good faith estimates, which are derived from management's knowledge of the industry and independent sources. Similarly, we believe our internal research is reliable, however, such research has not been verified by any independent sources.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report. 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 expect to incur operating losses for the near-term future and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.
- We have historically derived our revenue from the sale or lease of our LENSAR Laser System and the associated procedure licenses and sale of consumables used in each procedure involving our LENSAR Laser System. The commercial success of our ALLY System will depend upon receipt of additional regulatory clearances or certifications and our ability to maintain and grow significant market acceptance for it.
- Our growth depends on our ability to gain regulatory clearances and certifications, as well as our ability to meet production goals for our ALLY System.
- Global health developments and economic uncertainty resulting from COVID-19 have adversely impacted, and may continue to adversely impact, our business, results of operations, cash flows and financial position.
- Patients may not be willing to pay for the price difference between a standard cataract procedure and an advanced cataract procedure in which a laser system such as ours is used, an increment which is typically not covered by Medicare, private insurance or other third-party payors.
- If we are not able to effectively grow our U.S. sales and marketing organization or maintain or grow an effective network of international distributors, our business prospects, results of operations and financial condition could be adversely affected.
- Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms or at all.
- We cannot assure our ability to continue as a going concern in the future.
- If the supply or manufacture of our systems or other products associated with the systems is materially disrupted, including by supply chain shortages and price increases, it may adversely affect our ability to manufacture products and could negatively affect our operating results.
- Our results have been in the past, and could be in the future, adversely affected by economic uncertainty or deteriorations in economic conditions.
- We currently compete, and expect to compete in the future against other companies, some of which have longer operating histories, more established products or greater resources than we do.
- To successfully market, sell and lease our products in markets outside of the United States, we must address many international business risks with which we have limited experience.
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- We may not receive, or may be delayed in receiving, the necessary clearances, certifications or approvals for our future products, or modifications to our current products, and failure to timely obtain necessary clearances, certifications or approvals for our ALLY System and future products or modifications to our current products would adversely affect our ability to grow our business.
- If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

PART I

Item 1. Business

We are a commercial-stage medical device company focused on designing, developing and marketing advanced femtosecond laser systems for the treatment of cataracts and the management of pre-existing or surgically induced corneal astigmatism. Our current systems, the LENSAR Laser System and ALLY® Adaptive Cataract Treatment System, or ALLY System, incorporate a range of proprietary technologies designed to assist the surgeon in obtaining better visual outcomes, efficiency and reproducibility by providing advanced imaging, simplified procedure planning, efficient design and precision. We believe the cumulative effect of these technologies results in laser systems that can be quickly and efficiently integrated into a surgeon's existing practice, is easy to use and provides surgeons the ability to deliver improved visual outcomes with enhanced precision and the ability to do so consistently. We are continuing to innovate through the ALLY System, which combines all of the features from our LENSAR Laser System with a dual-pulse laser, integrated in a small, compact cataract treatment system that is designed to allow surgeons to perform a femtosecond laser assisted cataract procedure in a single operating room. This system is designed to be a significant medical advancement and provide improved efficiency and financial benefit to a surgeon's practice and to ambulatory surgery centers, or ASCs. The ALLY System received clearance from the U.S. Food and Drug Administration, or FDA, in June 2022, and we began commercialization of the ALLY System in August 2022. In addition, we submitted the ALLY System for certification in the European Union, or EU, in September 2022 and intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions.

Market Overview

The global market for the treatment of cataracts is characterized by large patient populations with increases driven by the aging population and the availability of new technologies, such as laser-assisted systems and an influx of new, innovative intraocular lenses, or IOLs, which can improve visual outcomes post-operatively. Cataract surgery is one of the highest volume surgical procedures in the world, and according to the American Academy of Ophthalmology, or AAO, the most common procedure performed by the ophthalmic surgeon. According to the 2022 Cataract Surgical Equipment Market Report, global estimated cataract/refractive lens exchange surgical procedures are expected to grow from 27.7 million in 2022 to 37.6 million in 2027. In the United States, cataract surgery is expected to increase from almost 4.7 million procedures in 2022 to approximately 5.8 million in 2027. By contrast, worldwide laser-assisted cataract surgery is expected to grow from an estimated 914,000 procedures in 2022 to an estimated 1.3 million procedures in 2027. There are approximately 10,000 ophthalmic surgeons in the United States focused on performing cataract procedures.

Cataracts and Cataract Surgery

A cataract occurs when the normally clear lens of the eye becomes cloudy or opaque, causing a decrease in vision. The clouding of this lens caused by a cataract can cause blurring and distortion of vision, colors that seem faded, glare or halos from lights at night, diminished vision and double vision. Cataracts typically affect both eyes, but it is not uncommon for a cataract in one eye to advance more rapidly. In most cases, the cataract is a naturally occurring process that is age-related, although it can also be caused by heredity, an injury to the eye or after surgery for another eye problem, such as glaucoma. Currently, the only way to treat cataracts is to surgically remove the natural lens of the eye.

Traditional cataract surgeries are performed by a surgeon using a metal or diamond blade to perform the corneal incisions to enter the eye, and a bent needle to perform the anterior capsulorhexis to provide the surgeon access to the nucleus of the cataract for fragmentation and subsequent removal. Over the last decade, laser systems have been developed to assist surgeons in performing or facilitating these aspects of the cataract procedure, including assessing and fragmenting the cataract. In either case, cataract nucleus disassembly and removal is achieved using a process with ultrasound called phacoemulsification. Currently, Medicare and most commercial third-party payors only cover the cost of traditional cataract surgery and the placement of a monofocal IOL, which may not produce the targeted visual outcome. To achieve their targeted visual outcome, patients may elect to have an advanced procedure that involves use of a laser system and/or implantation of a premium IOL, and/or addresses their pre-existing astigmatism

in which case the patient is responsible for the cost differential between the amount reimbursed by a third-party payor and the cost of the advanced procedure.

The majority of patients suffering from cataracts also present with visually significant astigmatism. Astigmatism is an imperfection in the symmetry of the cornea, creating a different, additional focal plane in a specific axis within the cornea. This causes a distortion of the light as it converges on the retina and causes blurry vision. In 2022, Market Scope referenced data from a clinical study of 6,000 patients performed by Warren Hill, MD that estimates that approximately 70 – 90% of cataract patients present with addressable astigmatism prior to cataract surgery. To reduce the need for prescription distance or reading glasses following cataract surgery, it is important that little or no astigmatism remain. Conventionally, residual post-operative astigmatism has been targeted at less than or equal to 0.5 diopters, the unit measure of the refractive power of a lens. Surgeons may attempt to address low to moderate magnitudes of astigmatism using a procedure called limbal relaxing incisions, or LRIs, or arcuate incisions, or AIs. LRIs or AIs are performed by making two small incisions on the cornea, usually 180 degrees apart that are intended to return the cornea to a rounder, symmetrical shape. Corneal incisions used by surgeons as a means to manage astigmatism that are performed with a laser are referred to as AIs. More recently, and where the magnitude of astigmatism is higher, toric IOLs may be used to both correct the patient's near or far vision and address any pre-existing astigmatism.

Laser-Assisted Cataract Surgery. In the last 10 to 15 years, special laser systems have been developed to assist surgeons in performing or facilitating the various aspects of the cataract procedures. Laser-assisted cataract surgery involves the same steps as traditional surgery but uses advanced imaging techniques to design a precise surgical plan and a femtosecond laser, the same type of laser engine used to cut the flaps in LASIK corrective procedures, to make the AIs and perform the capsulorhexis. The intent is to create an incision with a specific location, depth and length that can be performed exactly without the variable of surgeon experience or the individual variances in the anatomy of the patient. The laser can also be used to soften and fragment the nucleus of the cataract before phacoemulsification, which can reduce the amount of phacoemulsification energy required to break up and remove the cataract and reduce the chance of certain complications. After phacoemulsification, the surgeon replaces the natural lens with an IOL and the incision is closed without the need for suture.

The Transition to Advanced Refractive Cataract Procedures

Currently, Medicare and most commercial third-party payors only cover the cost of treating the medical condition of the cataract, which can be accomplished with traditional cataract surgery and the placement of a monofocal IOL. Standard or traditional cataract surgery does not specifically address the outcomes associated with astigmatism and presbyopia, which may be addressed in an advanced refractive procedure involving laser-assisted cataract removal and implantation of a premium IOL. However, since the advantages of these advanced refractive cataract procedures are not deemed medically necessary, patients seeking either or both of these alternatives must pay the difference between the reimbursed amount and the cost of the advanced procedure that includes implantation of a premium IOL.

We believe that these advanced procedures that include implantation of a premium IOL offer physicians and patients additional benefits and improved outcomes that justify the additional cost. For example, some of the benefits of laser-assisted cataract surgery include:

- ***Improved accuracy***. Most laser systems cleared for the treatment of cataracts contain imaging tools that assist the surgeon in modeling the eye and developing a surgical plan for the procedure, including the precise placement and location of the capsulorhexis and identifying the axis of astigmatism in each patient. After the surgeon has developed and chosen the plan to proceed, the system itself can make the appropriate capsulotomy, including the incisions prescribed in the plan, without reliance on the surgeon's manual capabilities to size, shape and locate the capsulorhexis, and appropriately place the AIs to minimize any further inducement of astigmatism. This is intended to optimize reproducibility and precision in the optimal placement of the capsulorhexis or location of the AIs, customized to each patient and IOL selection.

- ***Reproducibility***. Studies have shown that laser capsulotomies are consistently more round and more precise in sizing to enable better centering and capsulorhexis overlap of the IOL and that IOL positioning is an

important factor in determining visual outcomes minimizing the variances associated with manual techniques.

- ***Reduced complications and quicker visual recovery***. By using a laser to soften and fragment the cataract before phacoemulsification, less phacoemulsification energy is required to emulsify and remove the cataract. This may make the procedure safer to the inner eye and reduce the chance of complications, such as cystoid macular edema, or swelling of the eye. Use of the laser also creates less endothelial cell loss than phacoemulsification alone, contributing to clearer corneas and quicker visual recovery after surgery.

Typically, patients undergoing an advanced refractive cataract procedure are paying a significant portion of the cost of the surgery out of pocket. As a result, they have heightened expectations for their visual outcomes, normally targeting vision correction within 0.5 diopters of their predicted refractive outcome, sometimes referred to as best uncorrected visual acuity. We believe these procedures and outcomes must appropriately address and manage the correction of the patient's pre-existing astigmatism. Pre-existing astigmatism is frequently not being addressed in the preoperative surgical planning and more frequently is not part of the treatment. In many cases, we believe the failure to manage the astigmatism in such a large percentage of patients is due to the lack of useful technology in surgery. For example, research indicates that for each 1 degree that a toric IOL is off-axis, its ability to reduce astigmatism is decreased by approximately 3.3%. To that end, very small errors in the measurements, calculations and treatments used in the cataract procedure can significantly decrease its effectiveness in achieving the targeted visual outcome. We believe this lack of precision can be attributed to one or more of the following limitations of procedures performed with competing laser systems:

- ***Imaging that requires manual inputs***. Prior to performing a cataract surgery with most existing laser systems, the surgeon must manually identify and locate the pupil and anterior capsule to place the cursors necessary to perform the capsulorhexis. The result is more likely to be a capsulorhexis that likely is marginally better than a manual surgery by being more concentric and rounder, but still reduces the accuracy and reproducibility of the laser to provide useful treatment for a surgeon. In addition, several competing laser systems do not measure automatically for lens tilt and adjust the laser treatment accordingly when fragmenting the natural lens**.**

- ***Inaccuracies that appear when managing astigmatism.*** Once the surgeon performs the appropriate calculations to determine the surgical plan, he or she will mark the eye with an ink marker to identify the proper steep axis of astigmatism used to accurately align the toric, trifocal or toric multifocal IOL. The reliability of these manual marks can be impacted by events as minor as manually transposing data from the office to the surgical record, the thickness of the marker or bleeding of the ink used when mixed with fluids. The accuracy is also impacted by the natural rotation of the patient's eye when they move from the seated position when the measurements are taken, to a supine position for surgery. This rotation varies per patient, and the manual marking to orient the eye has to be started when the patient is seated and requires other markers before the ink marker. This can increase the cumulative effect of "stackable error," contributing to a lack of precision in aligning the IOL.

- ***Inability to integrate with preoperative devices to guide surgical treatment.*** Surgeons use a variety of different devices such as corneal topographers and imaging to obtain the preoperative measurements and data needed to develop the treatment plan. Most competing laser systems are unable to integrate with many of these devices, leaving surgeons to manually input, set up, and develop the laser treatment plan.

- ***Deficient cataract density imaging system.*** Cataracts come in varying densities and lens compositions. These can range from soft, which are more easily removed with less energy, to very hard, which require much more energy, care and time during the phacoemulsification procedure. Many competing laser systems' imaging does not provide useful data and cataract grading systems designed to assist the surgeon in choosing the optimal tissue specific treatments utilizing only the energies and fragmentation necessary to reduce the amount of phacoemulsification required, contributing to less cell loss and quicker visual recoveries.

As a result, we believe a significant opportunity exists for a laser system that can improve surgeon precision and assist in achieving targeted visual outcomes in patients with astigmatism.

Our Products

We believe the inability to achieve the targeted visual outcome is largely due to a failure to appropriately address corneal astigmatism even when using competing laser systems. We believe this lack of precision can be attributed to several limitations of competing laser devices, including imaging systems that require manual inputs, inaccuracies that result from reliance on manually transposing data and manually marking the eye for treatment, and competing systems' inability to use iris registration to integrate with preoperative devices. In addition, these devices may not have the ability to precisely, and in a reproducible basis through the imaging and measurement technology determine the location on optical axis or pupil center based on the surgeon's choice to place the anterior capsulorhexis. This can affect the outcomes due to less certain effective lens position with the IOL implantation. These devices also lack a cataract density imaging system, which allows the surgeon to customize the fragmentation and energy settings based on each individual patient's cataract.

We developed our LENSAR Laser System and ALLY System to provide an alternative laser cataract treatment tool that allows the surgeon to better address astigmatism and improve visual outcomes. Our system incorporates a range of proprietary technology features that are designed to provide surgeons the following key benefits:

- ***Advanced imaging***. Our Augmented Reality™ imaging and processing technology collects a broad spectrum of biometric data and then reconstructs and presents a precise, three-dimensional model of each individual patient's eye that is used to develop and implement the surgeon's procedure plan.

- ***Simplified procedures***. Our system is designed to automate and perform various critical steps in the cataract procedure with the goal of providing surgeons with the confidence to perform these advanced procedures that include implantation of a premium IOL.

- ***Efficient design***. We designed the ergonomics of the system and its wireless capabilities to enable the system to integrate seamlessly into a surgeon's existing surgical environment. According to Market Scope's 2022 annual survey, over 80% of U.S. cataract surgeons, indicated the importance of data transfer between diagnostic devices as 'required' to 'nice to have'.

- ***Precision and reproducibility***. The system has multiple features specifically designed to enable precise placement and centration of the IOL in patients in a consistent and reproducible manner that is not possible in manual cataract surgery or using competing laser systems.

We believe the cumulative effect of these technologies are advanced laser systems that can be quickly integrated into a surgeon's existing practice and is easy to use. The LENSAR Laser System and ALLY System provide surgeons the ability to deliver improved outcomes when addressing astigmatism in connection with cataract removal and to perform the surgery with enhanced precision and reproducibility.

We are focused on continuous innovation and continue to develop our proprietary, next generation system, the ALLY System. Our ALLY System is designed to combine our current core femtosecond laser technology features with enhanced laser capabilities into a single small unit that allows surgeons to perform a femtosecond laser assisted cataract procedure in a single operating room. The ALLY System's enhanced laser feature includes the ability to perform laser procedures much faster as well as enabling broader application ability due to it being the only commercial femtosecond laser incorporating a dual pulse laser. Our ALLY System received clearance from the FDA in June 2022, and we executed a controlled and targeted initial launch of the ALLY System beginning in August 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023, and we intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. The FDA clearance is the first stage of a planned, two step commercial release strategy. As the second stage of the strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as a predicate device. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, we are unable to submit a 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until

the predicate device receives FDA clearance. Accordingly, we are delivering the ALLY System to surgeons in the initial launch with the phacoemulsification features disabled and/or removed.

Currently, almost all cataract procedures, whether manual or laser-assisted, involve the use of a phacoemulsification system to fracture and remove the cataract. For most surgeons that also use a laser-assisted system, the laser system is stationed in a separate room from the phacoemulsification system, as the size of most operating rooms will not accommodate placement of all the other necessary equipment, and these two critical pieces of equipment operate independently. This configuration results in significant interruption in the patient flow, by requiring the patient to be moved from one room to the next during the course of the procedure.

We have designed our ALLY System to have a small footprint, allowing it to be placed in any operating room or in-off surgery suite, to allow the surgeon to switch seamlessly and quickly between femtosecond laser and phacoemulsification device without moving patients from room-to-room. Importantly, this system was designed with the ergonomics in-mind to be used in the operating room or the in-office surgical suite. The footprint is significantly smaller than current laser systems and only slightly larger than stand-alone phacoemulsification systems. The additional enhancements to our existing laser technology that are incorporated into our ALLY System include a more versatile laser that uses pulse characteristics designed for tissue specific targeting with significantly faster speeds in different applications. We expect this system could be a considerable advancement and will provide significant surgical workflow and financial benefit to a surgeon's practice and ASC or hospital.

We believe several converging marketplace factors will encourage adoption of our ALLY System. These include:

- the advent of many new types of advanced IOLs with complex optics, developed to correct near and distance vision with astigmatism, and the ability of the ALLY System to assist surgeons in optimizing the accurate positioning using any of these lenses to correct astigmatism for better visual outcomes;

- continued pressure to improve efficiencies driven by the reduction of reimbursement in standard cataract surgery cases coupled with the ability to provide better patient visual outcomes, which we believe will motivate surgeons and patients to seek refractive outcome-based patient-pay procedures; and

- the COVID-19 pandemic increased awareness of efficiencies associated with faster patient throughput, less movement from having to use two rooms to complete an advanced cataract procedure, fewer patient encounters to plan, treat and to complete the advanced cataract procedure, placing the system in the ASC, operating room or in-office surgical suite. Early data suggests performing a sterile femtosecond-laser-assisted cataract surgery, or FLACS, procedure using the ALLY System resulted in approximately 5-minute time savings or $472 per case and shortened the surgical day.

According to the 2022 Cataract Surgical Equipment Market Report, there were an estimated 2,527 femtosecond laser systems installed at the end of 2022, of which 2,330 were in markets that we service. The number of total femtosecond laser systems installed is expected to grow to over 3,447 devices by 2027. We believe the expected growth in the FLACS market, combined with the results from our blinded survey, suggest a significant market opportunity as surgeons replace, or add femtosecond laser systems.

To help encourage and facilitate this transition to our ALLY System, we are focused on reducing the cost of the system without compromising the capabilities or performance of the laser. With that in mind, the ALLY System was designed to offer more functionality and better performance than other laser systems. We believe the ALLY System's surgical efficiencies and combined functions the ALLY System offers could help drive broader penetration into the overall cataract surgery market and could potentially create a paradigm shift in the treatment of cataracts and management of astigmatism in cataract surgery. The overall cost of the ALLY System, may, however, increase due to, among other factors, pricing increases in component parts for our systems resulting from inflationary pressures and related macroeconomic conditions.

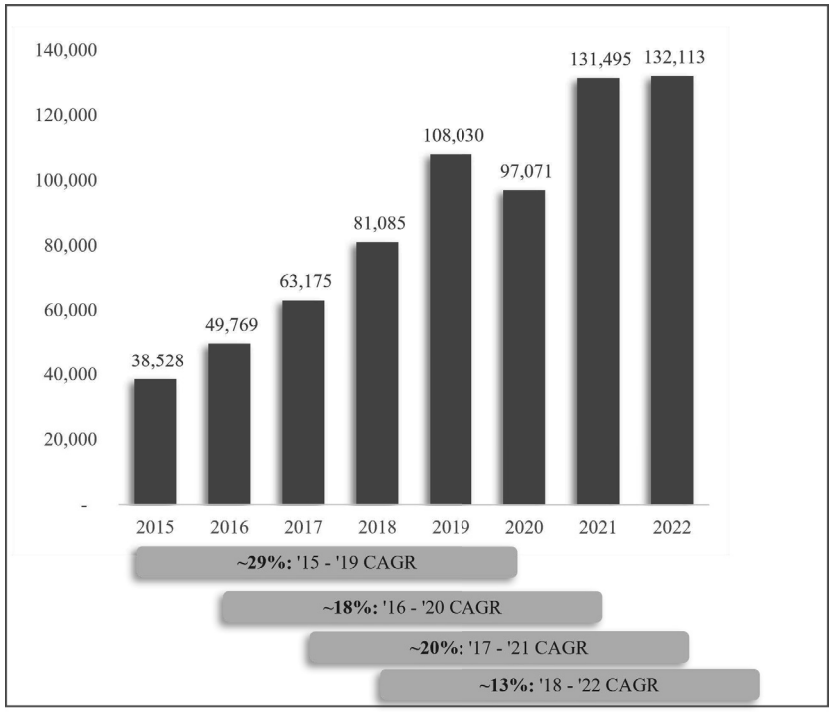
Our Strengths

We attribute our current and anticipated future success to the following factors:

- ***Disruptive technology platform providing improved visual outcomes.*** Our systems were built specifically for laser refractive cataract surgery. Central to our systems is our Augmented Reality technology, which begins by using Scheimpflug imaging to scan the anterior segment of the eye, collecting a broad spectrum of biometric data. The system then uses a process called wave-tracing to take a series of two-dimensional images derived from the imaging and scanning and, through precision processing of this biometric data, reconstruct a three-dimensional model of each individual patient's eye. Using this model, surgeons can identify relevant anatomy and specific measurements within the eye, enabling them to plan and precisely place the laser pulses necessary to accomplish the desired treatment. Data presented in 2019 at the American Society of Cataract and Refractive Surgery, or ASCRS, demonstrated that 93% of patients receiving a toric IOL using the LENSAR Laser System achieved refractive correction within 0.5 diopter of the targeted outcome. In addition to improving visual outcomes, our systems are designed to improve the efficiency and simplify the procedure for surgeons by including pre-programmable surgeon preferences, wireless integration with pre-operative diagnostic data, cataract density imaging, and accurate laser incision planning. We believe these features give surgeons an unprecedented reproducibility and ability to optimize their treatments to achieve LASIK-like vision correction while also improving overall efficiency for the surgeon's practice.

- ***Demonstrated and growing commercial success.*** We believe our disruptive technology platform has enabled us to rapidly take market share in a highly competitive market. Based on the 2022 Cataract Surgical Equipment Market Report, it was estimated that we would achieve 16.3% market share in femtosecond laser assisted cataract surgery in 2022 in terms of revenue. Additionally, when looking at the average procedures per installed device, each of our systems averaged 503 procedures in 2022 compared to the estimated industry average of 362 procedures per year per installed device, based on a 2022 Cataract Surgical Equipment Market Report. The following chart shows procedure volume per year from 2015 to 2022:

Procedures per Year



Source: Management.

- ***Improved visual outcomes that drive more advanced, patient-pay procedures.*** Standard cataract procedures are generally covered by Medicare and other third-party payors, including commercial health plans.

However, based on the 2022 Market Scope IOL Market Report, approximately 71.8% of U.S. patients receiving a standard cataract procedure do not have significant astigmatism addressed surgically and must rely on glasses for distance or near vision. Moreover, surgeon reimbursement for these standard procedures continues to decline. More advanced procedures, such as laser-assisted cataract surgery and the use of toric and multifocal premium IOLs, can address these additional vision challenges but are generally not covered by Medicare or other third-party payors. Accordingly, patients are required to pay the additional cost associated with the use of these advanced technologies. Historically, some patients may have been reluctant to incur the additional cost of a more advanced procedure that includes implantation of a premium IOL, and some surgeons may have been reluctant to recommend these procedures because of concerns that the targeted visual outcome might not be achieved. We believe the clinical data supporting the effectiveness of our laser system in assisting surgeons to achieve desired outcomes will motivate additional patients to seek, and additional surgeons to offer, these more advanced procedures that include implantation of a premium IOL.

- ***Focus on innovation to facilitate surgeon adoption.*** Our systems encompass improved innovations such as wireless capability, advanced imaging, iris registration, and other features to improve their effectiveness and enhance efficiency. We have designed the ALLY System to be a compact cataract treatment system to operate in an operating room or in-office surgical suite and allow the surgeon to switch seamlessly and quickly between femtosecond laser and phacoemulsification without moving patients from room-to-room. We believe these innovations, which are intended to improve patient flow and efficiency, have the potential to allow surgeons to perform more premium procedures each surgery day, helping them to meet the expected increase in demand for cataract/refractive lens exchange surgical procedures.

- ***Innovative intellectual property protected by a comprehensive patent portfolio.*** As of December 31, 2022, we owned approximately 173 issued patents and 114 pending patent applications globally. This portfolio covers key aspects of our technology, including the augmented reality imaging and processing, iris registration and patient interface features of our system. We have also filed and acquired significant patent rights relating to our next generation cataract treatment system. For example, we have approximately 14 pending US patent applications, 9 issued US patents, 49 pending foreign and PCT applications, and 15 issued foreign patents related to integrated systems.

- ***Proven management team and board of directors.*** Our senior management team and board of directors consists of seasoned medical device professionals with deep industry experience. Our team has successfully led and managed dynamic growth phases in organizations and commercialized several products specifically in the cataract and refractive surgery field. Members of our team have worked with well-regarded, ophthalmology-focused medical technology companies such as Chiron Corporation, Alcon Inc., Advanced Medical Optics, Inc., Allergan, Inc., Bausch + Lomb and STAAR Surgical.

While we believe these factors will contribute to further growth and success, we cannot assure you that the market for cataract surgery will continue to grow as we anticipate or that new disruptive technologies will not be introduced to displace our laser systems. Moreover, we must maintain and grow market acceptance for our laser system and convince physicians and patients that the out-of-pocket costs associated with procedures that use our laser systems will produce their targeted results. If we are unable to accomplish those goals, our business could suffer.

Technology

Our LENSAR Laser System and ALLY System have been built specifically for refractive cataract surgery, and at the core of our commitment to continuous technological innovation is our focus on providing cataract surgeons the tools to deliver their patients improved outcomes. The key technological features of our system include:

- ***IntelliAxis Refractive Capsulorhexis***: Designed to improve precision and accuracy in outcome-based astigmatic cataract procedures, this proprietary technology enables a surgeon to precisely mark by producing small tabs in the capsulorhexis on the steep axis using advanced iris registration to guide toric IOL placement and alignment, both during and after the surgical procedure.

- ***Augmented Reality***: Our patented augmented reality technology provides a surgeon with a sophisticated, three-dimensional view of a patient's eye. This enhanced view, which reflects each patient's own unique eye

size and shape, allows surgeons to identify relevant anatomy and specific biometric measurements within the patient's eye, enabling them to precisely place the laser pulses necessary to accomplish the desired treatment. Surgeons are then able to develop better-informed approaches and subsequent treatment for refractive cataract surgical procedures. This technology also simplifies the procedure for surgeons by including pre-programmable surgeon preferences, wireless integration with pre-operative diagnostic data, cataract density imaging for using the lowest energy needed to treat, and accurate laser incision planning. We believe this improves the efficiency and reproducibility of the procedure for surgeons.

- ***Wireless Transfer of Pre-Operative Data***: Pre-operative diagnostic data can be transferred wirelessly from many preoperative corneal topographers and diagnostic devices to our system, which can guide more precise astigmatism planning and reduce or eliminate risks associated with transcription errors and manually marking the eye.

- ***Pre-Operative Data Analysis***: With the assistance of our clinical applications and clinical outcomes groups, practices' individualized astigmatism treatment protocols can be refined and customized based on site specific pre-, intra-, and post-operative data, with the objective to help surgeons to deliver incrementally better patient outcomes over time as compared to earlier generations.

- ***Cataract Density Imaging***: Another unique aspect of our Augmented Reality imaging system is the ability of the system to grade and compare the cataract density and tissue specific areas to treat within the lens nucleus. The benefit of this is the surgeon can customize the treatment and deliver only the energy and fragmentation patterns necessary to optimally treat the cataract. This not only increases efficiency in removal of the cataract when the surgeon gets to the phacoemulsification, but also provides the surgeon choices in pre-programmed treatment algorithms or their own customized preferences in the energy and fragmentation parameters based on their surgical technique. These can be stored and used each time the system identifies a cataract with similar characteristics.

- ***Corneal Incision-Only Mode***: By allowing a surgeon to perform laser corneal incisions independent of capsulorhexis and fragmentation, the surgeon has greater flexibility to treat a patient who may benefit from post-operative arcuate incisions and may achieve greater efficiency with abbreviated scanning that omits lens boundaries.

Sales and Distribution

We have built and are continuing to grow our commercial organization, which includes a direct sales force in the United States and third-party distributors in China, South Korea, Germany, and other targeted international markets. Depending on the dynamics of a particular geographic region, we and our distributors typically market and sell our systems to ASCs, hospitals and physicians. In the United States, we sell our products through a direct sales organization that, as of December 31, 2022, consisted of approximately 45 commercial team professionals, including regional sales managers, clinical applications and outcomes specialists, field service, marketing, technical and customer support personnel. As of December 31, 2022, we had a total of approximately 270 systems installed in a total of 16 countries, with approximately 40% of those systems in the United States where we have a direct sales relationship with our customers, and with China, South Korea, and Germany representing our largest markets outside the United States, where we sell our products through distributor relationships. We believe there is significant opportunity for us to expand our presence in these countries and other countries where we have no or only a limited number of installed systems. For the year ended December 31, 2022, one customer accounted for 10% of our revenue and no customers accounted for 10% or more of our accounts receivable, net.

We have been able to achieve our success to date with a limited number of regional sales managers in the United States and independent distributors in international markets, growing our business substantially year-over-year in terms of both revenues and number of procedures, with the exception of 2020 due to the impact on our operations of the COVID-19 pandemic. We believe that increasing the size and geographic breadth of our sales and marketing management team and number of regional sales managers in the United States and expanding our network of independent distributors in additional international markets will allow further penetration in the cataract surgery market. To support these commercial efforts, in the United States, we anticipate adding additional field sales professionals, including clinical outcome specialists, and expanding our marketing support and commitment to

physician and staff training programs to optimize results and communicate the strengths of our cataract surgery solutions. Outside the United States, we expect to expand the geographical reach of our distributors. We believe the expansion of our domestic and international commercialization efforts will provide us with significant opportunity for future growth as we continue to penetrate existing and new markets. Our ALLY System currently is cleared for marketing only in the United States, and our growth, market presence and ability to sell the ALLY System will depend on, among other factors, whether the ALLY System receives regulatory clearance in other regions outside the United States and the timing of these clearances or certifications.

Manufacturing

We manufacture our ALLY System, and previously manufactured our LENSAR Laser System, at a facility in Orlando, Florida. In connection with the commercial launch of the ALLY System, we modified our manufacturing operations from producing the LENSAR Laser System to the ALLY System. We purchase custom and off-the-shelf components from several suppliers and subject them to stringent quality specifications and processes. Some of the components necessary for the assembly of the ALLY System and maintenance of the LENSAR Laser System are currently provided by single-sourced suppliers (the only approved supply source for us among other sources). We have entered into various purchase orders, as well as a limited number of long-term supply agreements, for the manufacture and supply of certain components. These arrangements commit us to a remaining minimum purchase obligation of approximately $5.8 million as of December 31, 2022. We expect to meet these requirements. We generally do not maintain large volumes of finished goods. We currently have and intend to have long-term supply agreements or sufficient supply of raw material inventory to adequately source the expected near-term demand of our ALLY System. We strive to maintain enough inventory of our various component parts to avoid the impact of a potential short-term disruption in the supply and longer-term supply chain disruptions that originated during the COVID-19 pandemic. Our ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory.

Intellectual Property

We seek patent and trademark protection for our key technology, products and product improvements, both in the United States and in select foreign countries. We plan to continue to enforce and defend our patent and trademark rights. While our patents protect, among other things, the aspects of our technology that provide us with a competitive advantage, we also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. In an effort to protect our trade secrets, we have a policy of requiring our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements also provide that all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential, except in specified circumstances.

We own numerous issued patents and pending patent applications. As of December 31, 2022, we owned approximately 50 U.S. patents, 34 pending U.S. patent applications, 123 issued foreign patents, and 80 pending foreign and Patent Cooperation Treaty applications. Our patents are expected to expire between 2026 and 2038, with some design patents expiring in 2046. We have 123 issued foreign patents in a total of 12 countries and regions, including China, Macau, Taiwan, Germany, France, United Kingdom, Italy, Australia, Canada and the European Patent Office. Our patents contain a broad range of claims related to devices and methods for performing cataract surgery using, among other things, refractive corrections, lens targeting and positioning and we believe provide significant protection for our current commercialized products.

Our material registered and unregistered trademarks include: LENSAR, ALLY Adaptive Cataract Treatment System, INTELLIAXIS, INTELLIAXIS REFRACTIVE CAPSULORHEXIS, STREAMLINE, LENSAR CATARACT LASER WITH AUGMENTED REALITY AND DESIGN, ALLY Adaptive Cataract Treatment System Design, and LENSDOCTOR SOFTWARE, INTELLIAXIS-C, and INTELLIAXIS-L.

Our intellectual property portfolio further secures a premier technology position for the development and commercialization of devices that incorporate both a phacoemulsification system and a femtosecond laser, such as our ALLY System. In addition to patent applications we have filed related to our System, we have pursued and consummated agreements with third parties to acquire patent rights, such as those described below, which provide

important exclusivity with respect to our development and commercialization of our ALLY system. Our business plan includes aggressively pursuing additional patent rights related to ALLY, and we expect to continue to add to our current portfolio.

Patton License Agreement

In September 2019, we entered into a license agreement, or the Patton License, with Doug Patton and Ophthalmic Synergies, LLC, or the Licensors, pursuant to which we were granted a worldwide, exclusive license to use certain patents held by, and patent applications made by, the Licensors relating to combining a femtosecond laser and phacoemulsification system into a single device. Under the Patton License, we made an initial, upfront payment to the Licensors of $3.5 million. During 2022, we made certain milestone payments relating to regulatory approval and commercial sales, in an aggregate amount of $2.4 million. We are not required to make any further payments under the Patton License.

In October 2021, we acquired full ownership of the patents and patent applications that were licensed under the Patton License.

Oertli Collaboration

In January 2020, we entered into a development agreement with Oertli Instrumente AG, or the Development Agreement, pursuant to which we are collaborating on developing the phacoemulsification component of a combined femtosecond laser and phacoemulsification device in our ALLY System. The Development Agreement provides that we and Oertli will be joint and several owners of intellectual property resulting from inventive contributions from both parties, and that we and Oertli will each be entitled to practice such intellectual property rights in our respective sole discretion, without regard to the other party. Additionally, we pay Oertli an hourly fee for their work under the Development Agreement. We have also entered into a long-term supply agreement with Oertli for the phacoemulsification component of our ALLY System.

Competition

We participate in the highly competitive global market for treatments for cataracts. We face significant competition from large multinational medical device companies as well as smaller, emerging players focused on product innovation. In providing surgical solutions for cataract patients, our primary competitors are Alcon Inc.; Bausch + Lomb, a division of Bausch Health Companies Inc.; and AMO, a division of Johnson & Johnson, each of which has its own femtosecond lasers and phacoemulsification devices. Additionally, we compete with Ziemer Ophthalmic Systems AG, a private company based in Switzerland, in the femtosecond laser market. We are also aware of a French based company, KeraNova S.A., that is working to develop a product that, if they receive commercial clearance for their device in the future, could potentially be another competitor. In addition, we are aware of several smaller companies with IOL technologies under development or that have limited approvals.

These competitors are focused on bringing new technologies to market and acquiring products and technologies that directly compete with our products or have potential product advantages that could render our products obsolete or noncompetitive.

Many of these competitors are large public companies or divisions of publicly-traded companies and have several competitive advantages, including:

- greater financial and human resources for product development and sales and marketing;
- significantly greater name recognition;
- their own IOLs;
- longer operating histories; and
- more established sales and marketing programs and distribution networks.

Because of the size of the cataract market, we expect that companies will continue to dedicate significant resources to developing and commercializing competing products, and we anticipate that our current marketed products and any future products will be subject to intense competition. We believe that the principal competitive factors in our market include:

- improved outcomes for patients;
- acceptance by surgeons;
- ease of use and reliability;
- product price and availability of reimbursement;
- product bundling and multiple product purchasing agreements;
- technical leadership;
- effective marketing and distribution; and
- speed to market.

Regulation

United States

We manufacture and market medical devices and, therefore, are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation in the United States 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, 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.

FDA Premarket Clearance and Approval Requirements

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 control needed to ensure safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's general controls for medical devices, or General Controls, 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 appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Class II devices are subject to FDA's General Controls, and any other special controls as deemed necessary by FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, unless an exemption applies. A Class III product is a product which has a new intended use or uses advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness. Our currently marketed medical device products are Class II medical devices subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed

prior to May 28, 1976 (pre-amendments device) and for which a premarket approval application, or 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.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device in the U.S. The FDA's 510(k) clearance process usually takes from three to twelve months from the date the application is submitted and filed with the FDA but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. If the FDA determines that the device, or its intended use, is not "substantially equivalent," the FDA may deny the request for clearance.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing or recall the modified device, or both, until 510(k) clearance or pre-market approval is obtained. We have modified aspects of some of our devices since receiving regulatory clearance and we have made the determination that new 510(k) clearances or pre-market approvals were not required.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. More recently, in September 2019, the FDA finalized the aforementioned guidance to describe an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the "safety and performance based pathway" and develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

FDA PMA Approval Process

Although unlikely for the types of medical devices marketed by us, the FDA may classify devices, or the particular use of a device, into Class III, and the device sponsor must then fulfill more rigorous PMA requirements. A PMA

application, which is intended to demonstrate that a device is safe and effective, must be supported by extensive data, including extensive technical and manufacturing data and data from preclinical studies and human clinical trials. After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which imposes stringent design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application 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 approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original 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.

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and compliance with corrections and removal 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. The FDA and the Federal Trade Commission also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the United States have similar regulations to which we are subject.

We are also required to register with the FDA as a medical device manufacturer. As such, our manufacturing sites are subject to periodic inspection by the FDA for compliance with the FDA's QSR. These regulations 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, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. 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 approvals for our products; or
- criminal prosecution.

Requirements for Surgical Lasers as Radiation Emitting Products

In addition to the requirements that apply to medical devices, our devices must also comply with an independent set of requirements that apply to radiation emitting electronic products, which includes lasers. Under the electronic product radiation control provisions of the FDCA, the FDA has established regulations specifying certain requirements for different types of radiation emitting electronic products. Among other requirements, manufacturers of surgical lasers must comply with FDA regulations that establish performance standards for laser products and require that manufacturers of products subject to performance standards submit reports to FDA demonstrating compliance. Unless otherwise exempted, manufacturers of certain radiation emitting devices must submit certain reports to FDA, including for new and modified products, for product defects, and annual reports, and comply with recordkeeping requirements. FDA regulations also provide specific certification and labeling requirements, and the labels for these products must contain certain information, such as warnings, declarations, and instructions for use.

Outside the United States

In order for us to market our products in countries outside the United States, we must obtain regulatory approvals, clearances or certifications and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals, clearance or certifications and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes which are substantially longer than the U.S. process. Failure to obtain regulatory authorizations, certifications or approvals in a timely manner and to meet all 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 sanctions and fines.

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

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC, or the EU Medical Devices Directive, which has been repealed and replaced by Regulation (EU) No 2017/745, or the EU Medical Devices Regulation. Our current certificate has been granted under the EU Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices

in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificate expire.

Medical Devices Directive

In the EU, there is currently no premarket government review of medical devices. Under the EU Medical Devices Directive all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I of the EU Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement. To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. . As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements 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, 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 are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossier and the manufacturer's quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the European Conformity, or CE, mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directives, the EU Medical Devices Regulation is directly applicable in EU member states, without the need for adoption of EU member states to implement into national laws.

The EU Medical Devices Regulation became effective on May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices into the market in the EU must comply with the EU Medical Device Vigilance System. Under this system, serious incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health or a serious public health threat. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be reported to the relevant authorities of the EU Member States, and communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Brexit

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for the Great Britain (i.e., England, Wales, and Scotland) medical device market and the EU regulatory regime no longer applies in Great Britain. Under the terms of the Ireland/Northern Ireland Protocol, the EU regulatory requirements continue to apply to medical devices placed on the Northern Ireland market.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the future regulation of medical devices in the United Kingdom. Regulations implementing the new regime were originally scheduled to come into

force in July 2023, but the MHRA has recently postponed the mandatory deadline until July 2024. Medical devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. Devices certified under the EU Medical Devices Regulation may be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. However, devices certified under the EU Medical Devices Directive may be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, all medical devices will require a UK Conformity Assessed, or UKCA, mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2024. However, UKCA marking will not be recognized in the EU. Following the transitional period, compliance with the UK regulations will be a prerequisite to be able to affix the UKCA mark to medical devices, without which they cannot be sold or marketed in Great Britain.

In addition, new regulations applicable in Great Britain now require that all medical devices must be registered with the MHRA prior to being placed on the market. Additionally, manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA.

Other Healthcare Laws

Although none of the procedures performed using our products are currently covered by any government or commercial third-party payors, applicable agencies and regulators may nonetheless interpret that we are subject to numerous state and federal healthcare fraud and abuse laws, including anti-kickback, false claims and transparency laws with respect to payments and other transfers of value made to physicians and other licensed healthcare professionals, that are intended to reduce waste, fraud and abuse in the health care industry and analogous state laws that may apply to healthcare items and services by any payors including private insurers and self-pay patients. These laws are broad, subject to evolving interpretations and vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. We must operate our business within the requirements of these laws and, if we were accused of violating them, could be forced to expend significant resources on investigation, remediation and monetary penalties. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, can be excluded from federal health care programs and become subject to substantial civil and criminal penalties, and have often become subject to consent decrees, settlement agreements or corporate integrity agreements severely restricting the manner in which they conduct their business.

Because we have commercial operations overseas, we are also subject to the Foreign Corrupt Practices Act, or FCPA, and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits, among other things, improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of medical devices are subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many

EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

The aforementioned EU rules are generally applicable in the EEA.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Physicians may be less likely to use our ALLY System or other future products, if cleared, certified or otherwise approved for marketing, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. Sales of any of our products may therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

For devices like our ALLY System, we expect the reimbursement to the facility or physician from third-party payors would be intended to cover the overall cost of treatment, including the cost of our devices used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. We do not directly bill any third-party payors; instead, we receive payment from the physician practice, hospital or other facility that uses our devices. Cataract surgery, including the implantation of a basic, single focus IOL, is reimbursed by Medicare but at a relatively low level and that level of reimbursement further declined in recent years. Failure by physicians, hospitals, and other users of our ALLY System or other devices we may develop the future, if cleared, certified or approved, to obtain sufficient coverage and reimbursement from healthcare payors for procedures in which such devices are used, or adverse changes in government and private third-party payors' policies could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

In addition, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and other facilities for procedures during which our devices are used. Because we expect the cost of our ALLY System, if cleared, certified or approved, would generally be recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our devices. An example of such payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula. In the past, with respect to reimbursement for physician services under the Medicare Physician Fee Schedule, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments, which began in 2019, that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

The containment of healthcare costs is a priority of federal, state and foreign governments, and the prices of pharmaceutical or device products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our ALLY System or other products we may develop in the future, if cleared, to be cost-effective compared to other available therapies, they may not cover our products or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

With respect to our LENSAR Laser System and ALLY System, surgeons typically charge the patient a separate out-of-pocket fee for procedures using our device. The use of advanced IOLs designed to improve vision is also not reimbursed by Medicare beyond the standard reimbursement for a monofocal IOL and physicians charge the patient for the difference between the lower reimbursed amount and the cost of the advanced IOL. Surgeons typically offer the option of an advanced IOL to patients explaining that it is not covered by Medicare and will be an out-of-pocket expense. Use of our LENSAR Laser System and ALLY System is often accompanied by the implantation of an

advanced IOL. We believe that the ability of our LENSAR Laser System and ALLY System, when used with advanced IOLs to optimize vision results, will encourage surgeons to perform the procedure and their patients to pay the additional out-of-pocket costs.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative 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 ALLY System or other products we may develop in the future, if cleared. 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.

The implementation of the Affordable Care Act, or the ACA, in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

Moreover, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to 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. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

For EU member states, in December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation, which entered into force in January 2022 and will become applicable from January 12, 2025 onwards, intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek

advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information and could apply now or in the future to our operations or the operations of our partners. 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 govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. 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.

Human Capital

We are committed to revolutionizing refractive eye surgery. As a global leader in next generation femtosecond laser for cataract surgery, our success depends on talented and motivated individuals who share our passion for making a difference in patients' lives. We pride ourselves on having a highly collaborative, innovative environment where initiatives and teamwork are valued, and individual efforts are recognized. Together, we are one team, one vision.

In managing our business, we utilize a variety of human capital measures and objectives, including:

- ***Hiring Strategies*****:** We compete for highly skilled and talented individuals within the market. We promote hiring from within, and we source from outside to bring in new talent when necessary. We strive to have a diverse and inclusive workforce, and ultimately the respective hiring team's goal is to choose the best candidate for each role.

- ***Retention and Stability*****:** We take pride in the stability and dedication of our workforce. Over 45% of employees have been with the Company five or more years, and over 25% have been with the Company 10 or more years. In 2022, we experienced a full-time employee turnover rate of approximately 15%.

- ***Workforce Demographics*****:** As of December 31, 2022, we had approximately 110 employees that support our manufacturing, research and development, commercial and administrative functions. Primarily all of our workforce is based at our corporate headquarters in Orlando, Florida except for our commercial organization, which is spread throughout the United States based upon geographic responsibility.

- ***Culture*****:** We value our employees and the individual and collective contributions employees make to the Company. We believe work-life balance is integral to our employees performing at their best. Given our smaller business orientation, we require individual employees to have broader skillsets and enthusiastic and self-effacing dedication to our team-based working groups. We offer development opportunities that align with professional and personal goals. We aim to have quarterly Company-wide meetings to keep employees informed on Company updates and performance, as well as to celebrate corporate milestones and individual years of service achievements. In addition to social activities scheduled throughout the year, we typically have an annual corporate event to bring all employees together for team building. To provide work/life support and resources for employees, we provide access to two Employee Assistance Programs.

- ***Competitive Pay and Benefits*****:** Our compensation programs are designed to align the compensation of our employees with our corporate performance and to provide the proper incentives to attract, retain, and motivate

employees to achieve superior results. The structure of our compensation programs is intended to balance incentive earnings for both short-term and long-term performance. Specifically:

- We provide employee wages that we believe are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location.
- We have also engaged outside compensation and benefits consulting firms to help independently evaluate the effectiveness of our executive and benefit programs and to provide benchmarking against our peers within the industry.
- We look to align our executives' long-term equity compensation with our stockholders' interests. In addition, we currently provide equity benefits to all employees to encourage Company ownership and align all employee interests with that of our stockholders. We believe this incentivizes the entire employee base in relation to the successful achievement of the Company's goals.
- Annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process.
- All full-time employees are eligible for health insurance, paid and unpaid leaves, a retirement plan with company match and immediate vesting, and disability insurance. The Company also offers a generous holiday schedule and a Company-wide shut down during the December holidays.

Seasonality

We have historically experienced seasonal variations in the sales and leases of our products, with our fourth quarter typically being the strongest and the first or third quarter being the slowest. We believe these seasonal variations are consistent across our industry.

Corporate Information

We were incorporated in the State of Delaware on August 20, 2004 and became a direct, majority-owned subsidiary of PDL BioPharma, Inc., or PDL, in 2017. In October 2020, we completed a spin-off of LENSAR, Inc. from PDL in the form of a dividend involving the distribution of all outstanding shares of our common stock owned by PDL to the holders of PDL common stock, or Spin-Off. Following the completion of the Spin-Off, PDL no longer owns any equity interest in us, and we became an independent public company on October 1, 2020.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission, or SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. Our SEC filings are also available free of charge under the Investor Relations section of our website at www.lensar.com as soon as reasonably practicable after they are filed with or furnished to the SEC. We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investor Relations sections of our website at *www.lensar.com*. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by under the Investor Email Alerts option on the Investor Relations page of our website at *www.lensar.com.* Our website and the information available through our website are not incorporated into this Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited financial statements and the related notes, as well as our other public filings with the SEC, before deciding to invest in our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects, as well as the price of our common stock, could be materially and adversely affected.

Risks Related to Our Business

Our results have been in the past, and could be in the future, adversely affected by economic uncertainty or deteriorations in economic conditions.

Global economic uncertainty, including due to factors such as increased inflation and rising interest rates, have contributed to our business and operational performance. If economic uncertainty continues or increases or if economic conditions deteriorate, including due to the ongoing and legacy effects of the COVID-19 pandemic, these conditions may have a material adverse impact on our revenue, profit margins, cash flow and liquidity in the future. In particular, our business is impacted by inflation, such as the recent inflationary pressures related to global supply chain disruptions that have increased the cost of certain raw materials, labor and transportation used in our business. These broad-based inflationary impacts have negatively impacted our financial condition, results of operations and cash flows since 2020, and we expect these inflationary impacts to continue for the foreseeable future. A high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenues if our selling prices of our products do not increase as much or more than our increase in costs.

We expect to incur operating losses for the near-term future and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.

For the years ended December 31, 2022 and 2021, we had net losses of $19.9 million and $19.6 million, respectively. As of December 31, 2022, we had an accumulated deficit of $97.5 million. We expect to continue to incur losses for the near-term future as a result of building our commercial and clinical infrastructure, pursuing further FDA and other regulatory body clearance or certification of and our further commercial launch of our proprietary, next generation cataract treatment system, known as our ALLY System, and investing in research and development. In addition, as a public company, we will incur significant legal, accounting and other expenses. We cannot make assurances that we will ever generate sufficient revenue from our operations to achieve profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively affect the value of our securities and our ability to raise capital and continue operations.

We have historically derived our revenue from the sale or lease of our LENSAR Laser System and the associated procedure licenses and sale of consumables used in each procedure involving our LENSAR Laser System. The commercial success of our ALLY System will depend upon receipt of additional regulatory clearances or certifications and our ability to maintain and grow significant market acceptance for it.

We have historically derived our revenue from the sale or lease of our LENSAR Laser System and the associated procedure licenses and consumables used in each procedure involving our LENSAR Laser System, and expect that this will account for a majority of our revenue in the foreseeable future until we are able to fully commercialize our ALLY System. Accordingly, our ability to increase revenue is highly dependent on our ability to market and sell or lease our ALLY System and market the associated consumables. In 2022, we transitioned from manufacturing and selling our LENSAR Laser System to focus on our ALLY System. In September 2022, we submitted the ALLY System for certification in the European Union, or EU, and intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory clearance or certifications in other regions outside the United States and the timing of these clearance or certifications, among other factors. In addition, our future revenue and cash flows will depend on, among other factors, our installed base of systems.

Our ability to maintain our market share, execute our growth strategy, achieve commercial success and become profitable will depend upon the adoption and continued acceptance of our LENSAR Laser System and ALLY System by surgeons, hospital outpatient surgical facilities, in-office surgical suites and ambulatory surgery centers, or ASCs. Our systems are currently used in advanced cataract procedures for which surgeon reimbursement continues to decline and patients pay a significant portion of the cost of the procedure. We cannot predict the extent to which patients will continue to seek out these types of procedures. Further, we cannot predict if cataract surgeons will continue to use our LENSAR Laser System or how quickly cataract surgeons will accept the ALLY System, or any planned or future products we introduce, and, if accepted, how frequently any such products will be used. Our current products may not maintain, and our ALLY System or any planned or future products we may develop or market may never gain, broad market acceptance among cataract surgeons and the medical community for the procedures in which they are designed to be used. Our ability to maintain and increase market acceptance of our products depends on a number of factors, including:

- our ability to provide visual outcomes and economic data that show the safety, efficacy and cost effectiveness, including other patient benefits from use, of our LENSAR Laser System, ALLY System or other future products;
- acceptance by cataract surgeons and others in the medical community of our LENSAR Laser System and ALLY System;
- the potential and perceived advantages and disadvantages of our LENSAR Laser System and ALLY System as compared to competing products;
- the willingness of patients to pay out-of-pocket for procedures in which our LENSAR Laser System, ALLY System or other future products is used but for which limited reimbursement by third-party payors, including government authorities, is available;
- the effectiveness of our sales and marketing efforts, and of those of our international distributors;
- the prevalence and severity of any complications associated with using our LENSAR Laser System or ALLY System;
- the ease of use, reliability and convenience of our LENSAR Laser System and ALLY System relative to competing products;
- competitive response and negative selling efforts from providers of competing products;
- quality of outcomes for patients in procedures in which surgeons use our LENSAR Laser System and ALLY System;
- the results of clinical trials and post-market clinical studies relating to the use of our LENSAR Laser System and ALLY System;
- the technical leadership of our research and development teams;
- the absence of third party blocking intellectual property;
- our ability to introduce our products to the market with speed and on time with our projected timelines;
- pricing pressure, including from larger, well-capitalized and product-diverse competitors, corporate-owned ASCs, group purchasing organizations, and government payors; and
- the availability of coverage and adequate reimbursement for procedures using our LENSAR Laser System, ALLY System or other future products from third-party payors, including government authorities.

Failure to maintain or increase market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

Our growth depends on our ability to gain regulatory clearances and certifications, as well as our ability to meet production goals for our ALLY System.

The ALLY System, which has received clearance from the FDA, enables cataract surgeons to complete the femtosecond-laser-assisted cataract surgery, or FLACS, procedure seamlessly in a single, sterile environment. This clearance is the first stage of a planned, two-step commercial release strategy. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. In addition, we submitted the ALLY System for certification in the European Union, or EU, in September 2022 and intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. If we continue to experience supply chain constraints, we may be unable to deliver ALLY Systems as planned.

As the second stage of the strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as a predicate device. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, we are unable to submit a 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Further, we are relying on a third party to manufacture and obtain clearance on the phacoemulsification component of our ALLY System, and do not currently possess the internal resources or know-how to do so without their assistance. Accordingly, we have delivered the ALLY System to surgeons in the initial launch with the phacoemulsification features remaining disabled and/or removed.

If the third party is unable to obtain clearance of its phacoemulsification device, we may not be able to obtain FDA clearance on the phacoemulsification features of our ALLY System in a timely manner, if at all. Accordingly, if we are unable to get the phacoemulsification feature of the ALLY System cleared by the FDA and authorized or certified by other regulatory bodies, it could further impact our future revenue and cash flows. Any additional adverse developments with our 510(k) submission or that of our third-party supplier, including that third party's failure to obtain 510(k) clearance for their phacoemulsification device, for which the phacoemulsification component of our ALLY System is reliant as a predicate, could in turn further negatively impact our ability to obtain 510(k) clearance for the phacoemulsification features of our ALLY System or, even if clearance is obtained, the timing of any commercialization of both the femtosecond laser and phacoemulsification features within our ALLY System.

While we have engaged in market research to evaluate the interest in a dual-function device, the results of that research are based on a small population of cataract surgeons and may not be indicative of actual market interest. In addition, the success of our ALLY System or any other new product offering or product enhancements we pursue will depend on several factors, including our ability to:

- properly identify and anticipate cataract surgeon and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- exclude competition based on our intellectual property rights;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances, certifications or approvals for expanded indications, new products or product modifications;
- be fully FDA (or other regulatory authority)-compliant with manufacturing and marketing of new devices or modified products;
- provide adequate training to potential users of these products;

- receive adequate coverage and reimbursement for procedures performed with our ALLY System or any other products we may develop in the future; and

- develop an effective and dedicated sales and marketing team.

If we are not successful in expanding our product offering, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

Global health developments and economic uncertainty resulting from COVID-19 have adversely impacted, and may continue to adversely impact, our business, results of operations, cash flows and financial position.

The COVID-19 pandemic, and related global macroeconomic conditions, has significantly impacted our business, and could in the future have a material adverse impact. For example, if we or our commercial partners again experience prolonged shutdowns or business disruptions due to "shelter-in-place" orders, quarantines, suspension or restriction of elective surgeries and various business operations or similar orders or restrictions to control the spread of COVID-19 or other health crises by restricting non-essential activities, our ability to conduct our business could be materially and adversely impacted, and our business, liquidity and financial results would be adversely affected. Adverse developments originating during the COVID-19 pandemic have adversely affected, and may continue to adversely affect, the availability of parts and components needed for our systems, which, if such conditions persist or worsen, may have a material adverse impact on the commercial success of the ALLY System. In particular, we have faced increased costs associated with supply chain disruptions, inflationary pressures and resulting price increases, and expect these trends to continue. For example, we expect our contractual obligations to increase due to supply chain issues that have necessitated us to enter into longer-term and more expensive per unit contracts to build and source inventory to satisfy the expected commercial demand for the ALLY System. If these costs are passed along to customers through an increase to the overall cost of the ALLY System, customer demand may be adversely impacted.

The COVID-19 pandemic also led to extreme disruption and volatility in the global capital markets, which has increased the cost of, and adversely impacted access to, capital and increased economic uncertainty, and could adversely affect our liquidity and capital resources in the future. We cannot predict with certainty the extent to which global economic uncertainty will impact our business, financial condition and results of operations, particularly if the factors contributing to this uncertainty persist or worsen over an extended period of time. Furthermore, any new pandemic, epidemic or outbreak of an infectious disease in the markets in which we operate or in which we sell or lease our products could have similar negative effects on macroeconomic conditions generally and on our business, financial condition and results of operations.

COVID-19 disruptions adversely impacting our business and financial results may also have the effect of heightening many of the other risks described in this "Risk Factors" section, including risks relating to changes in global economic conditions; consumer demand; our ability to maintain and grow significant market acceptance; our ability to enhance our systems; our ability to grow our marketing team; patients' and surgeons' willingness and ability to pay for an advanced cataract procedure over a standard cataract procedure; our future capital needs; disruption in the long-term supply and manufacturing of our products by suppliers; increased credit risks associated with our customers; and regulatory restrictions and clearances.

Patients may not be willing to pay for the price difference between a standard cataract procedure and an advanced cataract procedure in which a laser system such as ours is used, an increment which is typically not covered by Medicare, private insurance or other third-party payors.

Payment for a standard cataract procedure is typically covered by Medicare, private insurance or other third-party payors. However, a cataract patient seeking a greater and more versatile visual outcome may desire an advanced cataract procedure involving a laser system such as ours. The patient is typically responsible for the additional costs associated with the use of these premium technologies in the physician's practice, hospital outpatient surgical facilities, in-office surgical suites and ambulatory surgery centers. Due to this additional cost, patients may not elect to have such a procedure and our business may not grow as anticipated. Our future success depends in part upon patients achieving better visual outcomes from procedures using our LENSAR Laser System or ALLY System, or procedures involving similar laser systems that meets their expectations. If patients are not adequately satisfied with the results of such procedures, they or their surgeons may be less willing to recommend these procedures to other patients.

Additionally, weak or uncertain economic conditions may cause individuals to be less willing to pay for advanced cataract procedures. Although we anticipate use of our ALLY System in certain aspects of the standard cataract procedure will be covered by or reimbursable through government or other third-party payors, our current LENSAR Laser System procedures are not covered by or reimbursable through government or other third-party payors. A decline in economic conditions in the United States or in international markets could result in a decline in demand for the procedures in which our systems are used and could have a material adverse effect on our business, financial condition and results of operations.

If we are not able to effectively grow our U.S. sales and marketing organization or maintain or grow an effective network of international distributors, our business prospects, results of operations and financial condition could be adversely affected.

In order to generate future sales growth within the United States, we will need to expand the size and geographic scope of our U.S. direct sales organization. Accordingly, our future success will depend largely on our ability to train, retain and motivate skilled regional sales managers and direct sales representatives with significant technical knowledge of our systems. Because of the competition for their services, we may not be able to retain such representatives on favorable or commercially reasonable terms, if at all. If we are unable to grow our global sales and marketing organization within the United States, we may not be able to increase our revenue, which would adversely affect our business, financial condition and results of operations.

Additionally, we rely exclusively on a network of independent distributors to generate sales and leases of our LENSAR Laser System and ALLY System as well as purchases of our consumables and licensed applications outside of the United States. For the year ended December 31, 2022, one customer accounted for 10% of our revenue. This customer concentration exposes us to a material adverse effect if any of these significant distributors were to significantly reduce purchases for any reason or favor competitors or new market participants. If a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train new personnel to market our LENSAR Laser System, and our ALLY System upon receiving regulatory clearance in the applicable region, as well as our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. In addition, our international distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing, sales, education and training efforts that we believe are necessary to enable the products to develop, achieve or sustain market acceptance. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent that distributor from helping competitors solicit business from our existing customers, which could further adversely affect us. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party distributors become unsatisfactory, we may experience delays in meeting our customers' demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose potential customers.

Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms or at all.

We expect our revenues and expenses to increase in connection with our on-going activities, particularly as we continue to execute on our growth strategy, including expansion of our sales and customer support teams. The primary factors determining our cash needs are the funding of operations, which we expect to continue to expand as the business grows, and enhancing our product offerings through the research and development, further regulatory clearances and launch of the ALLY System. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our commercial efforts and those of our distributors; the timing, scope and magnitude of our commercial and development activities; and the timing of further regulatory clearance or certification of our ALLY System. We have also experienced negative effects on our capital requirements from supply chain interruptions, and we expect that supply chain disruptions will negatively affect our capital requirements and the availability of funds to finance those requirements in the future. In addition, market conditions impacting financial institutions could impact our ability to access some or all of our cash, cash equivalents and marketable securities, and we may be unable to obtain alternative funding when needed and on acceptable terms, if at all.

As of the date of this Annual Report, we expect our current cash and cash equivalents, together with cash generated from the future sale and lease of our products, to be sufficient to operate our business for at least one year from the date of issuance of these financial statements. To finance our operations beyond that point, we may seek additional funds from public or private stock offerings, borrowings under credit facilities or other sources that we may not be able to maintain or obtain on acceptable or commercially reasonable terms, if at all. Our capital requirements will depend on many factors, including, but not limited to:

- the revenue generated by the sale, lease or use of our systems;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in procuring, manufacturing and selling our systems, including increased costs, uncertainties, and delays associated with global supply chain disruptions and inflationary pressures;
- the costs of commercializing the ALLY System, including increased costs associated with supply chain disruptions and inflationary pressures or other new products or technologies;
- the scope, rate of progress and cost of our clinical studies that we are currently conducting or may conduct in the future;
- the cost and timing of obtaining and maintaining regulatory approval, certification or clearance of our products and planned or future products;
- costs associated with any product recall that may occur;
- the costs associated with complying with state, federal and foreign laws and regulations;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the cost of enforcing or defending against non-competition claims;
- the number and timing of acquisitions and other strategic transactions;
- the costs associated with increased capital expenditures;
- anticipated and unanticipated general and administrative expenses, including expenses related to operating as a public company and insurance expenses; and
- costs associated with any adverse market conditions or other macroeconomic factors.

Such capital may not be available on favorable terms, or at all. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, which may impact our ability to obtain additional capital on favorable terms. Furthermore, if we issue equity securities to raise additional capital, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders. 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. In addition, if we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities or respond to competitive pressures, changes in our supplier relationships or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our business and financial goals or to

achieve or maintain profitability and could have a material adverse effect on our business, financial condition and results of operations.

We cannot assure our ability to continue as a going concern in the future.

As of December 31, 2022, we had $14.7 million in cash and cash equivalents and an accumulated deficit of $97.5 million. Based on our existing cash and cash equivalents on hand, together with expected cash to be generated from the future sale and lease of our products, we believe that we have sufficient cash on hand to support our operations and payment obligations for at least one year from the date of issuance of the financial statements included in this Annual Report. However, our liquidity beyond one year from the date of issuance of the financial statements is contingent upon, among other things, meeting or exceeding revenue and manufacturing targets in our current operating plan. This condition could raise potential doubt about our ability to continue as a going concern in the future. In order to mitigate potential future liquidity issues, we will need to seek additional capital which may be through the equity or debt financings, borrowings under credit facilities or from other sources. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all. To the extent that we raise additional capital through future equity offerings, the ownership interest of common stockholders will be diluted, which dilution may be significant. However, we cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us. In the event that we are unable to obtain any or sufficient additional funding, there can be no assurance that we will be able to continue as a going concern, and could be forced to delay, reduce or discontinue our regulatory approval and commercialization efforts.

If the supply or manufacture of our systems or other products associated with the systems is materially disrupted, including by supply chain shortages and price increases, it may adversely affect our ability to manufacture products and could negatively affect our operating results.

We manufacture our systems and provide the electronic license applications at our corporate headquarters in Orlando, Florida. This is also the location where we currently conduct substantially all of our research and development activities, customer and technical support, and management and administrative functions. If our facility suffers a crippling event, or a force majeure event such as an earthquake, hurricane, fire, flood or temporary shutdown due to a pandemic, epidemic or infectious disease, this could materially impact our ability to operate.

We purchase custom and off-the-shelf components from a number of suppliers and subject them to stringent quality specifications and processes. Some of the components necessary for the assembly of our systems and associated consumables are currently provided by single-sourced suppliers (the only approved supply source for us among other sources). We are also relying on a third party to manufacture the phacoemulsification component of the ALLY System. If one or more of our suppliers cease to provide us with sufficient quantities of materials in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we may experience delays in engaging additional or replacement suppliers for certain components. There may also be disruptions outside our control in the availability and pricing of various component parts needed for our ALLY System.

In particular, a global semiconductor supply shortage has had, and is continuing to have, wide-ranging effects across multiple industries. According to certain market reports, both China and Taiwan are leading manufacturers of the world's semiconductor supply. Conflict between China and Taiwan might lead to trade sanctions, technology disputes, or supply chain disruptions, which could, in particular, affect the semiconductor industry. If this were to occur, our ability to source an adequate supply of semiconductors would be further reduced, which would adversely affect our business. In addition, any further conflict between China and Taiwan could harm our operations globally, including the operations of our customers and suppliers.

We have seen significant disruptions in the supply of, timing of delivery of and fluctuations in pricing for various component parts needed for our products, including the integrated circuits used in our systems, and expect these trends to continue. Our efforts to maintain an adequate supply of inventory may not be sufficient and we may be unable to source the necessary component parts on commercially acceptable terms to reflect in the price of our system. The

long-term loss of these suppliers, or their long-term inability to provide us with an adequate supply of components or products, could potentially cause delay in the manufacture of our products, thereby impairing our ability to meet the demand of our customers and causing significant harm to our business. If it becomes necessary to identify and qualify a suitable second source to replace one of our key suppliers, that replacement supplier would not have access to our previous supplier's proprietary processes and would therefore be required to develop its own, which could also result in delay. Any disruption of this nature or increased expense could harm our commercialization efforts and could have a material adverse effect on our business, financial condition and results of operations. If these supply chain shortages and disruptions continue or worsen, there is no guarantee that the Company will be able to meet customer demand for the ALLY System. In addition, pricing increases in component parts for our systems resulting from inflationary pressures and other macroeconomic conditions may necessitate an increase in the overall cost to customers, which in turn may have an adverse impact on customer demand.

We and some of our suppliers and contract facilities are required to comply with regulatory requirements of the FDA (and other regulatory authorities). In particular, the FDA's Quality System Regulation, or QSR, which includes FDA's current Good Manufacturing Practice requirements, or cGMPs, covers the procedures and documentation of the design, testing, production, control, quality assurance, inspection, complaint handling, recordkeeping, management review, labeling, packaging, sterilization, storage and shipping of our device products. The FDA audits compliance with these regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. If our manufacturing facilities or those of any of our suppliers or contract facilities are found to be in violation of applicable laws and regulations, the FDA could take enforcement action. Similar requirements must be complied with in foreign countries and foreign regulatory authorities could also take enforcement action. Additionally, in the event we must obtain a replacement supplier or contract facility, it may be difficult for us to identify and qualify a supplier or contract facility that complies with QSR and cGMPs, which would adversely impact our operations.

We currently compete, and expect to compete in the future, against other companies, some of which have longer operating histories, more established products or greater resources than we do.

Our industry is global, highly competitive and subject to rapid and profound technological, market and product-related changes. We face significant competition from large multinational medical device companies, as well as smaller, emerging players focused on product innovation.

Our primary competitors in providing surgical solutions for cataract patients are Alcon Inc.; Bausch + Lomb Corporation; Johnson & Johnson; Carl Zeiss AG; Zeimer; and KERANOVA S.A. These competitors are focused on bringing new technologies to market and acquiring products and technologies that directly compete with our products or have potential product advantages that could render our products obsolete or noncompetitive.

Many of our current and potential competitors are large publicly traded companies or divisions of publicly-traded companies and have several competitive advantages, including:

- greater financial and human resources for product development and sales and marketing;
- significantly greater name recognition;
- longer operating histories; and
- more established sales and marketing programs and distribution networks.

In addition, many of our competitors have their own intraocular lens, or IOLs, while we do not, which could put us at a competitive disadvantage. If we are unable to compete effectively in this environment, it could adversely affect our business.

To successfully market, sell and lease our products in markets outside of the United States, we must address many international business risks with which we have limited experience.

We have historically sold and leased a significant portion of our LENSAR Laser Systems outside of the United States through a network of independent distributors and intend to increase our international presence in Germany, China

and South Korea, as well as other international markets, including through sales and leases of our ALLY System once regulatory clearance in these regions has been obtained. Our international business operations are subject to a number of risks, including:

- difficulties in staffing and managing our international operations;
- increased competition as a result of more products and procedures receiving regulatory approval, certification or clearance or otherwise becoming free to market in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- reduced or varied protection for intellectual property rights in some countries;
- export restrictions, trade regulations, and foreign tax laws;
- fluctuations in currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar international markets;
- customs clearance and shipping delays;
- political, social, and economic instability abroad, including the ongoing war between Russia and Ukraine, potential conflict between China and Taiwan, terrorist attacks, and security concerns in general;
- preference for locally produced products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

For example, the war between Russia and Ukraine has not had a direct material impact on our revenue to date; however, that could change depending on the magnitude of the conflict and the imposition of additional sanctions by the U.S. and other countries or the spread of the conflict to surrounding areas. Further, while we are not directly exposed to economic conditions in Russia or Ukraine, the conflict has had a substantial impact on global supply chains and may be a contributing factor to the supply chain shortages we are experiencing.

These risks and uncertainties could negatively impact our ability to successfully market, sell and lease our products in markets outside of the United States. Furthermore, our ability to deal with these issues could be affected by applicable U.S. laws. Any such risks could have an adverse impact on our business, financial condition, results of operations, cash flows, or reputation.

We are exposed to the credit risk of some of our customers, which could result in material losses.

Customers may lease our systems or finance the system through the product utilization, and we believe there has been an increase in demand for these types of customer leasing in recent years, especially in the United States. We may experience loss from a customer's failure to make payments according to the contractual lease terms or some other material decrease in the practice revenues and surgical procedure volume. Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, economic pressures or uncertainty, or other customer-specific factors. In addition, our credit risk may be highly concentrated, as we rely exclusively on a network of independent distributors to generate sales outside of the United

States. Further, ongoing consolidation among distributors, retailers and healthcare provider organizations could increase the concentration of credit risk. The factors affecting our customers' ability to make timely payments according to the contractual lease terms are out of our control, and as a result, exposes us to additional risks that may materially and adversely affect our business and results of operations. The occurrence of any such factors affecting our customers may cause delays in payments or, in some cases, defaults on payment obligations, which could result in material losses.

The programs we have designed to monitor and mitigate the associated risk may not be successful. There can be no assurance that such programs will be effective in reducing credit risks relating to these lease financing arrangements. If the level of credit losses we experience in the future exceed our expectations, such losses could have a material adverse effect on our business, financial condition and results of operations or adversely affect our ability to sell such assets as part of our monetization strategy.

We may be unable to accurately forecast customer demand and our inventory levels.

We generally do not maintain large volumes of finished goods and anticipating demand for our products may be challenging as cataract surgeon demand and adoption rates can be unpredictable. In addition, as use of our LENSAR Laser System and ALLY System is adopted by more cataract surgeons, we anticipate greater fluctuations in demand for our products, which makes demand forecasting more difficult. Our forecasts are based on management's judgment and assumptions, each of which may introduce error into our estimates. If we underestimate customer demand or if insufficient manufacturing capacity is available, we would miss revenue opportunities and potentially lose market share and damage our customer relationships. In connection with the commercial launch of the ALLY System, we are modifying our manufacturing operations from producing the LENSAR Laser Systems to the ALLY System. We could underestimate the worldwide demand for the ALLY System and be unable to fulfill customer requests. Conversely, if we overestimate customer demand, our excess or obsolete inventory may increase significantly, which would reduce our gross margin and adversely affect our financial results.

Failure to secure adequate coverage or reimbursement by government or other third-party payors for certain procedures using our ALLY Adaptive Cataract Treatment System or our other future products, or changes in current coverage or reimbursement, could materially impact our revenue and future growth.

Adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs, for certain procedures (e.g., phacoemulsification) using our ALLY System or other products we may develop in the future, if approved, is central to the acceptance and adoption of these products. Hospitals, healthcare facilities, physicians and other healthcare providers that may purchase and use our ALLY System generally rely on third-party payors to pay for a part of the costs and fees associated with certain procedures using our ALLY System. If third-party payors reduce their levels of payment, if our costs of production increase faster than increases in reimbursement levels or if third-party payors deny reimbursement for procedures using our ALLY System, our ALLY System may not be adopted or accepted by hospitals, healthcare facilities, physicians or other healthcare providers and the prices paid for a procedure using our ALLY System may decline, which could have a material adverse effect on our business, financial condition or results of operations.

Physicians are reimbursed separately for their professional time and effort to perform a cataract procedure that is covered by third-party payors. Such party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our ALLY System would be used. These updates could directly impact the demand for our future products. For example, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule, or PFS, through 2019, but no annual update from 2020 through 2025. MACRA also introduced a Quality Payment Program for Medicare physicians, nurses and other "eligible clinicians" (as defined in MACRA) that adjusts overall reimbursement under the PFS based on certain performance categories. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our ALLY System or any other products we may develop in the future. However, there is no uniform policy of coverage and reimbursement among payors in

the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor. Many private payors require extensive documentation of a multi-step diagnosis before authorizing procedures using our products. Some private payors may apply their own coverage policies and criteria inconsistently, and physicians and other healthcare providers may not be able to receive approval and reimbursement for certain procedures using our ALLY System consistently. Any perception by physicians and other healthcare providers that the reimbursement for procedures using our ALLY System or other future products is inadequate to compensate them for the work required, including diagnosis, documentation, obtaining third-party payor approval for the procedure and other burdens on their office staff or that they may not be reimbursed at all for the procedures using our ALLY System or other future products, may negatively affect the adoption and use of our ALLY System or other future products and technologies, and the prices paid for such products may decline.

The healthcare industry in the United States, and in our other operating regions, has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Third-party payors are imposing lower payment rates and negotiating reduced contract rates with hospitals, other healthcare facilities, surgeons and other healthcare providers and being increasingly selective about the products, technologies and procedures they chose to cover and provide reimbursement for. Third-party payors may adopt policies in the future restricting access to products and technologies like ours or the procedures performed using such products. Therefore, we cannot be certain that any procedures performed with our ALLY System or other future products will be covered and reimbursed. There can be no guarantee that should we introduce new products and technologies, third-party payors will provide adequate coverage and reimbursement for those products or the procedures in which they are used. If third-party payors do not provide adequate coverage or reimbursement for such products, then our sales may be limited to circumstances where our products and procedures using our products are being largely or entirely self-paid by patients, as is currently the case with procedures using our systems.

Additionally, market acceptance of our products and technologies in foreign markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. In Europe, reimbursement is entirely regulated at member state level and varies significantly between countries, and member states are facing increased pressure to limit public healthcare spending. We may not obtain additional international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact future market acceptance of our ALLY System or any of other products we may develop in the future in the international markets in which those approvals are sought.

We provide a limited warranty for our products.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

Product liability suits brought against us could cause us to incur substantial liabilities, limit the selling or leasing of our existing products and interfere with commercialization of any products that we may develop.

If our product offerings are defectively designed or manufactured, contain defective materials, or are used or deployed improperly, or if someone alleges any of the foregoing, whether or not such claims are meritorious, we may become subject to substantial and costly litigation. Any product liability claims brought against us, with or without merit, could divert management's attention from our business, be expensive to defend, result in sizable damage awards against us, damage our reputation, increase our product liability insurance rates, prevent us from securing continuing coverage, or prevent or interfere with commercialization of our products. In addition, we may not have sufficient insurance coverage for all future claims. Product liability claims brought against us in excess of our insurance coverage would likely be paid out of cash reserves, harming our financial condition and results of operations.

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

We do not carry insurance for all categories of risk that our business may encounter. We can give no assurance that the coverage under our product liability insurance in the United States will be available or adequate to satisfy any claims. Product liability insurance is expensive and subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We do not carry specific hazardous waste insurance coverage, and our insurance policies generally exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals and certifications could be suspended.

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

Our financial results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. For example, we have historically experienced seasonal variations in the selling or leasing of our products and procedures involving our products, with our fourth quarter typically being the strongest and the first or third quarter being the slowest. We believe these seasonal changes are consistent across our industry. Other factors that may cause fluctuations in our quarterly and annual results include:

- fluctuations in the demand for the more advanced, patient-pay procedures in which our systems are used;
- adoption of our LENSAR Laser Systems and ALLY Systems;
- our ability to establish and maintain an effective and dedicated sales organization in the United States and network of independent distributors outside the United States;
- pricing pressure applicable to our products from competitor pricing;
- results of clinical research and trials on our products or competitive products;
- the mix of sales and leases of our systems;
- timing of delivery of systems, new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- decisions by surgeons, hospitals and ASCs to defer acquisitions of systems in anticipation of the introduction of new products or product enhancements by us or our competitors;

- sampling by and additional training requirements for cataract surgeons upon the commercialization of a new product by us or one of our competitors;
- regulatory approvals, clearances or certifications and legislative changes affecting the products we may offer or those of our competitors;
- interruption in the manufacturing or distribution of our systems;
- delays in, or failure of, component and raw material deliveries by our suppliers;
- the ability of our suppliers to timely provide us with an adequate supply of components;
- the effect of competing technological, industry and market developments; and
- changes in our ability to obtain regulatory clearance, certification or approval for our product candidates.

As a result, you should not rely on our results in any past period as an indication of future results and you should anticipate that fluctuations in our quarterly and annual operating results may continue and could generate volatility in the price of our common stock. Quarterly or annual comparisons of our financial results should not be relied upon as an indication of our future performance.

If we fail to manage our anticipated growth effectively, or are unable to increase or maintain our manufacturing capacity, we may not be able to meet customer demand for our products and our business could suffer.

We have experienced significant period-to-period growth in our business and we must continue to grow in order to meet our business and financial objectives. However, continued growth may create numerous challenges, including:

- new and increased responsibilities for our management team;
- increased pressure on our operating, financial and reporting systems;
- increased pressure to anticipate and satisfy market demand;
- additional manufacturing capacity requirements;
- strain on our ability to source a larger supply of components, including as a result of ongoing supply chain issues, in order to meet our required specifications on a timely basis;
- management of an increasing number of relationships with our customers, suppliers and other third parties;
- entry into new international territories with unfamiliar regulations and business approaches;
- the need to hire, train and manage additional qualified personnel; and
- transitioning manufacturing from our LENSAR Laser System to our ALLY System.

Our current and planned capacity may not be sufficient to meet our current business plans. There are uncertainties inherent in expanding our manufacturing capabilities, and we may not be able to sufficiently increase our capacity in a timely manner. For example, manufacturing and product quality issues may arise as we increase production rates at our manufacturing facility or launch new products. Also, we may not manufacture the right product mix to meet customer demand as we introduce new products. As a result, we may experience difficulties in meeting customer demand, in which case we could lose customers or be required to delay new product introductions, and demand for our products could decline. If we fail to manage any of the above challenges effectively, our business may be harmed.

If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.

Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, although we have no current commitments with respect to any acquisition or investment, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees related thereto. Integrating any business, product or technology we acquire could be expensive and time-consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will be adversely affected. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

Our future growth depends on our ability to retain members of our senior management and other key employees. If we are unable to retain or recruit qualified personnel for growth, our business results could suffer.

We have benefited substantially from the leadership and performance of our senior management as well as certain key employees. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense, and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel, or that we will be able to do so without incurring substantial additional costs. We have begun to experience increases in compensation levels in connection with our recruitment and retention efforts, which may increase further in the future. The loss of services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

In addition to competing for market share for our products, we also compete against our competitors for personnel, including qualified sales representatives that are necessary to grow our business. Universities and research institutions also compete with us for scientific personnel that are important to our research and development efforts. We also rely on consultants and advisors in our research, operations, clinical and commercial efforts to implement our business strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our strategic plan requires us to continue growing our sales, marketing, clinical and operational infrastructure in order to generate, and meet, the demand for our products. If we fail to retain or attract these key personnel, we could fail to take advantage of the market for our products, adversely affecting our business, financial condition and results of operation.

We rely significantly on the use of information technology. Cybersecurity risks – any technology failures causing a material disruption to operational technology or cyber-attacks on our systems affecting our ability to protect the integrity and security of customer and employee information – could harm our reputation and/or could disrupt our operations and negatively impact our business.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. The future operation, success and growth of our business depends on streamlined processes made available through our uninhibited access to information systems, global communications, internet activity and other network processes.

Like most companies, despite our current security measures, our information technology systems, and those of our third-party service providers, may be vulnerable to information security breaches, acts of vandalism, computer viruses and interruption or loss of valuable business data. Stored data might be improperly accessed due to a variety of events beyond our control, including, but not limited to, natural disasters, terrorist attacks, telecommunications failures, computer viruses, hackers and other security issues. In addition, a variety of our software systems are cloud-based

data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks. We have technology security initiatives in place to mitigate our risk to these vulnerabilities, but these measures may not be adequately designed or implemented to ensure that our operations are not disrupted or that data security breaches do not occur.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. Any breach of our network may result in damage to our reputation, the loss of valuable business data, the misappropriation of our valuable intellectual property or trade secret information, misappropriation of personal information, key personnel being unable to perform duties or communicate throughout the organization, significant costs for data restoration and other adverse impacts on our business. Ransomware attacks, including those from organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe, and if made against us could lead to significant interruptions in our operations, loss of data and income, reputational loss, diversion of funds, and may also result in fines, litigation and unwanted media attention. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting payments. Despite our existing security procedures and controls, if our network were compromised, it could give rise to unwanted media attention, materially damage our customer relationships, decrease sales and leases of our products, increase overhead costs, harm our business, reputation, results of operations, cash flows and financial condition, result in fines or litigation, and may increase the costs we incur to protect against such information security breaches, such as increased investment in technology, the costs of compliance with consumer protection laws and costs resulting from consumer fraud.

The costs of mitigating cybersecurity risks are significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; and costs related to maintaining redundant networks, data backups and other damage-mitigation measures.

We do not carry cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources.

Failure to comply with data privacy and security laws could have a material adverse effect on our business.

Our business processes health-related and other personal information. When conducting clinical studies, we face risks associated with collecting trial participants' information, especially health information, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of information and in protecting the security of such information. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal information or prevent use of their accounts. Data breaches could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil or criminal liability, or both. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed.

We may be subject to state, federal and foreign laws relating to data privacy and security in the conduct of our business, including state breach notification laws, the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the EU's General Data Protection Regulation 2016/679 and applicable national supplementing laws, or GDPR, and the California Consumer Privacy Act, or CCPA, as amended by the California Privacy Rights Act, or CPRA. The CCPA went into effect on January 1, 2020, and creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the CPRA generally went into effect on January 1, 2023, and significantly amends the CCPA. It 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 also 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. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. This legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources to compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies.

Furthermore, the Federal Trade Commission, or 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. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

The GDPR imposes comprehensive compliance obligations regarding our processing of personal data, including a principle of accountability and the obligation to demonstrate that appropriate legal bases are in place to justify data processing activities. Additionally, we are subject to laws and regulations regarding cross-border transfers of personal data, including laws relating to transfer of personal data outside of the European Economic Area, ("EEA"). On July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from these jurisdictions to relevant self-certified U.S. entities. The CJEU further noted that reliance on the European Commission standard contractual clauses (a potential alternative transfer mechanism to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We currently rely on the standard contractual clauses. If we cannot rely on existing mechanisms for transferring personal data from the EEA, or other jurisdictions, we could be prevented from transferring personal data of individuals in those regions; we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we will have to implement revised standard contractual clauses for existing arrangements within required time frame; and/or it could otherwise adversely affect the manner in which we provide our services and thus materially affect our operations and financial results. Failure to comply with the EU GDPR could result in penalties. Penalties for certain breaches are up to the greater of EUR 20 million or 4% of our global annual turnover. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).

Furthermore, these laws impose substantial requirements that require the expenditure of significant funds and employee time to comply, and additional states and countries are enacting new data privacy and security laws, which will require future expansion of our compliance efforts. We also rely on third parties to host or otherwise process some of this data. In some instances, these third parties have experienced immaterial failures to protect data privacy. There can be no assurances that the privacy and security-related measures and safeguards we have put in place in relation to these third parties will be effective to protect us and/ or the relevant personal data from the risks associated with the third-party processing of such data. Any failure by a third party to prevent security breaches could have adverse consequences for us, result in applicable fines and penalties, damage our reputation, and/ or result in civil claims. We will need to expend additional resources and make significant investments to comply with data privacy and security laws. Our failure to comply with our posted privacy policies or with any federal, state, or international privacy and security laws, regulations, industry standards or other legal obligations relating to data privacy and information security or any failure to prevent security breaches of such data could result in significant liability under applicable laws, cause disruption to our business, harm our reputation, have a material adverse effect on our business, and may result in claims, complaints, liabilities, proceedings or actions against us by governmental entities or others, or may require us to change our operations. Any such claims, complaints, proceedings or actions could force us to incur significant expenses in defense of such proceedings or actions, distract our management, increase our costs of doing business, and result in the imposition of monetary penalties.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis.

Reliable shipping is essential to our operations. We rely on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any of our products, it would be costly to replace such products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to deliver our products (or any other products we commercialize in the future) on a timely basis.

Intangible assets on our books may lead to significant impairment charges.

We carry a significant amount of intangible assets on our balance sheet, partially due to the value of the LENSAR brand name, but also intangible assets associated with our technologies, acquired research and development, currently marketed products, and marketing know-how. As a result, we may incur significant impairment charges if the fair value of the intangible assets would be less than their carrying value on our balance sheet at any point in time.

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets, for impairment. Intangible assets with an indefinite useful life (such as the LENSAR brand name), acquired research projects not ready for use, and acquired development projects not yet ready for use are subject to impairment review. We review other long-lived assets for impairment when there is an indication that an impairment may have occurred.

Our historical financial information may not be a reliable indicator of our future results.

Our historical financial information may not necessarily reflect what our financial position, results of operations or cash flows we will achieve in the future. Accordingly, the historical financial information presented in this Annual Report should not be assumed to be a reliable indicator of what our financial condition or results of operations actually could be in the future. In October 2020, we completed a spin-off of LENSAR, Inc. from PDL BioPharma, Inc., or PDL, and we became an independent public company on October 1, 2020 (the "Spin-Off"). As a result, historical financial information for periods prior to the Spin-Off may not necessarily reflect what our financial position, results of operations or cash flows would have been had we been an independent entity during such period or those that we will achieve in the future. The costs and expenses reflected in our historical financial data prior to the Spin-Off include an allocation for certain corporate functions historically provided by PDL, including shared services and infrastructure provided by PDL to us, such as costs of information technology, accounting, tax and legal services, and other corporate and infrastructure services that may be different from the comparable expenses that we would have incurred had we operated as a stand-alone company. Our historical financial information prior to the Spin-Off does not reflect changes that have occurred or may occur in the future in our cost structure and operations as a result of our transition to becoming a stand-alone public company, including changes in our employee base, potential increased costs associated with reduced economies of scale and increased costs associated with SEC reporting and other requirements. Accordingly, the historical financial information for periods that predate our spin-off from PDL should not be assumed to be indicative of what our financial condition or results of operations actually would have been as an independent, publicly traded company during such periods or to be a reliable indicator of what our financial condition or results of operations actually could be in the future.

We are subject to continuing contingent liabilities of PDL BioPharma, Inc. following the Spin-Off.

There are several significant areas where the liabilities of PDL may become our obligations. For example, under the Internal Revenue Code of 1986, as amended, and the related rules and regulations, each corporation that was a member of the PDL consolidated U.S. federal income tax reporting group during any taxable period or portion of any taxable period ending on or before the effective time of the Spin-Off is jointly and severally liable for the U.S. federal income tax liability of the entire PDL consolidated tax reporting group for that taxable period. In addition, the Tax Matters Agreement with PDL allocates the responsibility for taxes between PDL and us. Pursuant to this allocation, we may be responsible for taxes that we would not have otherwise incurred, or that we would have incurred but in different amounts or at different times, on a standalone basis outside of the PDL consolidated group, and the amount of such

taxes could be significant. However, if PDL is unable to pay any prior period taxes for which it is responsible, we could be required to pay the entire amount of such taxes.

Potential indemnification obligations to PDL pursuant to the Separation and Distribution Agreement could materially and adversely affect us.

In connection with the Spin-Off, the Company and PDL entered into a Separation and Distribution Agreement, dated September 30, 2020 (the "Separation and Distribution Agreement"), which sets forth the agreements between PDL and the Company regarding the principal transactions necessary to separate the Company from PDL and other agreements that govern certain aspects of the relationship with PDL after the completion of the Spin-Off. Among other things, the Separation and Distribution Agreement provides for indemnification obligations designed to make us financially responsible for substantially all of the liabilities that may exist relating to our business activities, whether incurred prior to or after the spin-off. If we are required to indemnify PDL under the circumstances set forth in the Separation and Distribution Agreement, we may be subject to substantial liabilities.

Risks Related to Government Regulation

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

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical studies; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance, certification and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval or certification 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. In addition, the FDA or other regulatory agencies may change their policies, adopt additional regulations, revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. We may be found non-compliant as a result of future changes in. or interpretations of, regulations by the FDA or other regulatory agencies. For example, on February 23, 2022, the FDA issued a proposed rule to amend 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. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business.

The FDA, foreign regulatory authorities and notified bodies enforce their regulatory requirements through, among other means, periodic unannounced inspections and audits. We do not know whether we will be found compliant in connection with any future FDA (or foreign regulatory authorities) inspections or notified bodies' audits. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, certifications or approvals; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a pre-market approval application, or PMA, from the FDA, unless an exemption applies. 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, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. To date, our products have received marketing authorization pursuant to the 510(k) clearance process.

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

In the United States, we have obtained clearance of our LENSAR Laser System and ALLY System through the 510(k) clearance process. Any modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval, prior to 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 to our products 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 ALLY System, which has received clearance from the FDA, enables cataract surgeons to complete the FLACS procedure seamlessly in a single, sterile environment. This clearance is the first stage of a planned, two step commercial release strategy. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. Our ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain

ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. As the second stage of the strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as a predicate device. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, we are unable to submit a 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, we are delivering the ALLY System to surgeons in the initial launch with the phacoemulsification features disabled and/or removed. If the third party is unsuccessful in obtaining clearance on its projected timelines, or at all, we could be delayed in our submission for 510(k) clearance for the phacoemulsification features of our ALLY System, and/or we may be required to find an alternative component from a different third party to replace the component the third party is developing. We may be unable to identify a replacement supplier, and even if we are, the use of a different third party component could require additional data or other activities that could increase our costs or delay our projected timing. If any of these events were to occur, we could be materially delayed in our efforts to seek 510(k) clearance of all features of our ALLY System. Even if the third party obtains clearance for the phacoemulsification device, the FDA has significant discretion in the 510(k) clearance process, and we cannot guarantee that we will obtain clearance of our ALLY System as proposed.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory authority or notified body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance, certification or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval or certification policies or regulations of the FDA or applicable foreign regulatory authority or notified body to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, certification or approval.

In September 2022, we submitted an application for certification of the ALLY System in the EU and we intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Subject to the transitional provisions and in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces the Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation, 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. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final

inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU and these three countries.

In the EU, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the future regulation of medical devices in the United Kingdom. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the MHRA has recently postponed the mandatory deadline until July 2024. Medical devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. Devices certified under the EU Medical Devices Regulation may be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. However, devices certified under the EU Medical Devices Directive may be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, all medical devices will require a UK Conformity Assessed, or UKCA, mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2024. However, UKCA marking will not be recognized in the EU. Following the transitional period, compliance with the UK regulations will be a prerequisite to be able to affix the UKCA mark to medical devices, without which they cannot be sold or marketed in Great Britain.

Following the end of the "Brexit" transitional period, from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became the UK's independent and sovereign regulatory agency for medical devices. Post-Brexit, amendments have been made to the existing UK medical devices legislation which require medical devices to be registered with the MHRA before being placed on the Great Britain market. Manufacturers based outside of the UK need to appoint a UK Responsible Person to register devices with the MHRA before they can be placed on the market lawfully. Following a government consultation on changes to the UK's medical device regulations, the response to which was published on June 26, 2022, it is anticipated that amendments to the legislation will soon be published by the government. The MHRA has recently stated that the new regulations will apply from July, 1 2024, a postponement of twelve months from its original July 1, 2023 deadline. The new regulations will require that medical devices placed on the market in Great Britain (England, Scotland, and Wales) must undergo a UK Conformity Assessment, and display a UKCA mark in order to be placed on the market. However, within the government's consultation response, it has proposed that transition periods will be included in the revised legislation so that products with existing and valid conformity assessments (CE mark or UKCA mark) could continue to be placed on the Great Britain market for a maximum of 3-5 years after the regulations become mandatory, depending on which legislation the medical device has been certified under. However, UKCA marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the Great Britain and will continue to be governed according to EU requirements. These modifications may have an effect on the way we intend to conduct our business in these countries.

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 are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory approval, certification or clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities or notified bodies, which may include any of the following sanctions:

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

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

In addition, the FDA and foreign regulatory authorities may change their clearance or certification policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance, certification or approval of our future products under development or impact our ability to modify our currently cleared or certified products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances, certifications or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products. For more information, see "—Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, certifications or approvals for our products or to manufacture, market or distribute our products after clearance, certification or approval is obtained."

Our products must be manufactured in accordance with federal, state and foreign regulations, and we or any of our suppliers could be forced to recall products 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.

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. In addition, failure to comply with applicable FDA (or other regulatory authorities) requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's (or foreign regulatory authorities' or notified bodies') refusal to grant pending or future clearances, certifications or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us 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.

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

Our LENSAR Laser System and ALLY System are ophthalmic surgical lasers indicated for the creation of anterior capsulotomies, use in patients undergoing surgery requiring laser-assisted fragmentation of the cataractous lens, and for creating cuts/incisions in the cornea. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those approved by the FDA or a foreign regulatory authority or certified by a notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory authority determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

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

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA (or similar foreign authorities), 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 (or similar foreign authorities) 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 (or similar foreign authorities) could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, certification or approval, seizure of our products or delay in clearance, certification or approval of future products.

The FDA and foreign regulatory authorities 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 (or foreign regulatory authorities) may require, or we may decide, that we will need to obtain new clearances, certifications or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, certifications 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 warning letters from the FDA (or foreign regulatory authorities), 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 (or similar foreign authorities). We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA (or similar foreign authorities). If the FDA (or similar foreign authorities) disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If we do not obtain and maintain international regulatory registrations, clearances, certifications or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance, certification or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances, certifications or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances, certifications or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances, certifications or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances, certifications or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory clearances, certifications or approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations (approvals or certifications) that we have received. If we are unable to maintain our authorizations or certifications in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance, certification or approval by regulatory authorities or notified bodies in other countries, and registration, clearance, certification or approval by one

or more foreign regulatory authorities or notified bodies does not ensure registration, clearance, certification or approval by regulatory authorities or notified bodies in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance, certification or approval in one country may have a negative effect on the regulatory process in others.

The clinical trial process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. We intend to conduct additional clinical trials and to generate clinical data that will help us demonstrate the benefits of our system compared to manual cataract surgery conducted without a laser system, or with competing laser systems.

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 or notified bodies may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of 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 ("IDE") application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials, and similar risks may apply in foreign jurisdictions;

- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;

- regulators, Institutional Review Boards, or IRBs, 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 or notified bodies 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 (or other reviewing bodies), regulatory authorities, or both, for re-examination;

- regulators, IRBs, other reviewing bodies, 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 or certification policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for certification or 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, any further disruptions related to the COVID-19 pandemic or similar health crises may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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 or certification of our product candidates.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. 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 efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

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, or other reviewing bodies, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under cGMP, requirements and other regulations. Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards

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

Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require clearance, certification or approval by regulatory authorities or notified bodies in those countries. Clearance, certification or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. 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. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

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

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes

in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

In addition, the regulatory landscape related to medical devices in the EU recently evolved. On May 26, 2021, the EU Medical Devices Regulation became applicable, and repealed and replaced the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The modifications brought by this new Regulation may have an effect on the way we intend to develop our business in the EU and EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed, which could adversely affect our ability to grow our business in a timely manner.

Disruptions at the FDA and other government agencies and notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA, foreign regulatory agencies and notified bodies to review and clear, certify or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's, foreign regulatory agencies' and notified bodies' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's, foreign regulatory agencies' and notified bodies' ability to perform routine functions. Average review times at the FDA, foreign regulatory agencies and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, foreign regulatory agencies and notified bodies may also slow the time necessary for new medical devices or modifications to cleared, certified or approved medical devices to be reviewed and cleared, certified or approved by necessary government agencies (or other notified bodies), 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.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, or other regulatory authorities or notified bodies, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. Several notified bodies have been designated under the EU Medical Devices Regulation. However, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation as a consequence of which review times may have lengthened. This situation may impact the way we are conducting our business in the EU and the EEA and the ability of our notified body to timely review and process our regulatory submissions and perform its audits.

Enacted and future healthcare legislation may increase the difficulty and cost for us to commercialize our ALLY Adaptive Cataract Treatment System or other products we may develop in the future and may affect the prices we may set.

In the United States, the EU and other jurisdictions, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States medical device industry.

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

Moreover, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures and could seriously harm our business.

For EU states, in December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment ("HTA"), amending Directive 2011/24/EU, was adopted. This regulation, which became effective in January 2022 and will become applicable from January 12, 2025 onwards, intends to boost cooperation among EU member states in assessing health technologies, including some medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, we may not be able to achieve or sustain profitability or successfully market our ALLY System or any other products we may develop and obtain clearance for in the future.

We may be subject to certain federal, state and foreign laws pertaining to healthcare fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

Although none of the procedures using our products are currently covered by any state, federal or foreign government healthcare programs or other third-party payors, applicable agencies and regulators may interpret that our commercial,

research and other financial relationships with healthcare providers and institutions are nonetheless subject to various federal, state and foreign laws intended to prevent healthcare fraud and abuse, including the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts and free or reduced price items and services. 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 federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers. The federal False Claims Act has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed or for services that are not medically necessary. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The federal False Claims Act also includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, also created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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;

- the Physician Payments Sunshine Act and its implementing regulations, which require 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 government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, which apply to items and services reimbursed by any third-party payor, including private insurers and self-pay patients; state laws that require device manufacturers to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- EU and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to anti-corruption, anti-bribery and similar laws and any violations by us of such laws could result in fines or other penalties.

A majority of our revenue is derived from operations outside of the United States and is subject to requirements under the U.S. Treasury Department's Office of Foreign Assets Control, anti-corruption, anti-bribery and similar laws, such as the Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, and other anti-corruption, anti-bribery and anti-money laundering laws in countries in which we conduct activities. The FCPA prohibits, among other things, improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Recently, the U.S. Department of Justice has increased its enforcement activities with respect to the FCPA.

Our safeguards to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective. Any violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, and would likely harm our reputation, business, financial condition and result of operations.

Our employees, independent contractors, principal investigators, consultants, vendors, distributors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and contractor research organizations, or CROs, may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, misconduct by these parties could include among other infractions or violations intentional, reckless or negligent conduct or unauthorized activity that violates: (i) FDA (and foreign regulatory authorities') regulations, including those laws that require the reporting of true, complete and accurate information to the FDA (or foreign regulatory authorities); (ii) manufacturing standards; (iii) federal, state and foreign healthcare fraud and abuse laws and regulations; (iv) laws that require the true, complete and accurate reporting of financial information or data; or (v) other commercial or regulatory laws or requirements. Specifically, 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. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Intellectual Property Matters

Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our products, brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights.

We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

In addition, our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, our trade secrets, data and know-how may not prevent unauthorized use, misappropriation, or disclosure to unauthorized parties, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. We may not be successful in protecting our proprietary rights, and unauthorized parties may be able to obtain and use information that we regard as proprietary.

We own numerous issued patents and pending patent applications. As of December 31, 2022, we owned approximately 50 U.S. patents, 34 pending U.S. patent applications, 123 issued foreign patents, and 80 pending foreign and Patent Cooperation Treaty applications. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent, or denial or the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to commercialize our products.

Competitors could purchase our products and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. Further, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, including the protection of surgical and medical methods, and we may encounter significant problems in protecting our proprietary rights in these countries.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us,

including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval or certification to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

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 on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Even if a lapse is cured, reviving the patent or application, there is a risk that the revival can be challenged by third parties in proceeding and litigation, and that the revival can be overruled. Non-compliance events that could result in abandonment or lapse of a patent or patent application include

failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

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

Future changes to existing patent law could lead to uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, U.S. and foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. In several recent patent cases, the U.S. Supreme Court has narrowed the scope of patent protection available or weakened the rights of patent owners in certain situations. We cannot predict future changes in the interpretation of patent laws and regulations or changes to patent laws and regulations that might be enacted into law by U.S. and foreign legislative bodies and patent offices. Those changes may materially affect our ability to obtain additional patent protection in the future, the value of our patents, and our ability to enforce our patents.

If we cannot license and maintain rights to use third-party technology on reasonable terms, we may not be able to successfully commercialize our products. Our licensed or acquired technology may lose value or utility or over time.

In the past, we have licensed technology from third parties and may choose or need to do so in the future, including to develop or commercialize new products or services. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product, and we may not be able to obtain necessary licenses to such patents or patent applications. If we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable, our business may suffer. In addition, any technology licensed or acquired by us may lose value or utility, including as a result of a change of in the industry, in our business objectives, others' technology, our dispute with the licensor, and other circumstances outside our control. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products or services. If we are unable to negotiate reasonable royalties or if we have to pay royalties on technology that becomes less useful for us or ceases to provide value to us, our profit margin will be reduced and we may suffer losses.

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell or export our products or to use our technologies or product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Because of the confidential nature of patent applications, we do not know at any given time what patent applications are pending that may later issue as a patent and be asserted by a third party against us. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel, or was invalid or unenforceable for other reasons. In litigation or administrative proceedings, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents or have the scope of those rights narrowed.

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

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our intellectual property to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products or technologies that contain the allegedly infringing intellectual property, which could be costly and disruptive, and may be infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit and even those where we prevail, 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. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including third-party lost profits, the disgorgement of our profits, or substantial royalties (all of which may be increased, including three times the awarded damages, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets) and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area are often settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement. We could encounter delays in product introductions while we attempt to develop alternative methods or products, and these alternative methods or products may be less competitive, which could adversely affect our competitive business position. If we fail to obtain any required licenses or make any necessary changes to our

products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. However, third parties may assert infringement 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.

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

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property 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. Furthermore, even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages 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 proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

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

In addition to patent protection, we also rely on protection of trade secrets, know-how and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event 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 assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. The protections we place on our intellectual property or other proprietary rights may not be sufficient. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require

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

Further, it is possible that others will independently develop the same or similar technology or products or otherwise work around our patented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology or products similar to ours or competing technologies or products, our competitive market position could be materially and adversely affected.

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

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

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

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

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

opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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.

Many of our employees and consultants were previously employed at or engaged by other medical device or other biotechnology 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. Our efforts 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 may not be successful, and we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as:

- they may not perform to our standards or legal requirements;
- they may not produce reliable results;
- they may not perform in a timely manner;
- they may not maintain confidentiality of our proprietary information;
- disputes may arise with respect to ownership of rights to technology developed with our partners, and those dispute may be resolved against us; and
- disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration.

Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business.

We are jointly developing certain technologies with Oertli Instrumente AG, or Oertli, and our agreements with Oertli may restrict our freedom to practice and may not protect us against potential competition with respect to jointly-developed intellectual property.

We have entered into development and supply agreements with Oertli pursuant to which we are collaborating on the development and supply of the phacoemulsification component in our ALLY System. Under these agreements, intellectual property invented individually by either party is owned exclusively by such party and intellectual property jointly developed by us and Oertli will be jointly and severally owned by us and Oertli, and by the terms of our agreements, we and Oertli are entitled to practice such jointly owned intellectual property in our respective sole discretion. Our agreements with Oertli do not restrict how individually or jointly developed intellectual property may be used, exploited, or enforced. With respect to jointly developed intellectual property, both parties will be subject to default rules under the laws of various countries pertaining to joint ownership. Some countries require the consent of all joint owners to exploit, license or assign jointly owned patents, and if either party is unable to obtain that consent from the other party, the party requesting consent may be unable to exploit the invention or to license or assign its rights under these patents and patent applications in those countries. Additionally, in the United States, the other party may be required to be joined as a party to any claim or action a party may wish to bring to enforce these patent rights, which may limit its ability to pursue third party infringement claims. In some countries, Oertli will have a right to develop and commercialize products and technology invented during the course of our agreements, and to license to third parties the right to do so. This may lead to the development and commercialization of products and technology by others that are based on technology similar to our ALLY System, which may impair our competitive position in the marketplace and have an adverse impact on our business. If we cannot obtain distribution rights for such jointly-owned intellectual property or Oertli-owned intellectual property, our future product development and commercialization plans and competitive position in our industry may be adversely affected, which may have a material adverse impact on our business, financial condition and results of operation.

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

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

Risks Related to Owning Our Common Stock

The large number of shares eligible for public sale could depress the market price of our common stock.

Members of our management and our board of directors hold a significant portion of our common stock and may sell their shares of our common stock to the extent not restricted by contract or under securities laws. We have filed a registration statement registering shares that we may issue under our equity compensation plan and employee stock

purchase plan, and may file additional registration statements relating to shares or awards held by our management and board of directors in the future. The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, and the perception that these sales could occur may also depress the market price of our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

We also may issue our shares of common stock from time to time as consideration for future acquisitions and investments. If any such acquisition or investment is significant, the number of shares that we may issue may in turn be significant. In addition, we may also grant registration rights covering those shares in connection with any such acquisitions and investments.

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

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (1) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (2) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (3) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (4) we will not be required to hold non-binding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

In addition, we are eligible to delay the adoption of new or revised accounting standards applicable to public companies until those standards apply to private companies, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of this election, our financial statements may not be comparable to the financial statements of other public companies.

We also currently intend to take advantage of the reduced disclosure requirements regarding executive compensation. We are also entitled to take advantage of other exemptions, including the exemptions from the advisory vote requirements and executive compensation disclosures under the Dodd-Frank Wall Street Reform and Customer Protection Act, and the exemption from the provisions of Section 404(b) of the Sarbanes-Oxley Act. We may remain an "emerging growth company" until as late as December 31, 2025 (the fiscal year-end following the fifth anniversary of the completion of the spin-off), though we may cease to be an "emerging growth company" earlier under certain circumstances, including (1) if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30, in which case we would cease to be an "emerging growth company" as of December 31, (2) if our gross revenue exceeds $1.235 billion in any fiscal year or (3) if we issue more than $1.0 billion in nonconvertible notes in any three-year period.

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

If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock.

While we have no specific plan to issue preferred stock, our amended and restated certificate of incorporation authorizes us to issue, without the approval of our stockholders, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate paying cash dividends in the foreseeable future. As a result, only appreciation of the price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

Certain provisions in our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment and, therefore, may depress the trading price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors, including, among other things:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the ability of our board of directors to determine to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- limitations on the removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairperson of our board of directors, the chief executive officer, the president (in absence of a chief executive officer) or our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors is required to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- the ability of our board of directors, by majority vote, to amend the amended and restated bylaws, which may allow our board of directors to take additional actions to prevent a hostile acquisition and inhibit the ability of an acquirer from amending the amended and restated bylaws to facilitate a hostile acquisition; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions may not be successful in protecting our stockholders from coercive or harmful takeover tactics by requiring potential acquirers to negotiate with our board of directors and by providing our board of directors with adequate time to assess any acquisition proposal. These provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a transaction involving a change in control that is in the best interest of our stockholders. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed as discouraging future takeover attempts.

We are also subject to certain anti-takeover provisions under the Delaware General Corporation Law, or DGCL. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, our board of directors has approved the transaction.

Our amended and restated certificate of incorporation designates certain courts as the sole and exclusive forums for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. Additionally, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Our amended and restated certificate of incorporation further provides that any person or entity purchasing or acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. This forum selection provision in our amended and restated certificate of incorporation may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. This exclusive forum provision will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

An active, liquid and orderly market for our common stock may not develop or be sustained, and the trading price of our common stock is likely to be volatile.

An active trading market for our common stock may not develop or be sustained, which could depress the market price of our common stock and could affect your ability to sell your shares. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section of this Annual Report, these factors include:

- a shift in our investor base;
- actual or anticipated fluctuations in our quarterly financial condition and operating performance;
- the operating and stock price performance of similar companies;
- introduction of new products by us or our competitors;
- success or failure of our business strategy;

- our ability to obtain financing as needed;
- changes in accounting standards, policies, guidance, interpretations or principles;
- the overall performance of the equity markets;
- the number of shares of our common stock publicly owned and available for trading;
- threatened or actual litigation or governmental investigations;
- changes in laws or regulations affecting our business, including tax legislation;
- announcements by us or our competitors of significant acquisitions or dispositions;
- any major change in our board of directors or management;
- changes in earnings estimates by securities analysts or our ability to meet earnings guidance;
- publication of research reports about us or our industry or changes in recommendations or withdrawal of research coverage by securities analysts;
- large volumes of sales of our shares of common stock by existing stockholders;
- short sales of our common stock;
- investor perception of us and our industry; and
- changes in financial markets or general economic conditions, including the effects of recession or slow economic growth in the U.S. and abroad, interest rates, fuel prices, international currency fluctuations, corruption, political instability, acts of war, including the ongoing war between Russia and Ukraine, acts of terrorism, and the ongoing COVID-19 pandemic or other public health crises.

In addition, the stock market in general, and the market for medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. This could limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources, and could have a material adverse effect on our business, financial condition and results of operations.

General Risk Factors

We are obligated to develop and maintain proper and effective internal control over financial reporting and will be subject to other requirements that will be burdensome and costly.

As a public company, we are required to file with the SEC annual, quarterly and current reports that are specified in Section 13 of the Exchange Act. We are required to prepare financial statements that are fully compliant with all SEC reporting requirements on a timely basis. In addition, we are subject to other reporting and corporate governance requirements, including the requirements of the Nasdaq Stock Market, or Nasdaq, and certain provisions of the Sarbanes-Oxley Act and the regulations promulgated thereunder, which impose significant compliance obligations upon us.

We expect to continue to devote significant resources and time to comply with the internal control over financial reporting requirements of the Sarbanes-Oxley Act, including costs associated with auditing and legal fees and accounting and administrative staff. In addition, Section 404(a) under the Sarbanes-Oxley Act requires that we assess the effectiveness of our controls over financial reporting. Our future compliance with the annual internal control report

requirement will depend on the effectiveness of our financial reporting and data systems and controls across our operating subsidiaries. We cannot be certain that these measures will ensure that we design, implement and maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation or operation, could harm our operating results, cause us to fail to meet our financial reporting obligations, or cause us to suffer adverse regulatory consequences or violate applicable stock exchange listing rules. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock and our access to capital.

For as long as we are an "emerging growth company" under the JOBS Act, we will not be required to comply with Section 404(b) of the Sarbanes-Oxley Act, which would require our independent auditors to issue an opinion on their audit of our internal control over financial reporting, until the later of the year following our first annual report required to be filed with the SEC and the date we are no longer an "emerging growth company." If, once we are no longer an "emerging growth company," our independent registered public accounting firm cannot provide an unqualified attestation report on the effectiveness of our internal control over financial reporting, investor confidence and, in turn, the market price of our common stock, could decline.

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

We are subject to the periodic reporting requirements of the Exchange Act. The design of our disclosure controls and procedures can only 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.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us were to downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts were to cease coverage of us or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Increasing scrutiny and stakeholder expectations regarding environmental, social, and governance matters may cause us to incur expenses and liabilities or otherwise adversely impact our business, financial condition, or operations.

Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their environmental, social, and governance ("ESG") practices. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), changes in demand for certain offerings, enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations.

While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) or commitments to improve the ESG profile of our Company and/or offerings, such initiatives or achievements of such commitments may be costly and may not have the desired effect. For example, certain statements in our voluntary disclosures may be based on assumptions, estimates, hypothetical expectations, or third-party information. Additionally, expectations around the Company's management of ESG matters continues to evolve rapidly, in many instances due to factors that are out of our control. In addition, we may commit to certain initiatives or goals and we may not ultimately be able to achieve such commitments or goals due to factors that are within or outside of our

control. Moreover, actions or statements that we may take based on based on expectations, assumptions, or third-party information that we currently believe to be reasonable may subsequently be determined to be erroneous or be subject to misinterpretation. Even if this is not the case, our current actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG initiatives and disclosures, even if such initiatives are currently voluntary.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently occupy approximately 35,000 square feet of office and manufacturing space at our corporate headquarters in Orlando, Florida under a lease that expires in November 2027, with a renewal of an additional five years at our option. We plan to expand our manufacturing and office space to accommodate our expected growth associated with the potential launch and manufacture of our ALLY System, subject to FDA clearance.

Item 3. Legal Proceedings.

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not party to any material legal proceedings.

Item 4. Mine Safety Disclosure.

Not applicable.

Part II

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

Market Information

Our common stock is traded on The Nasdaq Stock Market under the symbol "LNSR."

Stockholders

As of January 31, 2023, there were approximately 113 holders of record of our common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers, financial institutions and other nominees.

Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

None.

Dividend Policy

We currently do not anticipate paying any cash dividends in the foreseeable future. Instead, we anticipate that all of our earnings will be used to provide working capital, to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. In addition, if we were to enter into a credit facility in the future, we anticipate that the terms of such facility could limit or prohibit our ability to pay dividends.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

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 should be read in conjunction with our financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Please see the "Risk Factors Summary" and "Risk Factors" sections for a discussion of the uncertainties, risks and assumptions associated with these statements. A discussion of the year ended December 31, 2021 compared to the year ended December 31, 2020 has been reported previously in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 3, 2022, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

We are a commercial-stage medical device company focused on designing, developing and marketing an advanced femtosecond laser system for the treatment of cataracts and the management of pre-existing or surgically induced corneal astigmatism. Our systems incorporate a range of proprietary technologies designed to assist the surgeon in obtaining better visual outcomes, efficiency and reproducibility by providing advanced imaging, simplified procedure planning, efficient design and precision. We believe the cumulative effect of these technologies results in a laser system that can be quickly and efficiently integrated into a surgeon's existing practice, is easy to use and provides surgeons the ability to deliver improved visual outcomes.

Our current product portfolio includes the LENSAR Laser System with Streamline IV and IntelliAxis (both our first generation and ALLY® Adaptive Cataract Treatment System, or ALLY System) and its associated consumable components. The consumable portion of the system consists of a disposable patient interface device kit, or PID kit, and the system also requires a procedure license. Each procedure on each system requires the use of a PID kit. The PID kit includes a suction ring, vacuum filter and fluidic connection that are designed to facilitate placement of the laser while minimizing a patient's discomfort, intraocular pressure and trauma to the retina and maintaining corneal integrity. The procedure license is downloaded onto the system as required or as purchased by the customer. The system will not perform a procedure without a valid license. We sell licenses individually and also offer licenses in a subscription package with minimum monthly obligations and the ability to increase procedure numbers as the practice grows to address occasional increases in demand. We believe this structure allows the surgeon to implement a budget while also providing us with a predictable revenue stream.

We are focused on continuous innovation and have launched our proprietary next generation ALLY System. The ALLY System, which has received clearance from the U.S. Food and Drug Administration, or FDA, enables cataract surgeons to complete the femtosecond-laser-assisted cataract surgery, or FLACS, procedure seamlessly in a single, sterile environment. Our ALLY System received clearance from the FDA in June 2022, and we executed a controlled and targeted initial launch of the ALLY System beginning in August 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023, and we intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. The FDA clearance is the first stage of a planned, two step commercial release strategy. As the second stage of the strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as a predicate device. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, we are unable to submit a 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, we are delivering the ALLY System to surgeons in the initial launch with the phacoemulsification features disabled and/or removed. In 2022, we transitioned from manufacturing and selling our LENSAR Laser System to focus on our ALLY System. In September 2022, we submitted the ALLY System for certification in the European Union, or EU, and we intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory

clearance in other regions outside the United States and the timing of these clearances or certifications, among other factors. In addition, based on inventory of our LENSAR Laser System, our future revenue and cash flows will depend on, among other factors, our installed base of systems and the timing of and applicable clearances for our ALLY System.

We have built and are continuing to grow our commercial organization, which includes a direct sales force in the United States and distributors in Germany, China, South Korea and other targeted international markets. We believe there is significant opportunity for us to expand our presence in these countries and other markets and regions. In the United States, we sell our products through a direct sales organization that, as of December 31, 2022, consisted of approximately 45 commercial professionals, including regional sales managers, clinical applications and outcomes specialists, field service, marketing, technical and customer support personnel. We manufacture our systems at a facility in Orlando, Florida. We purchase custom and off-the-shelf components from a number of suppliers, including some single-source suppliers. We purchase the majority of our components and major assemblies through purchase orders with limited long-term supply agreements and generally do not maintain large volumes of finished goods. We strive to maintain enough inventory of our various component parts to avoid the impact of potential disruptions in the supply chain; however, availability of these components can be outside of our control, especially with the impact of the global supply chain disruptions with respect to certain products, including increasing lead times required for the ordering of component parts to meet targeted production goals, unpredictability with respect to suppliers' ability to fulfill orders in the requested quantities within the agreed timeframe, and the ability to find alternative component parts.

Our revenue increased from $34.5 million for the year ended December 31, 2021 to $35.4 million for the year ended December 31, 2022, representing an increase of 2.6%. Our net losses were $19.6 million and $19.9 million for the years ended December 31, 2021 and 2022, respectively. Our total installed base of LENSAR Laser Systems and ALLY Systems was approximately 270 as of December 31, 2022.

Factors to Consider

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to medical device companies, including risks inherent in:

- our laser system development and commercialization efforts;
- clinical studies;
- uncertainty of regulatory actions and marketing approvals or certifications;
- reliance on a network of international distributors and a network of suppliers;
- levels of coverage and reimbursement by government or other third-party payors for procedures using our products;
- patients' willingness and ability to pay for procedures with significant costs not covered by or reimbursable through government or other third-party payors;
- enforcement of patent and proprietary rights;
- the need for future capital;
- the ongoing impact of the COVID-19 pandemic and all safety requirements and suggestions regarding patient treatment as required or suggested by health care authorities;
- clearance or certification by regulatory agencies, including the FDA, or notified bodies for our ALLY System;
- supply chain shortages, labor market shifts and price increases resulting from various macroeconomic factors, including related to the ongoing COVID-19 pandemic; and
- competition associated with our products.

We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements.

Our revenues and operating expenses are also difficult to predict and depend on several factors, including the level of ongoing research and development requirements necessary to complete development and obtain further regulatory clearance or certification of our ALLY System, the number of laser systems we manufacture, sell, and lease on an annual basis, the availability of capital and direction from regulatory agencies or notified bodies, which are difficult to predict. We may be able to control the timing and level of research and development and selling, general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and payments.

Although procedure volume in 2021 and 2022 returned to levels consistent with those seen prior to the start of the COVID-19 pandemic in 2020, global supply chain disruptions that originated during the COVID-19 pandemic and other macroeconomic factors continue to influence our operations, particularly as it relates to building inventory for the ALLY System. We have experienced some supply chain disruptions and unavailability of various component parts needed for our systems, including increasing lead times required for the ordering of component parts to meet targeted production goals and unpredictability with respect to our suppliers' ability to fulfill orders in the requested quantities, within the agreed timeframe, as well as an increase of costs associated with certain raw materials and component parts. To date, we have maintained sufficient inventory to mitigate significant adverse impact from such disruptions and unavailability in the near-term and to meet the expected needs of our initial launch of the ALLY System; however, we are continuing to monitor developments with respect to the outbreak and its potential impact on our operations and to our employees, distributors, partners, suppliers, and regulators. The lingering impacts of COVID-19 into early 2023, along with global economic uncertainty, have impeded global supply chains, resulted in longer lead times and delays in procuring component parts and raw materials, and resulted in inflationary cost increases in certain raw materials, labor and transportation. In particular, a global semiconductor supply shortage has had, and is continuing to have, wide-ranging effects across multiple industries. We have seen significant disruptions in the supply of, timing of delivery of and fluctuations in pricing for various component parts needed for our products, including the integrated circuits used in our systems, and expect these trends to continue. While we are not directly exposed to economic conditions in Russia or Ukraine, the ongoing war between Russia and Ukraine has also had a substantial impact on global supply chains and may be a contributing factor to the supply chain shortages we are experiencing. Supply chain disruptions and broad-based inflationary impacts have negatively impacted the Company's financial condition, results of operations and cash flows since 2020 and these supply chain constraints may result in future impacts to our business. We expect these inflationary impacts to continue for the foreseeable future. A high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenues if our selling prices of our products do not increase as much or more than our increase in costs.

As a result of these and other factors, our historical results are not necessarily indicative of future performance, and any interim results we present are not indicative of the results that may be expected for the full fiscal year.

Components of Our Results of Operations

Revenue

Total revenue comprises product revenue, service revenue and lease revenue. We derive product revenue from the sale of our laser systems and sales of our PIDs and procedure licenses to our surgeon customers and to our distributors outside the United States. A PID and procedure license, which may also be referred to as an application license, is required to perform each procedure using our laser system. A procedure license represents a one-time right to utilize the system surgical application in connection with a surgery procedure. Service revenue is derived from the sale of extended warranties for our laser systems that provide additional maintenance and service beyond our standard limited warranty. In some situations, we lease our laser systems to surgeons, primarily through non-cancellable leases with a fixed lease payment. We consider all components of our revenue to be recurring source revenue, with the exception of sales of our systems. For the years ended December 31, 2022 and 2021, approximately 86% of our revenue was attributable to recurring sources.

Cost of Revenue

Total cost of revenue comprises cost of product revenue, cost of lease revenue and cost of service revenue.

Cost of product revenue primarily consists of the raw materials used in the manufacture of our products, plant overhead, personnel costs, such as salaries and wages, including stock-based compensation and benefits, packaging costs, depreciation expense, freight and other related costs, which include shipping, inspection and excess and obsolete inventory charges. Cost of service revenue primarily consists of costs associated with providing maintenance services under our standard limited warranty as well as extended warranty contracts. Cost of lease revenue primarily consists of depreciation expense associated with leased equipment and shipping costs associated with delivery of these systems.

Selling, General and Administrative Expense

Our selling, general and administrative expenses consist primarily of personnel costs, such as salaries and wages, including stock-based compensation and benefits, professional fees, marketing, insurance, travel and other expenses.

We are continuing to grow our sales efforts in the United States. We expect our selling, general and administrative expenses to continue to increase in association with our planned growth. Additionally, we anticipate additional increases in selling, general and administrative expenses as we commercialize the ALLY System and make it more broadly available.

Research and Development Expense

Our research and development expenses consist primarily of engineering, product development, clinical studies to develop and support our products, personnel costs, such as salaries and wages, including stock-based compensation and benefits, regulatory expenses, and other costs associated with products and technologies that are in development. Currently, our research and development expense primarily consists of costs associated with the continued development of our next generation system, the ALLY System, which combines all of the features from our LENSAR Laser System with a dual-pulse laser, integrated in a small, compact cataract treatment system that is designed to allow surgeons to perform a sterile femtosecond laser assisted cataract procedure in a single operating room or in-office surgical suite. Further development of the ALLY System is designed to combine our existing femtosecond laser technology with an option to add a phacoemulsification system into an integrated cataract treatment system. The Company recognized pre-launch inventory costs as research and development expenses through April 30, 2022, when future commercialization of our ALLY System was considered probable and the future economic benefit was expected to be realized.

Amortization of Intangible Assets

Intangible assets with finite useful lives consist primarily of acquired trademarks, acquired technology, and customer relationships. Acquired trademarks and acquired technology are amortized on a straight-line basis over their estimated useful lives of 15 to 20 years. Customer relationships are amortized on a straight-line basis or a double declining basis over their estimated useful lives up to 20 years, based on the method that better represents the economic benefits to be obtained.

Income Taxes

Changes in our tax rates or exposure to additional tax liabilities could adversely affect our earnings and financial condition. Beginning in 2022, the Tax Cuts and Jobs Act eliminated the option of expensing all research and development expenditures in the current year, instead requiring amortization over five years for expenditures in the United States and over fifteen years for foreign-based expenditures, pursuant to Internal Revenue Code of 1986, Section 174, or Section 174. In the future, Congress may consider legislation that would eliminate the capitalization and amortization requirement. There is no assurance that the requirement will be deferred, repealed or otherwise modified. The impact of Section 174 on the Company's cash from operations depends primarily on the amount of research and development expenditures incurred and whether the Internal Revenue Service issues guidance on the provision which differs from our current interpretation.

Seasonality

We have historically experienced seasonal variations in the sales and leases of our products, with our fourth quarter typically being the strongest and the first or third quarter being the slowest. We believe these seasonal variations are consistent across our industry.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

(Dollars in thousands)	2022	2021	Change from Prior Year %
Revenue:			
Product	$ 25,959	$ 26,246	(1.1)%
Lease	5,915	4,966	19.1%
Service	3,484	3,247	7.3%
Total revenue	$ 35,358	$ 34,459	2.6%
Cost of revenue (excluding intangible amortization):			
Product	$ 8,910	$ 11,845	(24.8)%
Lease	1,941	1,375	41.2%
Service	4,552	3,406	33.6%
Total cost of revenue	$ 15,403	$ 16,626	(7.4)%

Revenue

Total revenue for the year ended December 31, 2022 was $35.4 million, an increase of 2.6% when compared to total revenue of $34.5 million for the year ended December 31, 2021.

Product revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 decreased by $0.3 million, or 1.1%. The decrease was primarily attributable to a lower average selling price per procedure offset by increased procedure volume, which amounted to a $0.2 million decrease, during the year ended December 31, 2022.

The following table provides information about procedure volume:

	2022	2021	2020
Q1	38,901	28,122	23,225
Q2	33,359	30,966	18,265
Q3	28,453	30,765	25,078
Q4	31,400	41,642	30,503
Total procedure volume	132,113	131,495	97,071

Service revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 increased by $0.2 million.

Geographically, the United States represented 64% of product and service revenues for the years ended December 31, 2022 and 2021.

Lease revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 increased by $0.9 million, or 19.1%, primarily due to increased leased systems.

Cost of Revenue

Total cost of revenue for the year ended December 31, 2022 was $15.4 million, a decrease of 7.4% when compared to total cost of revenue of $16.6 million for the year ended December 31, 2021.

Cost of product revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 decreased by $2.9 million or 24.8%. The decrease was primarily attributable to the number of system sales, which have a lower gross margin than procedure licenses.

Cost of service revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 increased by $1.1 million or 33.6%. This increase was primarily attributable to an increase in service volume due to an increase in installed LENSAR Laser Systems and ALLY Systems.

Cost of lease revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 increased by $0.6 million, or 41.2%, primarily due to an increase in the number of newly leased systems between the years, which have a higher depreciation cost than older and some fully depreciated leased systems.

Operating Expenses

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2022 were $27.2 million, an increase of $3.3 million, or 13.7%, compared to $23.9 million for the year ended December 31, 2021. The increase was due to increases in sales and marketing expenses of $1.3 million, which was primarily the result of increased trade show and commercial activity related to the promotion of the ALLY System, and professional fees of $1.5 million. We expect selling, general and administrative expenses to continue to increase from current levels to support the commercialization of the ALLY System.

Research and Development. Research and development expenses were $11.8 million for the year ended December 31, 2022, a decrease of $0.5 million, or 4.4%, compared to $12.4 million for the year ended December 31, 2021. Research and development expenses in the year ended December 31, 2022 decreased from 2021 associated with the 510(k) submission to the FDA and subsequent U.S. FDA clearance of the ALLY System in June 2022. Inventory costs for the manufacture of ALLY Systems of $3.4 million and $3.7 million were included in research and development expense for the years ended December 31, 2022 and 2021, respectively.

Amortization of Intangible Assets. Amortization of intangible assets was approximately $1.1 million for the year ended December 31, 2022, which was consistent with the year ended December 31, 2021.

Non-GAAP Financial Measures

We prepare and analyze operating and financial data and non-GAAP measures to assess the performance of our business, make strategic and offering decisions and build our financial projections. The key non-GAAP measures we use, EBITDA and Adjusted EBITDA, are reconciled to net loss below for the years ended December 31, 2022 and 2021.

	Year Ended December 31,	
(Dollars in thousands)	**2022**	**2021**
Net loss	$ (19,914)	$ (19,601)
Less: Interest income	(263)	(51)
Add: Depreciation expense	2,258	1,524
Add: Amortization expense	1,148	1,240
EBITDA	(16,771)	(16,888)
Add: Stock-based compensation expense	6,611	6,866
Adjusted EBITDA	$ (10,160)	$ (10,022)

EBITDA is defined as net loss before interest expense, interest income, income tax expense, depreciation and amortization expenses. EBITDA is a non-GAAP financial measure. EBITDA is included in this filing because we believe that EBITDA provides meaningful supplemental information for investors regarding the performance of our business and facilitates a meaningful evaluation of actual results on a comparable basis with historical results. Adjusted EBITDA is also a non-GAAP financial measure. We believe Adjusted EBITDA, which excludes stock-based compensation expense, provides meaningful supplemental information for investors when evaluating our results and comparing us to peer companies as stock-based compensation expense is a significant non-cash charge due to the recapitalization of the Company. We use these non-GAAP financial measures in order to have comparable financial

results to analyze changes in our underlying business from quarter to quarter. However, there are a number of limitations related to the use of non-GAAP measures and their nearest GAAP equivalents. For example, other companies may calculate non-GAAP measures differently, or may use other measures to calculate their financial performance and, therefore, any non-GAAP measures we use may not be directly comparable to similarly titled measures of other companies. Investors should not consider our non-GAAP financial measures in isolation or as a substitute for an analysis of our results as reported under GAAP.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2022 and 2021, we had net losses of $19.9 million and $19.6 million, respectively, and, as of December 31, 2022, we had an accumulated deficit of $97.5 million. We expect to continue to incur losses and operating cash outflows for the near-term future as we continue to build our commercial and clinical infrastructure and pursue further regulatory clearances of our ALLY System.

Our primary sources of liquidity are our cash and cash equivalents, cash from the sale and lease of our systems and the sale of our consumables. We maintain cash balances with financial institutions in excess of insured limits. As discussed above, ongoing global supply chain disruptions, inflationary pressures and other macroeconomic conditions have negatively affected our capital requirements and more operating capital may be needed to fund our operations in the future. As of December 31, 2022, we expect our current cash and cash equivalents, together with cash generated from the future sale and lease of our products, to be sufficient to operate our business. Based on our current operating plan, we believe we have sufficient cash and cash equivalents on hand to support current operations for at least one year from the date of issuance of the financial statements included in this Annual Report. However, our liquidity beyond one year from the date of issuance of the financial statements is contingent upon, among other things, meeting or exceeding revenue and manufacturing targets in our current operating plan. This condition could raise potential doubt about our ability to continue as a going concern in the future. In order to mitigate our current and potential future liquidity issues, we will need to seek additional capital which may be through the equity or debt financings, borrowings under credit facilities or from other sources. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all.

We expect selling, general and administrative expenses to increase from current levels due to the continued commercial launch of the ALLY System, particularly if supply chain constraints begin to ease. The successful commercialization of the ALLY System depends in part on the Company's ability to produce the ALLY System in sufficient quantities, within requested timing and at an acceptable price to satisfy customer demand. Ongoing supply chain disruptions, unavailability of various parts needed to manufacture the ALLY System and price increases of component parts may have an adverse impact on the Company's ability to meet customer demand for the ALLY System.

Our liquidity needs will be largely determined by our ability to successfully commercialize our products and the progression, additional regulatory clearances or certifications and launch of the ALLY System in additional jurisdictions in the future.

In 2022, we transitioned from manufacturing and selling our LENSAR Laser System to focus on our ALLY System. In September 2022, we submitted the ALLY System for certification in the EU and we intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory clearance in other regions outside the United States and the timing of these clearance or certifications, among other factors. In addition, based on inventory of our LENSAR Laser System, our future revenue and cash flows will depend on, among other factors, our installed base of systems and the timing of and applicable clearances for our ALLY System.

We expect we will need to raise additional capital through equity or debt financings, borrowings under credit facilities or from other sources to continue our operations. We may issue securities, including common stock, preferred stock, warrants, and/or debt securities through private placement transactions or registered public offerings in the future. If we issue equity securities to raise additional capital, our existing stockholders may experience dilution, and the new

equity securities may have rights, preferences and privileges senior to those of our existing stockholders. 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. In addition, if we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Our ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of our control, and we may be unable to raise financing when needed, or on terms favorable to us. If the necessary funds are not available from these sources, we may have to delay, reduce or suspend the scope of our sales and marketing efforts, research and development activities, or other components of our operations. Any of these events could adversely affect our ability to achieve our business and financial goals or to achieve or maintain profitability and could have a material adverse effect on our business, financial condition and results of operations. Additionally, the extent and duration of the impact that global economic uncertainty may have on our stock price and on those of other companies in our industry is highly uncertain and may make us look less attractive to investors and, as a result, there may be a less active trading market for our common stock, our stock price may be more volatile, and our ability to raise capital could be impaired, which could in the future negatively affect our liquidity and financial position.

We expect our revenue and expenses to increase in connection with our on-going activities, particularly as we continue to execute on our growth strategy, including expansion of our sales and customer support teams. The primary factors determining our cash needs are the funding of operations, which we expect to continue to expand as the business grows, and enhancing our product offerings through the commercialization of the ALLY System, our next generation cataract treatment system. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our commercial efforts and those of our distributors; the ongoing impact of COVID-19 and supply chain issues on our business; and the timing, scope and magnitude of our commercial and development activities.

Our material contractual obligations and commercial commitments at December 31, 2022 primarily consist of $2.8 million in operating lease liabilities for our facility lease and $5.8 million in remaining minimum purchase obligations for inventory components for the manufacture and supply of certain components within the next 24 months. Our contractual obligations have increased due to supply chain issues that have necessitated us to enter into longer-term and more expensive per unit contracts to build and source inventory to satisfy the expected commercial demand for the ALLY System, if approved by regulatory authorities or certified by notified bodies in the applicable regions. We expect to meet these requirements through cash and cash equivalents and cash provided by operations. Some of these amounts are based on management's estimates and assumptions about these obligations, including their duration, timing, anticipated actions by third parties and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those described. Furthermore, the Company acquired certain intellectual property, which would result in additional royalty payments at a rate of 3% of certain revenue upon the phacoemulsification features being cleared for commercialization and operational in the ALLY System.

We currently have an effective shelf registration statement on Form S-3 (No. 333-255136) filed with the SEC on April 8, 2021 (the "Registration Statement") under which we may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, depositary shares, warrants, purchase contracts and units of up to $100.0 million in the aggregate. We also simultaneously entered into a sales agreement with SVB Leerink LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $35.0 million of our common stock from time to time in "at-the-market" ("ATM") offerings under the Registration Statement. Any sales by us pursuant to the Registration Statement, including any sales pursuant to the ATM offering, will be subject to any limits imposed under applicable law, including General Instructions I.B.1 and I.B.6 of Form S-3. During the year ended December 31, 2022, we sold 2,000 shares of our common stock, pursuant to ATM offerings, at a weighted average gross sales price of $6.46 per share. Proceeds from the sale were offset by offering costs and commissions associated with the transactions.

Cash Flows

The following table summarizes, for the periods indicated, selected items in our statements of cash flows:

(Dollars in thousands)	Year Ended December 31, 2022	2021
Net cash used in operating activities	$ (14,856)	$ (8,969)
Net cash used in investing activities	(115)	(354)
Net cash provided by financing activities	(1,992)	361
Net increase in cash, cash equivalents and restricted cash	$ (16,963)	$ (8,962)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $14.9 million, consisting primarily of a net loss of $19.9 million and an increase in net operating assets of $5.6 million, partially offset by non-cash charges of $10.6 million. Non-cash charges primarily consisted of depreciation, amortization, and stock-based compensation. Net operating assets decreased due to accounts receivable net, and inventories offset with accounts payable.

Net cash used in operating activities for the year ended December 31, 2021 was $9.0 million, consisting primarily of a net loss of $19.6 million offset by non-cash charges of $10.7 million. Non-cash charges consisted of depreciation, amortization, and stock-based compensation. Net operating assets remained unchanged due to changes in accounts receivable, net offset with inventory.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $0.1 million, which consisted primarily of capital expenditures for property and equipment.

Net cash used in investing activities for year ended December 31, 2021 was $0.4 million, which consisted primarily of capital expenditures for property and equipment.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2022 was $2.0 million, primarily due to the payment of $2.4 million in contingent consideration due to regulatory approval of the ALLY System offset from proceeds from the sale of common stock under the employee stock purchase plan.

Net cash provided by financing activities for the year ended December 31, 2021 was $0.4 million, primarily from the sale of common stock under the employee stock purchase plan.

Stock-Based Incentive Plan

The 2020 Incentive Award Plan provides for the grant of stock options, restricted stock, restricted stock unit awards and other stock-based awards to recipients. During the year ended December 31, 2021, we granted stock options to directors, employees, and non-employees. During the year ended December 31, 2022, we granted stock options and restricted stock units to employees and non-employees. We intend to grant stock options and restricted stock units as part of our overall compensation package to directors and employees.

At December 31, 2022, there was approximately $2.8 million, $0.3 million, and $2.7 million of total unrecognized compensation expense related to restricted stock awards, restricted stock units, and stock options, respectively, which

is expected to be recognized over a weighted-average period of 0.6 years, 2.2 years, and 2.6 years, respectively. Total unrecognized stock-based compensation expense is expected to be amortized as follows:

(Dollars in thousands)	Amount
2023	4,224
2024	987
2025	635
2026	24
2027	—
Thereafter	—
Total unrecognized stock-based compensation expense	$ 5,870

The amounts included in this table are based on restricted stock awards, restricted stock units, and stock options outstanding at December 31, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual stock-based compensation expense in future periods may vary from those reflected in the table.

In January 2023, the Company issued its annual equity grant to employees, which resulted in the issuance of 358,000 stock options and 44,000 restricted stock units. The Company also granted 423,000 restricted stock units to non-executive employees as a one-time retention grant. These grants resulted in $0.6 million of total unrecognized compensation expense, of which $0.1 million will be recognized in 2023.

Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with U.S. Generally Accepted Accounting Principles, or GAAP, and the discussion and analysis of our financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. The impact of accounting estimates and judgments on our financial condition and results of operations due to the COVID-19 pandemic and global macroeconomic conditions originating during the pandemic has introduced additional uncertainties. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates and such differences may be material.

We describe our significant accounting policies in Note 1, *Summary of Significant Accounting Policies*, of the notes to the financial statements. We believe the following accounting policies are the most critical in understanding the estimates and judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition, and cash flows.

Product and Service Revenue Recognition

Revenue is recognized from the sale of products and services when we transfer control of such promised products and services. The amount of revenue recognized reflects the consideration we expect to be entitled to receive in exchange for these products and services. A five-step model is utilized to achieve the core principle and includes the following steps: (1) identify the customer contract; (2) identify the contract's performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when the performance obligations are satisfied.

We principally derive our revenue from the sale and lease of systems and the sale of other related products and services, including PIDs, procedure licenses, and extended warranty service agreements. A procedure license represents a one-time right to utilize the system surgical application in connection with a surgery procedure. Without separately procuring procedure licenses granted by us, either together with the purchase of the system or under separate subsequent contracts, the customer does not have the right to use the surgical software application to perform surgical procedures. Typically, returns are not allowed.

Our contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately may require significant judgment. Judgment is required to determine the level of interdependency between the system and the sale of other related products and services. We evaluate each product or service promised

in a contract to determine whether it represents a distinct performance obligation. A performance obligation is distinct if (1) the customer can benefit from the product or service on its own or with other resources that are readily available to the customer and (2) the product or service is separately identifiable from other promises in the contract.

For contracts involving the sale or lease of a system, our performance obligations generally include the system, PID, procedure license, and extended warranty service agreements. In addition, our customer contracts contain provisions for installation and training services, which are not assessed as performance obligations as they are determined to be immaterial promises in the context of the contract and are required for a customer to use the system.

We have determined that the system, PID and procedure license are each capable of being distinct because they are each sold separately and the customer can benefit from these products with the other readily available resources that are sold by us. In addition, we have determined each are separately identifiable because the system, PID and procedure license (1) are not highly interdependent or interrelated; (2) do not modify or customize one another; and (3) do not include a significant service of integrating the promised goods into a bundled output. This is because we are able to fulfill each promise in the contract independently of the others and we would be able to fulfill our promise to transfer the system even if the customer did not purchase a PID or procedure license or to fulfill our promise to provide the PID or the procedure license even if the customer acquired the system separately.

The extended warranty, unlike our standard product warranty, is a performance obligation because it provides an incremental service that is beyond ensuring the product delivered will be consistent with stated contractual specifications.

When a contract contains multiple performance obligations, revenue is allocated to each performance obligation based on its relative standalone selling price.

We recognize revenue as the performance obligations are satisfied by transferring control of the product or service to a customer as described below. We record a contract liability, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received or due in advance of our performance.

Product revenue. We recognize revenue for the sale of the products at a point in time when control is transferred to customers.

Equipment. System sales are recognized as Product revenue when the Company transfers control of the system. This usually occurs after the customer signs a contract, we install the system, and we perform the requisite training for use of the system for direct customers. System sales to distributors are recognized as revenue upon shipment as they do not require training and installation.

PID and Procedure Licenses. The system requires both a PID and a procedure license to perform each procedure. We recognize Product revenue for PIDs when we transfer control of the PID. We recognize Product revenue for procedure licenses at the point in time when control of the procedure license is transferred to the customer. A procedure license represents a one-time right to utilize the system surgical application in connection with a procedure. For the sale of PIDs and procedure licenses, we may offer volume discounts to certain customers. To determine the amount of revenue that should be recognized at the time control over these products transfers to the customer, we estimate the average per unit price, net of discounts.

Service revenue. We offer an extended warranty that provides additional maintenance services beyond the standard limited warranty. We recognize Service revenue from the sale of extended warranties over the warranty period on a ratable basis as we stand ready to provide services as needed. Customers have the option of renewing the warranty period, which is considered a new and separate contract.

Lease Revenue

We lease equipment to customers under operating lease arrangements. At contract inception we perform an evaluation to determine if a lease arrangement conveys the right to control the use of an identified asset. To the extent such rights

of control are conveyed, we further make an assessment as to the applicable lease classification. The identification of specified assets and determination of appropriate lease classification may require the use of management judgment.

Some of our operating leases include a purchase option for the customer to purchase the leased asset at the end of the lease arrangement, subject to a new contract. We do not believe the purchase price qualifies as a bargain purchase option.

For lease arrangements with lease and non-lease components where we are the lessor, we allocate the contract's transaction price (including discounts) to the lease and non-lease components on a relative standalone selling price, which requires judgments. For those leases with variable lease payments, the variable lease payment is typically based upon use of the leased equipment or the purchase of procedure licenses and PIDs used with the leased equipment.

For operating leases, rental income is recognized on a straight-line basis over the lease term as lease revenue. Depreciation expense associated with the leased equipment under operating lease arrangements is reflected in cost of lease in the statements of operations.

Lessee leases

Lessee operating leases are included in other current liabilities and long-term operating lease liabilities in our balance sheets. We do not have lessee finance leases.

Operating lease ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease payments are discounted using our incremental borrowing rate as of the commencement date of each lease. Our remaining lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis as operating expense in our statements of operations over the lease term.

Inventory

Inventory, which consists of raw materials, work-in-process and finished goods, is stated at the lower of cost or net realizable value. Inventory levels are analyzed periodically on a first-in, first-out basis and written down to their net realizable value if they have become obsolete, have a cost basis in excess of its expected net realizable value or are in excess of expected requirements. We analyze current and future product demand relative to the remaining product shelf life to identify potential excess inventory. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage.

JOBS Act Accounting Election

Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of our first fiscal year in which we have total annual gross revenues of more than $1.07 billion; (2) the date we qualify as a "large accelerated filer," meaning, as of December 31, the market value of our common stock held by non-affiliates as of the prior June

30 exceeded $700.0 million; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2025 (the fiscal year-end following the fifth anniversary of the completion of the Spin-Off).

Recently Issued Accounting Standards

See Note 2, *Summary of Significant Accounting Policies*, to our financial statements included elsewhere in this Annual Report for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2022.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We had cash and cash equivalents of $14.7 million as of December 31, 2022. Our cash and cash equivalents are held in deposit demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. Management has reviewed the financial situation and government guarantees to depositors of this financial institution and believe there to be little or no credit risk to us. A hypothetical 10% change in interest rates would not have had a material impact on the value of our cash and cash equivalents as of December 31, 2022.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of accounts receivable and notes receivable. We limit our credit risk with respect to accounts receivable and notes receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers. We do have the ability to disable the system's ability to operate for lack of payment and, in the case of notes receivable, repossess the system if scheduled payments lapse. As of December 31, 2022, no customers accounted for 10% or more of our accounts receivable, net.

We currently have limited exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

The Company's management has evaluated, with the participation of the chief executive officer and the chief financial officer, 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. Based on this evaluation, the chief executive officer and chief financial officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

For so long as we qualify as an "emerging growth company" as defined under the JOBS Act, our independent registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

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 three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to our annual meeting of stockholders to be held in 2023 (the "2023 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-34 attached hereto and are filed as part of this Annual Report.

AUDITED FINANCIAL STATEMENTS

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
1.2	Sales Agreement, dated April 8, 2021 by and between LENSAR, Inc. and SVB Leerink LLC	Form S-3	333-255136	1.2	04/08/2021	
2.1+	Separation and Distribution Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	2.1	10/02/2020	
3.1	Amended and Restated Certificate of Incorporation of LENSAR, Inc.	Form 8-K	001-39473	3.1	10/02/2020	
3.2	Amended and Restated Bylaws of LENSAR, Inc.	Form 10-K	001-39473	3.2	03/12/2021	
4.1	Form of Certificate of Common Stock	Form 10/A	001-39473	4.1	09/14/2020	
4.2	Description of Registered Securities	Form 10-K	001-39473	4.2	03/12/2021	
10.1+	Transition Services Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	10.1	10/02/2020	
10.2	Tax Matters Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	10.2	10/02/2020	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.3#	2020 Incentive Award Plan	Form S-8	333-249323	10.1	10/05/2020	
10.4#	Form of Restricted Stock Agreement pursuant to 2020 Incentive Award Plan	Form S-8	333-249323	10.2	10/05/2020	
10.5#	Form of Stock Option Agreement pursuant to 2020 Incentive Award Plan	Form 10-K	001-39473	10.5	03/03/2022	
10.6#	Form of Restricted Stock Unit Agreement pursuant to 2020 Incentive Award Plan	Form 10-K	001-39473	10.6	03/03/2022	
10.7#	2020 Employee Stock Purchase Plan	Form 10/A	001-39473	10.5	09/14/2020	
10.8#	Employment Agreement, dated as of July 21, 2020, by and between LENSAR, Inc. and Nicholas Curtis	Form 10	001-39473	10.6	08/26/2020	
10.9#	Employment Agreement, dated as of July 21, 2020, by and between LENSAR, Inc. and Alan Connaughton	Form 10	001-39473	10.7	08/26/2020	
10.10#	Employment Agreement, dated as of July 21, 2020, by and between LENSAR, Inc. and Thomas R. Staab II	Form 10	001-39473	10.8	08/26/2020	
10.11#	Form of Indemnification Agreement between LENSAR, Inc. and its directors and officers	Form 10	001-39473	10.9	08/26/2020	
10.12†	Exclusive License Agreement, dated September 23, 2019, by and among Doug Patton, Ophthalmic Synergies, LLC and LENSAR, Inc.	Form 10	001-39473	10.10	08/26/2020	
10.13†	Development Agreement, dated January 29, 2020, by and between LENSAR, Inc. and Oertli Instrumente AG	Form 10	001-39473	10.11	08/26/2020	
10.14+	Industrial Real Estate Lease, dated as of July 30, 2010, by and between LENSAR, Inc. and Challenger-Discovery, LLC, as amended as of March 15, 2016, December 16, 2016, August 20, 2020 and September 9, 2020	Form 10/A	001-39473	10.12	09/14/2020	
10.15#	Non-Employee Director Compensation Program, as amended	Form 10-K	001-39473	10.15	03/03/2022	
21.1	Subsidiaries of the Registrant	Form 10-K	001-39473	21.1	03/12/2021	
23.1	Consent of Independent Registered Public Accounting Firm					*
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended					*
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
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 Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
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					*
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 (as formatted as Inline XBRL and contained in Exhibit 101)					*

+ Certain schedules and attachments to certain of these exhibits have been omitted pursuant to Regulation S-K, Item 601(a)(5).

† Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Regulation S-K, Item (601)(b)(10).

# Indicates management contract or compensatory plan.

* Filed herewith.

** Furnished herewith.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

LENSAR, Inc.

Date: March 16, 2023

By: /s/ NICHOLAS T. CURTIS
Nicholas T. Curtis
Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2023

/s/ THOMAS R. STAAB, II
Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Nicholas T. Curtis **Nicholas T. Curtis**	Chief Executive Officer and Director (*principal executive officer*)	March 16, 2023
/s/ Thomas R. Staab, II **Thomas R. Staab, II**	Chief Financial Officer (*principal financial officer*)	March 16, 2023
/s/ Kendra W. Wong **Kendra W. Wong**	Principal Accounting Officer (*principal accounting officer*)	March 16, 2023
/s/ William J. Link, Ph.D. **William J. Link, Ph.D.**	Chairperson of the Board of Directors	March 16, 2023
/s/ Richard L. Lindstrom, M.D. **Richard L. Lindstrom, M.D.**	Director	March 16, 2023
/s/ John P. McLaughlin **John P. McLaughlin**	Director	March 16, 2023
/s/ Elizabeth G. O'Farrell **Elizabeth G. O'Farrell**	Director	March 16, 2023
/s/ Aimee S. Weisner **Aimee S. Weisner**	Director	March 16, 2023
/s/ Gary M. Winer **Gary M. Winer**	Director	March 16, 2023

LENSAR, Inc.
INDEX TO FINANCIAL STATEMENTS

As of December 31, 2022 and 2021 and for the Years Ended December 31, 2022 and 2021

AUDITED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of LENSAR, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of LENSAR, Inc. (the "Company") as of December 31, 2022 and 2021, and the related statements of operations, of changes in stockholders' equity and of cash flows for each of the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these financial statements 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 1 to the financial statements, the Company's ability to fund its future operations is contingent upon meeting or exceeding the current operating plan, if not, the Company will require additional financing to fund future operations. Management's plans in regard to this matter are described in Note 1 to the financial statements.

/s/ PricewaterhouseCoopers LLP
Tampa, Florida
March 16, 2023

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

LENSAR, Inc.
STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,	
	2022	2021
Revenue		
Product	$ 25,959	$ 26,246
Lease	5,915	4,966
Service	3,484	3,247
Total revenue	35,358	34,459
Cost of revenue (exclusive of amortization)		
Product	8,910	11,845
Lease	1,941	1,375
Service	4,552	3,406
Total cost of revenue	15,403	16,626
Operating expenses		
Selling, general and administrative expenses	27,170	23,887
Research and development expenses	11,814	12,358
Amortization of intangible assets	1,148	1,240
Operating loss	(20,177)	(19,652)
Other income		
Other income, net	263	51
Net loss	$ (19,914)	$ (19,601)
Net loss per share:		
Basic and diluted	$ (1.96)	$ (2.09)
Weighted-average number of shares used in calculation of net loss per share:		
Basic and diluted	10,159	9,374

The accompanying notes are an integral part of these financial statements

LENSAR, Inc.
BALANCE SHEETS
(In thousands, except per share amounts)

	As of December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,674	$ 31,637
Accounts receivable, net of allowance of $56 and $47, respectively	6,040	4,638
Notes receivable, net of allowance of $4 and $61, respectively	200	350
Inventories	11,740	6,488
Prepaid and other current assets	1,062	1,700
Total current assets	33,716	44,813
Property and equipment, net	563	756
Equipment under lease, net	6,316	6,690
Notes and other receivables, long-term, net of allowance of $9 and $2, respectively	442	121
Intangible assets, net	12,122	10,870
Other assets	2,685	3,215
Total assets	$ 55,844	$ 66,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,422	$ 2,694
Accrued liabilities	4,700	4,604
Deferred revenue	768	904
Operating lease liabilities	531	512
Total current liabilities	11,421	8,714
Long-term operating lease liabilities	2,272	2,803
Other long-term liabilities	167	69
Total liabilities	13,860	11,586
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 10,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, par value $0.01 per share, 150,000 shares authorized at December 31, 2022 and 2021; 11,093 and 10,990 shares issued and outstanding at December 31, 2022 and 2021, respectively	111	110
Additional paid-in capital	139,381	132,363
Accumulated deficit	(97,508)	(77,594)
Total stockholders' equity	41,984	54,879
Total liabilities and stockholders' equity	$ 55,844	$ 66,465

The accompanying notes are an integral part of these financial statements

LENSAR, Inc.
STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (19,914)	$ (19,601)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,258	1,524
Amortization of intangible assets	1,148	1,240
Non-cash operating lease cost	521	517
Provision for expected credit losses	36	74
Write-down of inventory	50	320
Loss on disposal of property and equipment	11	133
Stock-based compensation expense	6,611	6,866
Changes in operating assets and liabilities:		
Accounts receivable	(1,440)	(2,654)
Prepaid and other current assets	637	157
Inventories	(6,889)	2,333
Accounts payable	2,729	213
Accrued liabilities	96	75
Other	(710)	(166)
Net cash used in operating activities	(14,856)	(8,969)
Cash flows from investing activities		
Purchase of property and equipment	(115)	(354)
Net cash used in investing activities	(115)	(354)
Cash flows from financing activities		
Payment of contingent consideration	(2,400)	—
Proceeds from issuance of common stock under employee stock purchase plan	408	361
Net cash (used in) provided by financing activities	(1,992)	361
Net decrease in cash and cash equivalents	(16,963)	(8,962)
Cash and cash equivalents at beginning of the year	31,637	40,599
Cash and cash equivalents at end of the year	$ 14,674	$ 31,637

The accompanying notes are an integral part of these financial statements

LENSAR, Inc.
STATEMENTS OF CASH FLOWS, continued
(In thousands)

	Year Ended December 31,	
	2022	2021
Supplemental cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ 3	$ 19
Supplemental schedule of non-cash investing and financing activities		
Transfer from Inventories to Equipment under lease, net	$ 1,553	$ 4,332
Transfer from Inventories to Property and equipment, net	$ 34	$ —

The accompanying notes are an integral part of these financial statements

LENSAR, Inc.
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	10,933	$ 109	$ 125,094	$ (57,993)	$ 67,210
Issuance of common stock under the 2020 ESPP	57	1	360	—	361
Stock-based compensation under the 2020 Plan	—	—	6,909	—	6,909
Net loss	—	—	—	(19,601)	(19,601)
Balance as of December 31, 2021	10,990	110	132,363	(77,594)	54,879
Issuance of common stock under the 2020 ESPP	107	1	407	—	408
Issuance of common stock under the ATM offering, net of offering costs	2	—	—	—	—
Stock-based compensation under the 2020 Plan	—	—	6,611	—	6,611
Restricted stock awards cancelled	(6)	—	—	—	—
Net loss	—	—	—	(19,914)	(19,914)
Balance as of December 31, 2022	11,093	$ 111	$ 139,381	$ (97,508)	$ 41,984

The accompanying notes are an integral part of these financial statements

NOTES TO FINANCIAL STATEMENTS
(In thousands, except per share amounts)

Note 1. Overview and Basis of Presentation

Overview and Organization

LENSAR, Inc. ("LENSAR" or the "Company") is a global medical device business focused on the design, development and commercialization of advanced technology for the treatment of cataracts and management of astigmatism to achieve improved visual outcomes for patients. The Company is a public company whose stock is listed and trading under the symbol "LNSR" on The Nasdaq Stock Market LLC ("Nasdaq"). The Company's revenue is derived from the sale and lease of the Company's laser systems, which may include equipment, a consumable referred to as the Patient Interface Device ("PID"), procedure licenses, training, installation, limited warranty and maintenance agreements through extended warranty. The Company has developed its next-generation ALLY® Adaptive Cataract Treatment System ("ALLY System"), which combines all of the features from the LENSAR Laser System with a dual-pulse laser, integrated in a small, compact cataract treatment system that is designed to allow surgeons to perform a sterile femtosecond laser assisted cataract procedure in a single operating room or in-office surgical suite. The ALLY System, which has received clearance from the U.S. Food and Drug Administration ("FDA"), enables cataract surgeons to complete the femtosecond-laser-assisted cataract surgery ("FLACS") procedure in a single, sterile environment. The Company executed a controlled and targeted initial launch of the ALLY System beginning in August 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. In addition, we submitted the ALLY System for certification in the European Union, or EU, in September 2022 and intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. The Company's ability to place systems in 2022 was limited by supply chain constraints that delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory.

The Company has incurred recurring losses and operating cash outflows since its inception and as of December 31, 2022 had an accumulated deficit of $97,508. The Company expects to continue to incur losses and cash outflows from operating activities for the near-term future. In addition, the Company's results of operations, financial condition and cash flows have been adversely affected by the COVID-19 pandemic, including supply chain shortages, inflationary pressures and price increases that originated during the pandemic. The Company has experienced some supply chain disruptions and increased costs or unavailability of various component parts needed for the development and supply of the ALLY System originally connected with the COVID-19 pandemic, including increasing lead times required for the ordering of component parts to meet targeted production goals and unpredictability with respect to the availability and delivery timing of these parts. The extent to which the COVID-19 outbreak, and current or future variants, will further negatively impact the Company's business or operating results cannot be determined with certainty at this time. To date, the Company has maintained sufficient inventory to mitigate significant adverse impact from such disruptions and unavailability in the near-term and to facilitate the initial launch of the ALLY System; however, the Company is continuing to monitor developments with respect to such disruptions and their potential impact on the Company's business, results of operations and financial condition. If these supply chain shortages and disruptions continue or worsen, or the Company is unable to find suitable alternative component parts, there is no guarantee the Company will be able to meet customer demand for the ALLY System following its initial launch. In addition, pricing increases in component parts for the ALLY System resulting from inflationary pressures and related macroeconomic conditions may necessitate an increase in overall cost to customers, which in turn may have an adverse impact on customer demand.

Management believes the Company's cash and cash equivalents on hand, together with cash generated from the future sale and lease of products, will provide sufficient funds for its operating, investing, and financing cash flows for a period of at least twelve months from the date of issuance of these financial statements. However, the Company's liquidity beyond one year from the date of issuance of the financial statements is contingent upon meeting or exceeding the current operating plan. With the commercial launch of the ALLY System, the Company expects annual revenue and selling, general and administrative expenses to increase from current levels. In addition, the successful commercialization of the ALLY System depends in part on the Company's ability to produce the ALLY System in sufficient quantities, within requested timelines and at an acceptable price to satisfy customer demand. The Company's liquidity needs will be largely determined by the Company's ability to successfully commercialize its products and the progression, additional regulatory clearances or certifications and launch of the ALLY System in additional

jurisdictions in the future. Such success will depend in part on the availability of the necessary component parts for the ALLY System. The Company expects it will need to raise additional capital through equity or debt financings, borrowings under credit facilities or from other sources to continue its operations beyond the twelve months from the date of issuance of these financial statements. The Company may issue securities, including common stock, preferred stock, warrants, and/or debt securities through private placement transactions or registered public offerings in the future. The Company's ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of the Company's control, and the Company may be unable to raise financing when needed, or on terms favorable to the Company. If the necessary funds are not available from these sources, the Company may have to delay, reduce or suspend the scope of its sales and marketing efforts, research and development activities, or other components of its operations.

Basis of Presentation

These financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and pursuant to the regulations of the U.S. Securities and Exchange Commission ("SEC").

Note 2. Summary of Significant Accounting Policies

Accounting Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the financial statements. The accounting estimates that require management's most significant, difficult and subjective judgments include, but are not limited to, revenue recognition and allowance for expected credit losses, the valuation of notes receivable and inventory, the assessment of recoverability of intangible assets and their estimated useful lives, the valuation and recognition of stock-based compensation, operating lease right-of-use assets and liabilities, and the recognition and measurement of current and deferred income tax assets and liabilities. Management evaluates its estimates on an ongoing basis as there are changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from these estimates.

The COVID-19 pandemic and global macroeconomic conditions originating during the pandemic continue to directly and indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, reserves and allowances. The Company continues to monitor developments that are highly uncertain, including supply chain disruptions and price increases, as well as the economic impact on domestic and international suppliers, customers, and markets. The Company assessed certain accounting matters that require consideration of forecasted financial information, including, but not limited to, its current expected credit losses, the carrying value of the Company's intangible assets and other long-lived assets, and valuation allowances in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of December 31, 2022 and through the date of this report. As a result of these assessments, there were no impairments or material increases in expected credit losses or valuation allowances that impacted the Company's financial statements as of and for the years ended December 31, 2022 and 2021. However, the Company's future assessment of the magnitude and duration of COVID-19, as well as other macroeconomic factors, could result in material impacts to the financial statements in future reporting periods.

As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined that it operates in one operating segment and one reportable segment as the CODM reviews financial information presented on an entity-wide basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As of December 31, 2022 and 2021, 92% and 89% of long-lived

assets were in the United States, respectively. Revenue is attributed to a geographic region based on the location of the customer.

Cash and Cash Equivalents

The Company considers all highly liquid investments with initial maturities of three months or less at the date of purchase to be cash equivalents. The Company places its cash and cash equivalents with high credit quality financial institutions and, at times, exceeds federally insured limits. By policy, the Company limits the amount of credit exposure in any one financial instrument.

Accounts Receivable

The Company had $69 and $110 for allowance for credit losses as of December 31, 2022 and 2021, respectively. The Company makes estimates of the collectability of accounts receivable. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends, changes in customer payment patterns, and possible impact of current conditions and reasonable forecasts not already reflected in historical loss information when evaluating the adequacy of the allowance for credit losses. Amounts are charged off against the allowance for credit losses when the Company determines that recovery is unlikely, and the Company ceases collection efforts.

Fair Value Measurement

The fair value of the Company's financial instruments are estimates of the amounts that would be received if the Company were to sell an asset or the Company paid to transfer a liability in an orderly transaction between market participants at the measurement date or exit price. The assets and liabilities are categorized and disclosed in one of the following three categories:

- Level 1—based on quoted market prices in active markets for identical assets and liabilities.
- Level 2—based on observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—based on unobservable inputs using management's best estimate and assumptions when inputs are unavailable.

Fair value measurements are classified in their entirety based on the lowest level of input that is significant to their fair value measurement.

The carrying value of the Company's cash, cash equivalents, accounts receivable, accounts payable, accrued liabilities, and other current liabilities approximate fair value based on the short-term maturities of these instruments. The carrying value of the Company's notes receivable also approximates fair value based on the associated credit risk.

Inventory

Inventory, which consists of raw materials, work-in-process and finished goods, is stated at the lower of cost or net realizable value. The Company determines cost using standard costs which approximates actual costs determined on the first-in, first-out basis. Inventory levels are analyzed periodically and written down to their net realizable value if they have become obsolete, have a cost basis in excess of expected net realizable value or are in excess of expected requirements. The Company analyzes current and future product demand relative to the remaining product shelf life to identify potential excess inventory. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. The Company classifies inventory as current on the balance sheets when the Company expects inventory to be consumed for commercial use within the next twelve months.

Intangible Assets

Intangible assets with finite useful lives consist primarily of acquired product rights, acquired technology, and customer relationships. Acquired product rights and acquired technology are amortized on a straight-line basis over their estimated useful lives of 15 to 20 years. Customer relationships are amortized on a straight-line basis or a double declining basis over their estimated useful lives up to 20 years, based on the method that better represents the economic benefits to be obtained. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Such assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. The Company did not record any impairment of its intangible assets for the years ended December 31, 2022 and 2021.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Repairs and maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Leasehold improvements	Lesser of useful life or term of lease
Research and development equipment	3-8 years
Manufacturing equipment	3-5 years
Computer and office equipment	3 years
Transportation equipment	3-5 years
Furniture and fixtures	7 years
Software	3 years

Equipment Under Lease

Equipment under lease is related to systems which are leased to customers instead of sold. Equipment under operating lease is stated at cost less accumulated depreciation and is classified as Equipment under lease, net on the balance sheets. Depreciation is computed using the straight-line method over an estimated useful life of the greater of the lease term or five years to ten years.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

Policy Elections and Practical Expedients Taken

The Company applies the following policy elections:

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue.

The Company has elected to apply the practical expedient that allows an entity to not adjust the promised amount of consideration in customer contracts for the effect of a significant financing component when the period between the transfer of product and services and payment of the related consideration is less than one year.

Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of product revenue. Shipping and handling costs for the years ended December 31, 2022 and 2021 were $157 and $245, respectively.

General

Revenue is recognized from the sale of products and services when the Company transfers control of such promised products and services. The amount of revenue recognized reflects the consideration to which the Company expects to

be entitled to receive in exchange for these products and services. A five-step model is utilized to achieve the core principle and includes the following steps: (1) identify the customer contract; (2) identify the contract's performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when the performance obligations are satisfied.

The Company principally derives its revenue from the sale and lease of systems and the sale of other related products and services, including PIDs, procedure licenses, and extended warranty service agreements. Most customers are on pre-paid or 30-day payment terms, depending on the product purchased. Typically, returns are not allowed.

Judgment is required to determine the level of interdependency between the system and the sale of other related products and services. For bundled packages, which include the sale or lease of a system and provision of other products and services, the Company accounts for individual products and services separately if they are distinct—i.e., if a product or service is separately identifiable from other items in the bundled package and if the customer can benefit from it on its own or with other resources that are readily available to the customer. The system, training and installation services are one performance obligation. The other products and services, including PIDs, procedure licenses, and extended warranty services, which are either sold together with the system or on a standalone basis, are all accounted for as separate performance obligations. The transaction price of bundled packages is allocated to each performance obligation on a relative standalone selling price basis. 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, the Company estimates the selling price using available observable information.

The Company recognizes revenue as the performance obligations are satisfied by transferring control of the product or service to a customer, as described below.

Product Revenue. The Company recognizes revenue for the sale of the following products at a point in time:

> *Equipment*. The Company's LENSAR Laser System and ALLY System sales are recognized as Product revenue when the Company transfers control of the system. This usually occurs after the customer signs a contract, the Company installs the system, and the Company performs the requisite training for use of the system for direct customers. System sales to distributors are recognized as revenue upon shipment as they do not require training and installation.
>
> *PID and Procedure Licenses*. The systems require both a PID and a procedure license to perform each procedure. The Company recognizes Product revenue for PIDs when the Company transfers control of the PID. The Company recognizes Product revenue for procedure licenses at the point in time when control of the procedure license is transferred to the customer. A procedure license represents a one-time right to utilize the system surgical application in connection with a surgery procedure. For the sale of PIDs and procedure licenses, the Company may offer volume discounts to certain customers. To determine the amount of revenue that should be recognized at the time control over these products transfers to the customer, the Company estimates the average per unit price, net of discounts.

Service Revenue. The Company offers an extended warranty that provides additional maintenance services beyond the standard limited warranty. The Company recognizes Service revenue from the sale of extended warranties over the warranty period on a ratable basis as the Company stands ready to provide services as needed. Customers have the option of renewing the warranty period, which is considered a new and separate contract.

Lease Revenue. For system operating leases, the Company recognizes lease revenue over the length of the lease in accordance with ASC Topic 842, *Leases*, ("ASC 842"). For additional information regarding accounting for leases, see the Leases section within this footnote below and Note 5, *Leases*.

Contract Costs

The Company offers a variety of commission plans to the Company's salesforce. Certain compensation under these plans is earned by sales representatives solely as a result of obtaining a customer contract. These are considered incremental costs of obtaining a contract and are eligible for capitalization under ASC Topic 340-40, *Other Assets and Deferred Costs – Contracts with Customers*, to the extent they are recoverable. Incremental costs of obtaining a

contract are deferred over the period the related revenue is recognized and the Company has elected not to defer costs related to goods or services to be delivered over a period that is one year or less.

Significant Financing Component

The Company provides extended payment terms to certain customers that represent a significant financing component. The Company adjusts the amount of promised consideration for the time value of money using its discount rate and recognizes interest income separate from the revenue recognized on contracts with customers.

Limited Warranty Obligations

The Company offers limited warranties on the Company's products which provide the customer assurance that the product will function as the parties intended because it complies with agreed-upon specifications; therefore, these assurance-type warranties are not treated as a separate revenue performance obligation and are accounted for as guarantees under U.S. GAAP. The Company regularly reviews its warranty liability and updates these balances based on historical warranty cost trends.

Concentrations of Customers

For the year ended December 31, 2022, one customer accounted for 10% of the Company's revenue and no customers accounted for 10% or more of the Company's accounts receivable, net as of December 31, 2022. For the year ended December 31, 2021, two customers accounted for 16%, and 13% of the Company's revenue, respectively, and three customers accounted for 37%, 13%, and 10% of the Company's accounts receivable, net, respectively, as of December 31, 2021.

Research and Development

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of engineering, product development, clinical studies to develop and support the Company's products, regulatory expenses, and other costs associated with products and technologies that are in development. Research and development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototypes, testing, materials, travel expenses, and depreciation. Research and development expenses for the years ended December 31, 2022 and 2021 included $3.4 million and $3.7 million of ALLY System inventory costs. Following the Company's receipt of 510(k) clearance for the ALLY System from the FDA in June 2022, all ALLY System inventory costs were capitalized to inventory.

Income Taxes

The Company is subject to U.S. federal, state, and local corporate income taxes at the entity level.

The provision for income taxes is determined using the asset and liability approach. Tax laws require items to be included in tax filings at different times than the items are reflected in the financial statements. A current liability is recognized for the estimated taxes payable for the current year. Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are adjusted for enacted changes in tax rates and tax laws in the year in which such laws are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

Leases

The Company accounts for leasing arrangements in accordance with ASC Topic 842. The Company determines if an arrangement is a lease or contains an embedded lease at inception if it contains the right to control the use of an identified asset under a leasing arrangement with an initial term greater than 12 months. The Company determines whether a contract conveys the right to control the use of an identified asset for a period of time if the contract contains both the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the identified asset.

Policy Elections and Practical Expedients Taken

The Company has lease arrangements with lease and non-lease components, which are accounted for separately.

For leases that commenced before the effective date of ASC 842, the Company elected the practical expedients to not reassess the following: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases.

For short term leases, defined as leases with a lease term of 12 months or less, the Company elected to not recognize an associated lease liability and right of use ("ROU") asset. Lease payments for short term leases are expensed on a straight-line basis over the lease term.

The Company has a policy to exclude from the consideration in a lessor contract all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific lease revenue-producing transaction and collected by the Company from a lessee.

Lessee Arrangements

Lessee operating right of use assets are included in Other assets in the Company's balance sheet. Lessee operating lease liabilities are included in Operating lease liabilities and Long-term operating lease liabilities in the Company's balance sheet. The Company does not have lessee financing leases.

Operating lease ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of remaining lease payments over the lease term. The Company uses the implicit rate when readily determinable at lease inception. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date, including the lease term and the Company's credit risk, in determining the present value of lease payments. The Company's remaining lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis as operating expense in the statements of operations over the lease term.

For lease arrangements with lease and non-lease components where the Company is the lessee, the Company separately accounts for lease and non-lease components, which consists primarily of common area maintenance services. Non-lease components are expensed as incurred.

Lessor Arrangements

The Company leases equipment to customers under operating leases. Leases are generally not cancellable until after an initial term and may or may not require the customer to purchase a minimum number of procedures and consumables throughout the contract term.

For lease arrangements with lease and non-lease components where the Company is the lessor, the Company allocates the contract's transaction price (including discounts) to the lease and non-lease components on a relative standalone selling price basis using the Company's best estimate of the standalone selling price of each distinct product or service in the contract. Lease elements generally include a system, while non-lease elements generally include extended warranty services, PIDs and procedure licenses. The stand-alone selling prices for the extended warranty services,

PIDs and procedure licenses are determined based on the prices at which the Company separately sells such products and services. The system stand-alone selling prices are determined using the expected cost plus a margin approach. Allocation of the transaction price is determined at the inception of the lease arrangement. The Company's leases primarily consist of leases with fixed lease payments. For those leases with variable lease payments, the variable lease payment is typically based upon use of the leased equipment or the purchase of procedure licenses and consumables used with the leased equipment. Non-lease components are accounted for under ASC 606. For additional information regarding ASC 606, see Note 3, *Revenue from Contracts with Customers.*

Some leases include options to extend the leases on a month-to-month basis if the customer does not notify the Company of the intention to return the equipment at the end of the lease term. The Company typically does not offer options to terminate the leases before the end of the lease term. A new contract is generated if a customer intends to continue using the equipment under the initial term and the new contract term is not included in the initial lease term.

In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following criteria 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. If any of these criteria are met, the lease is classified as a sales-type lease. If none of these criteria are met the lease is classified as an operating lease. For the years ended December 31, 2022 and 2021, the Company does not have any sales-type leases.

For operating leases, rental income is recognized on a straight-line basis over the lease term as lease revenue. The cost of customer-leased equipment is recorded within equipment under lease, net in the balance sheets and depreciated over the equipment's estimated useful life. Depreciation expense associated with the leased equipment under operating lease arrangements is reflected in cost of lease in the statements of operations. Some of the Company's operating leases include a purchase option for the customer to purchase the leased asset at the end of the lease arrangement, subject to a new contract. The purchase price does not qualify as a bargain purchase option. The Company manages its risk on its investment in the equipment through pricing and the term of the leases. Lessees do not provide residual value guarantees on leased equipment. Equipment returned to the Company may be leased or sold to other customers. Initial direct costs, recorded in prepaid and other current assets, are deferred and recognized over the lease term.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation – Stock Compensation*, ("ASC 718"). Stock-based compensation is measured at the grant date based on the fair value of the award and is generally expensed over the requisite service period. Stock-based compensation expense is recognized using a straight-line attribution method over the requisite service period, except for portions of awards subject to performance conditions, which will be recognized ratably over the service period for each separate performance vesting tranche once it is probable the performance condition will be met. The Company made accounting policy elections to account for modifications to the requisite service period using the bifurcated approach and to account for forfeitures as they occur.

See Note 11, *Stock-Based Compensation,* for a discussion of stock-based compensation plans.

Recently Issued Accounting Pronouncements Not Yet Adopted

The Company reviewed recent pronouncements issued by the FASB and other authoritative standards groups with future effective dates and concluded the pronouncements are either not applicable to the Company or are not expected to have a material impact on the Company's financial position or results of operations.

Note 3. Revenue from Contracts with Customers

Disaggregation of Revenue

The following table summarizes the Company's product and service revenue disaggregated by geographic region, which is determined based on customer location, for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
United States	$ 18,776	$ 15,004
South Korea	2,180	4,380
Europe	4,409	5,805
Asia (excluding South Korea)	3,576	3,855
Other	502	449
Total[1]	$ 29,443	$ 29,493

1 The table above does not include lease revenue of $5,915 and $4,966 for the years ended December 31, 2022 and 2021, respectively. Refer to Note 5, *Leases*.

Contract Balances

The following table provides information about receivables and contract liabilities from contracts with customers:

		As of December 31,	
	Classification	2022	2021
Accounts receivable, current	Accounts receivable, net	$ 6,040	$ 4,638
Notes receivable, current	Notes receivable, net	$ 200	$ 350
Notes receivable, long-term	Notes and other receivables, long-term, net	$ 442	$ 121
Contract asset, current	Prepaid and other current assets	$ 332	$ —
Deferred revenue, current	Deferred revenue	$ 768	$ 904
Deferred revenue, non-current	Other long-term liabilities	$ 17	$ 66
Contract liability, long-term	Other long-term liabilities	$ 150	$ —

Accounts Receivables, Net—Accounts receivables, net, include amounts billed and due from customers. The amounts due are stated at their net estimated realizable value and are classified as current or noncurrent based on the timing of when the Company expects to receive payment. Most customers are on pre-paid or 30-day payment terms, depending on the product purchased. The Company maintains an allowance for expected credit losses to provide for the estimated amount of receivables that will not be collected. The allowance is based upon an assessment of customer credit worthiness, historical payment experience, the age of outstanding receivables, collateral to the extent applicable and reflects the possible impact of current conditions and reasonable forecasts not already reflected in historical loss information.

The following table summarizes the activity in the allowance for accounts receivable:

	Amount
Accounts receivable, allowance for credit losses as of December 31, 2020	$ 19
Change in provision for credit losses	28
Write-offs	—
Accounts receivable, allowance for credit losses as of December 31, 2021	47
Change in provision for credit losses	26
Write-offs	(17)
Accounts receivable, allowance for credit losses as of December 31, 2022	$ 56

Notes Receivables, Net—Notes receivable, net includes amounts billed and due from customers under extended payment terms with a significant financing component. Interest rates on notes receivable range from 5.0% to 7.0%. The Company recorded interest income on notes receivable during the years ended December 31, 2022 and 2021 of $17 and $34 in other income, net in the statements of operations.

The following table summarizes the activity in the allowance for notes receivable:

	Amount
Notes receivable, allowance for credit losses as of December 31, 2020	$ 18
Change in provision for credit losses	45
Write-offs	—
Notes receivable, allowance for credit losses as of December 31, 2021	63
Change in provision for credit losses	10
Write-offs	(60)
Notes receivable, allowance for credit losses as of December 31, 2022	$ 13

Maturities of notes receivables, net under extended payment terms with a significant financing component as of December 31, 2022 are as follows:

Fiscal Year	Amount
2023	230
2024	136
2025	136
2026	136
2027	112
Total undiscounted cash flows	750
Present value of notes receivable	655
Difference between undiscounted and discounted cash flows	$ 95

Contract Assets – The Company's contract assets represent revenue recognized for performance obligations completed before an unconditional right to payment exists, and therefore invoicing has not yet occurred. The Company classifies contract assets in Prepaid and other current assets in the Company's balance sheets.

The following table provides information about contract assets from contracts with customers:

	Amount
Contract assets at December 31, 2021	$ —
Contract assets recognized	355
Payments received	(23)
Contract assets at December 31, 2022	$ 332

Contract Liabilities—The Company’s contract liabilities represent services and products sold to customers for which the performance obligation has not been completed by the Company. The Company classifies contract liabilities as current or noncurrent based on the timing of when it expects to recognize revenue. The noncurrent portion of deferred revenue is included in other long-term liabilities in the Company’s balance sheets.

The following table provides information about contract liabilities from contracts with customers:

	Amount
Contract liabilities as of December 31, 2020	$ 1,051
Billings not yet recognized as revenue	798
Beginning contract liabilities recognized as revenue	(879)
Contract liabilities at December 31, 2021	970
Billings not yet recognized as revenue	822
Beginning contract liabilities recognized as revenue	(857)
Contract liabilities at December 31, 2022	$ 935

Transaction Price Allocated to Future Performance Obligations

At December 31, 2022, the revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more was approximately $10,217. The Company expects to satisfy its remaining performance obligations over the next five years, with $4,253 to be satisfied in the next twelve months, $2,494 to be satisfied in the next two years, $1,901 to be satisfied in the next three years, $917 to be satisfied in the next four years, and $652 to be satisfied thereafter. The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with original expected lengths of one year or less or (ii) contracts for which the Company recognizes revenue at the amount to which it has the right to invoice for the products delivered or services performed.

Costs to Obtain Contracts

The following table provides information about the costs to obtain contracts associated with contracts with customers for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Beginning balance	$ 43	$ 109
Additions	350	509
Amortization	(389)	(575)
Ending balance	$ 4	$ 43

Note 4. Inventories

Inventory balances were as follows:

	As of December 31,	
	2022	2021
Finished Goods	$ 4,002	$ 4,319
Work-in-process	797	173
Raw Materials	6,941	1,996
Total	$ 11,740	$ 6,488

Write downs of inventories to net realizable value amounted to $50 and $264 for the years ended December 31, 2022 and 2021, respectively.

Note 5. Leases

Lessee Arrangements

The Company has an operating lease for a corporate office. In August 2020, the Company amended the lease to extend through November 30, 2027 commencing on September 1, 2020. The lease amendment constitutes a modification as it extends the original lease term, which requires evaluation of the remeasurement of the lease liability and corresponding right-of-use-asset. The reassessment resulted in continuing to classify the lease as an operating lease and remeasurement of the lease liability on the basis of the extended lease term and the incremental borrowing rate at

the effective date of modification of 10%. The Company's operating lease has a remaining lease term of 4.9 years as of December 31, 2022, and contains an option to extend the lease for five years.

The components of lease expense are as follows:

	Year Ended December 31,	
	2022	2021
Operating lease cost	$ 579	$ 578
Short-term lease cost	37	30
Total lease cost	$ 616	$ 608

Supplemental cash flow information related to leases, including the lease modification, is as follows:

	Year Ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 537	$ 522
Right-of-use-assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ —

The following table presents the lease balances within the balance sheet, weighted-average remaining lease term, and weighted-average discount rates related to the Company's operating leases:

		As of December 31,	
Operating Leases	Classification	2022	2021
Operating lease ROU assets	Other assets	$ 2,630	$ 3,151
Operating lease liabilities, current	Operating lease liabilities	$ 531	$ 512
Operating lease liabilities, long-term	Long-term operating lease liabilities	2,272	2,803
Total operating lease liabilities		$ 2,803	$ 3,315
Weighted-average remaining lease term		4.9 years	5.9 years
Weighted-average discount rate		10.00%	10.00%

Maturities of operating lease liabilities as of December 31, 2022 are as follows:

Fiscal Year	Amount
2023	552
2024	567
2025	582
2026	598
2027	562
Total operating lease payments	2,861
Less: imputed interest	(58)
Total operating lease liabilities	$ 2,803

Lessor Arrangements

The Company has operating leases for LENSAR Laser Systems and ALLY Systems, which occur primarily in the United States. The Company's leases have remaining lease terms of less than one year to four years. Lease revenue for the years ended December 31, 2022 and 2021 was as follows:

	Year ended December 31,	
	2022	2021
Lease revenue	$ 5,915	$ 4,966

Equipment under lease is as follows:

	As of December 31,	
	2022	2021
Equipment under lease	$ 14,771	$ 13,488
Less accumulated depreciation	(8,455)	(6,798)
Equipment under lease, net	$ 6,316	$ 6,690

Depreciation expense on equipment under lease amounted to $1,916 and $1,214 for the years ended December 31, 2022 and 2021, respectively.

Maturities of operating lease payments as of December 31, 2022 are as follows:

Fiscal Year	Amount
2023	1,520
2024	331
2025	129
2026	23
Total undiscounted cash flows	$ 2,003

Note 6. Property and Equipment

The following table provides details of property and equipment, net:

	As of December 31,	
	2022	2021
Leasehold improvements	$ 112	$ 112
Manufacturing equipment	1,001	940
Computer and office equipment	102	102
System and laser	1,204	1,219
Software	240	56
Furniture and fixtures	50	50
Transportation equipment	38	38
Total	2,747	2,517
Less accumulated depreciation	(2,239)	(1,945)
Construction in progress	55	184
Property and equipment, net	$ 563	$ 756

Depreciation expense on property and equipment amounted to $342 and $310 for the years ended December 31, 2022 and 2021, respectively. The Company recognizes molds and tools that suppliers use in producing certain products under a long-term supply arrangement in construction in progress while the molds are under construction. When the molds are completed, they are transferred to property and equipment. The assets capitalized amounted to $61 and $662 as of December 31, 2022 and 2021, respectively.

Note 7. Intangible Assets

The components of intangible assets were as follows:

	As of December 31, 2022			As of December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:						
Customer relationships [1,2]	$ 4,292	$ (2,028)	$ 2,264	$ 4,292	$ (1,685)	$ 2,607
Acquired technology [1,3,4]	13,900	(4,042)	9,858	11,500	(3,275)	8,225
Acquired trademarks [1]	570	(570)	—	570	(532)	38
	$ 18,762	$ (6,640)	$ 12,122	$ 16,362	$ (5,492)	$ 10,870

[1] Certain intangible assets were established upon PDL BioPharma, Inc.'s ("PDL") acquisition of LENSAR in May 2017. They are being amortized on a straight-line basis over a period of 15 years. The intangible assets for customer relationships are amortized on a straight-line basis or a double declining basis over their estimated useful lives up to 20 years based on the method that better represents the economic benefits to be obtained.

[2] The Company acquired certain intangible assets for customer relationships from a domestic distributor in an asset acquisition, which are being amortized on a straight-line basis over a period of 10 years.

[3] The Company acquired certain intangible assets from a medical technology company in an asset acquisition, which are being amortized on a straight-line basis over a period of 15 years.

[4] In 2019, the Company acquired certain intellectual property from a third party. Pursuant to the Company's agreement with the third party, the Company made milestone payments of $2,400 during the year ended December 31, 2022, which were contingent upon regulatory approval and commercialization of the ALLY System. Refer to Note 9, Commitments and Contingencies, for further discussion about the contingent consideration. The intangible assets will be amortized on a straight-line basis over a period of 15 years.

Amortization expense for the years ended December 31, 2022 and 2021 was $1,148 and $1,240, respectively.

Based on the intangible assets recorded at December 31, 2022, and assuming no subsequent additions to or impairment of the underlying assets, the remaining amortization expense is expected to be as follows:

Fiscal Year	Amount
2023	1,098
2024	1,165
2025	1,234
2026	1,224
2027	1,215
Thereafter	6,186
Total remaining estimated amortization expense	$ 12,122

Note 8. Accrued Liabilities

Accrued liabilities consist of the following:

	As of December 31,	
	2022	2021
Compensation	$ 3,348	$ 3,375
Professional services	437	526
Customer advances	171	—
Warranty	120	45
Other	624	658
Total	$ 4,700	$ 4,604

Note 9. Commitments and Contingencies

Purchase Obligation

The Company is a party to various supply agreements for the manufacture and supply of certain components. The supply agreements commit the Company to a minimum purchase obligation of approximately $5,848 over the next 24 months. The Company expects to meet these requirements.

Royalty and Milestone Payments

In connection with the acquisition of certain intellectual property, the Company paid $2,400 in milestone payments during the year ended December 31, 2022. The milestone payments were contingent upon regulatory clearance and commercialization of the ALLY System. In addition, the Company acquired certain intellectual property, which would result in additional royalty payments at a rate of 3% of certain revenue upon the phacoemulsification features being cleared for commercialization and operational in the ALLY System.

Employee Retention Credit

In March 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act provides for an employee retention credit ("ERC"), which is a refundable tax credit against certain employment taxes paid in 2020 and 2021. The Company filed for the ERC in the amount of approximately $1,600 in the first quarter of 2023. Should the Company receive the full ERC, it will owe $250 in contingent professional fees. Given the uncertainty the ERC will be allowed by the Internal Revenue Service and the amount received, if any, cannot be estimated, the Company has not recognized any amounts in the financial statements as of December 31, 2022.

Legal Matters

The medical device market in which the Company participates is largely technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. The Company makes provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition or cash flows.

Note 10. Stockholders' Equity

Preferred Stock

The Company has a single class of preferred stock, of which no shares were issued and outstanding.

Common Stock

The Company has a single class of common stock in which stockholders are entitled to one vote for each share of common stock. No cash dividend was declared on common stock during the years ended December 31, 2022 and 2021.

The Company currently has an effective shelf registration statement on Form S-3 (No. 333-255136), which was filed with the SEC on April 8, 2021 (the "Registration Statement"), under which the Company may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, depositary shares, warrants, purchase contracts and units of up to $100.0 million in the aggregate. The Company also simultaneously entered into a sales agreement providing for the offering, issuance and sale by the Company of up to an aggregate $35.0 million of its common stock from time to time in "at-the-market" ("ATM") offerings under the Registration Statement. During the year ended December 31, 2022, the Company sold 2 shares of its common stock, pursuant to ATM offerings, at a

weighted average sales price of $6.46 per share. Proceeds from the sale were offset by offering costs and commissions associated with the transactions.

Note 11. Stock-Based Compensation

Stock-Based Incentive Plans

The 2020 Plan

In July 2020, the Board of Directors approved the LENSAR Inc. 2020 Incentive Award Plan (the "2020 Plan"). The 2020 Plan provides for the grant of stock options, restricted stock, restricted stock unit awards and other stock-based awards to recipients. The amount and terms of grants are determined by the Company's Board of Directors or a duly authorized committee thereof. Participants must pay the Company, or make provisions to pay, any required withholding taxes by the date of the event creating the tax liability. Participants may satisfy the tax liability in cash or in stock. A total of 3,333 shares of common stock were initially reserved for issuance pursuant to the 2020 Plan. The number of shares available for issuance under the 2020 Plan includes an annual increase on the first day of each fiscal year beginning fiscal 2021, equal to the lesser of (i) 5% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as determined by the Board of Directors. As of December 31, 2022 the Company has reserved 4,429 shares of common stock for issuance under the 2020 Plan.

A summary of the shares available for issuance under the 2020 Plan is as follows:

	Number of Shares
Balance at December 31, 2020	1,188
Authorized	547
Granted/Awarded	(674)
Cancelled	21
Balance at December 31, 2021	1,082
Authorized	549
Granted/Awarded	(678)
Cancelled	49
Balance at December 31, 2022	1,002

Stock Options

The exercise price of incentive stock options ("ISOs") and nonqualified stock options ("NSOs") shall not be less than 100% of the fair market value on the grant date of the option and the term may not exceed 10 years. The exercise price of ISOs granted to a 10% stockholder shall not be less than 110% of the estimated fair market value on the grant date of the option and the term may not exceed five years. To date, options have a term of 10 years and generally vest over one to four years from the grant date.

Option award activity under the 2020 Plan is set forth below:

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	—	$ —	—	$ —
Options granted	674	$ 7.59		
Options exercised	—	$ —		
Options cancelled	(21)	$ 8.27		
Outstanding at December 31, 2021	653	$ 7.57	9.3	$ —
Options granted	592	$ 6.19		
Options exercised	—	$ —		
Options cancelled	(43)	$ 6.88		
Outstanding at December 31, 2022	1,202	$ 6.91	8.7	$ —
Vested and expected to vest at December 31, 2022	1,202	$ 6.91	8.7	$ —
Vested and exercisable at December 31, 2022	431	$ 7.49	8.4	$ —

The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $3.90 and $4.85, respectively. The total fair value of options vested during the years ended December 31, 2022 and 2021 was approximately $2,501 and $466, respectively. Total unrecognized compensation expense of $2,728 related to stock options will be recognized over a weighted average period of 2.6 years.

The following table summarizes information about stock options outstanding and vested as of December 31, 2022:

	Options Outstanding			Options Vested	
Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Term (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$4.86 - $5.95	27	9.5	$ 5.75	—	$ —
$6.04 - $6.04	428	9.0	$ 6.04	—	$ —
$6.07 - $7.00	305	8.7	$ 6.90	137	$ 6.94
$7.08 - $8.27	369	8.2	$ 7.68	253	$ 7.61
$8.40 - $8.62	73	8.3	$ 8.61	41	$ 8.61
	1,202	8.7	$ 6.91	431	$ 7.49

The Company estimated the fair value of stock-options using the Black-Scholes option pricing model. The fair value of employee and non-employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee and non-employee stock options was estimated using the following assumptions for the years ended December 31, 2022 and 2021:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	1.5 - 4.2%	0.6 - 1.3%
Expected term (years)	6	6
Expected volatility	70%	72 - 73%
Dividends	0.0%	0.0%

Expected term: The expected term for the Company's stock-based compensation awards was based on an index of the expected terms of a group of comparable publicly-traded medical device and other peer companies, which the Company believed was representative of the expected term of its awards.

Risk-free interest rate: The risk-free interest rate was based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected term.

Expected volatility: The expected volatility for the Company's stock-based compensation awards was based on an index of the historical volatilities of a group of comparable publicly-traded medical device and other peer companies, which the Company believed was representative of the volatility of its common stock.

Expected dividend yield: The Company does not intend to pay dividends for the foreseeable future. Accordingly, the Company used a dividend yield of zero in the assumptions.

Restricted Stock Awards

Restricted stock has the same rights as other issued and outstanding shares of the Company's common stock. The compensation expense related to these awards is determined using the fair market value of the Company's common stock on the date of the grant. Under the Company's restricted stock plans, restricted stock awards typically vest over three years and compensation expense associated with these awards is recognized on a straight-line basis over the vesting period.

Restricted stock award activity under the 2020 Plan is set forth below:

	Restricted Stock Awards Outstanding	
	Number of Units	Weighted-average grant-date fair value per share
Non-vested at December 31, 2020	2,050	$ 10.30
Granted	—	$ —
Vested	(718)	$ 10.31
Cancelled	—	$ —
Non-vested at December 31, 2021	1,332	$ 10.29
Granted	—	$ —
Vested	(704)	$ 10.29
Cancelled	(6)	$ 10.81
Non-vested at December 31, 2022	622	$ 10.29

The total fair value of restricted stock awards vested during the years ended December 31, 2022 and 2021 was $7,240 and $7,406, respectively.

At December 31, 2022, there was approximately $2,796 of total unrecognized compensation expense related to restricted stock awards, which is expected to be recognized over a weighted-average period of 0.6 years. The number of restricted stock awards that are expected to vest are as follows: 237 in the quarter ending March 31, 2023; 136 in the quarter ending June 30, 2023; 174 in the quarter ending September 30, 2023; and 75 in the quarter ending December 31, 2023. These are based on restricted stock awards outstanding at December 31, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual vesting in future periods may vary from those reflected above.

Restricted Stock Units

Restricted stock units granted to employees and non-employees generally vest over one to four years in annual equal increments. The fair value of restricted stock units is based on the Company's closing stock price on the date of grant.

Restricted stock award activity under the 2020 Plan is set forth below:

	Restricted Stock Units Outstanding	
	Number of Units	Weighted-average grant-date fair value per share
Non-vested at December 31, 2021	—	$ —
Granted	86	$ 6.33
Vested	—	$ —
Cancelled	—	$ —
Non-vested at December 31, 2022	86	$ 6.33

At December 31, 2022 there was approximately $346 of total unrecognized compensation expense related to restricted stock units, which is expected to be recognized over a weighted-average period of 2.2 years.

2020 Employee Stock Purchase Plan

In September 2020, the Board of Directors approved the LENSAR Inc. 2020 Employee Stock Purchase Plan (the "2020 ESPP"), under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total of 340 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, beginning in 2022, by an amount equal to the lesser of (i) 1.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (ii) a lesser amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2020 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986.

As of December 31, 2022, 164 shares of common stock have been issued to employees participating in the 2020 ESPP and 176 shares were available for future issuance under the 2020 ESPP. The grant date fair value of the shares to be issued under the Company's 2020 ESPP was estimated using the Black-Scholes valuation model.

The following table sets forth the total stock-based compensation expense recognized under the 2020 Plan and the 2020 ESPP in the Company's statements of operations:

	Year Ended December 31,	
	2022	2021
Cost of revenue—product	$ 219	$ 216
Cost of revenue—service	126	122
Selling, general and administrative expenses	5,648	5,914
Research and development expenses	618	614
Total	$ 6,611	$ 6,866

Total unrecognized stock-based compensation expense is expected to be amortized as follows:

Fiscal Year	Amount
2023	4,224
2024	987
2025	635
2026	24
2027	—
Thereafter	—
Total unrecognized stock-based compensation expense	$ 5,870

The amounts included in this table are based on restricted stock awards, restricted stock units, and stock options outstanding at December 31, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual stock-based compensation expense in future periods may vary from those reflected in the table.

Note 12. Income Taxes

For financial reporting purposes, loss before income taxes includes the following components:

	Years Ended December 31,	
	2022	2021
United States	$ (19,914)	$ (19,601)
Foreign	—	—
Total	$ (19,914)	$ (19,601)

The provision for income taxes for the years ended December 31, 2022 and 2021 consisted of the following:

	Year Ended December 31,	
	2022	2021
Current income tax expense (benefit)		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred income tax (benefit)		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Total provision	$ —	$ —

A reconciliation of the income tax provision computed using the U.S. statutory federal income tax rate compared to the income tax provision included in the statements of operations is as follows:

	Year Ended December 31,	
	2022	2021
Tax at U.S. statutory rate on income before income taxes	$ (4,182)	$ (4,116)
Change in valuation allowance	3,317	3,930
State taxes	(369)	(684)
Section 162(m)	363	310
Stock-based compensation	170	559
Deferred adjustment	706	—
Other	(5)	1
Total	$ —	$ —

Deferred tax assets and liabilities are determined based on the differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The significant components of the Company's net deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 5,855	$ 4,417
Intangible assets	5,866	6,287
Capitalization of research and experimentation expenses	2,533	—
Stock-based compensation	1,150	1,675
Fixed assets	272	—
Other	658	639
Total deferred tax assets	16,334	13,018
Valuation allowance	(16,331)	(13,014)
Total deferred tax assets, net of valuation allowance	3	4
Deferred tax liabilities:		
Other	(3)	(4)
Total deferred tax liabilities	(3)	(4)
Net deferred tax assets	$ —	$ —

The deferred tax assets associated with net operating losses included in the table above for the years ended December 31, 2022 and 2021 reflect the net operating losses the Company expects to generate on its federal and state income tax returns.

As of December 31, 2022 and 2021, the Company maintained federal net operating loss carryforwards of $23,985 and $17,965, respectively. As of December 31, 2022 and 2021, the Company also maintained state net operating loss carryforwards of $16,974 and $12,786, respectively. The federal net operating losses generated during years ended December 31, 2022 and 2021 may only be utilized to offset 80% of taxable income annually and may be carried forward indefinitely. The state net operating losses will begin to expire in the year 2028 if not utilized, though certain state losses can be carried forward indefinitely.

As of December 31, 2022, the Company determined that it continued to be more likely than not that its net deferred tax assets would not be realized in the near future and maintained a $16,331 valuation allowance against these deferred tax assets. The net change in total valuation allowance between the years ended December 31, 2022 and 2021, was an increase of $3,317. The Company's designation was based on its review and analysis of all the available evidence as of the balance sheet date, both positive and negative.

The uncertainty provisions of ASC 740 also require the Company to recognize the impact of a tax position in its consolidated financial statements only if the technical merits of that position indicate that the position is more likely than not of being sustained upon audit. During the years ended December 31, 2022 and 2021, the Company did not record a reserve for uncertain tax positions.

The Company's income tax returns for periods separate from the consolidation with PDL are subject to examination by U.S. federal, state and local tax authorities for tax years 2020 forward. The Company's separate state and local tax returns are generally not subject to examination by authorities for tax years prior to 2017; however, as we utilize our net operating losses, prior years can be subject to examination from 2011 forward. The Company is not currently under examination in any significant tax jurisdictions. Interest and penalties associated with unrecognized tax benefits accrued on the balance sheet were $0 as of December 31, 2022 and 2021.

The 2017 Tax Cuts and Jobs Act requires taxpayers to capitalize research and experimental ("R&E") expenditures effective for taxable years beginning after December 31, 2021. R&E expenditures attributable to U.S.-based research must be amortized over a period of 5 years and R&E expenditures attributable to research conducted outside of the U.S. must be amortized over a period of 15 years.

In August 2022, two pieces of U.S. tax legislation that have significant tax-related provisions were signed into law: (1) the Creating Helpful Incentives to Produce Semiconductors Act of 2022 (the "CHIPS Act"), which creates a new advanced manufacturing investment credit under new Internal Revenue Code Section 48D, and (2) the Inflation Reduction Act of 2022 (the "IRA"), which has a number of tax-related provisions, including: (a) a 15 percent book minimum tax on "adjusted financial statement income of applicable corporations," (b) a plethora of clean energy tax incentives in the form of tax credits, and (c) a one percent excise tax on certain corporate stock buybacks. The Company will monitor additional guidance and impact that the CHIPs Act, the IRA and other potential legislation may have on its income taxes. For the period ended December 31, 2022, the Company does not believe the provisions from these legislative updates will have a material impact on the Company's income taxes.

Note 13. Net Loss per Share

The following is a reconciliation of the numerator (net loss) and the denominator (number of shares) used in the basic and diluted net loss per share calculations:

	Year Ended December 31,	
	2022	2021
Net loss attributable to common stockholders	$ (19,914)	$ (19,601)
Weighted average number of shares of common stock	10,159	9,374
Basic and diluted net loss per share	$ (1.96)	$ (2.09)

The Company's basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period.

As the Company has reported a net loss for all periods presented, basic and diluted net loss per share attributable to common stockholders are the same for those periods. The Company excluded 708 shares of underlying unvested restricted stock awards and units and 1,202 outstanding stock options for the year ended December 31, 2022 and 1,332 shares of underlying unvested restricted stock awards and 653 outstanding stock options for the year ended December 31, 2021 from its net loss per diluted share calculations because their effect was anti-dilutive.

The anti-dilutive weighted-average shares excluded from the net loss per share diluted shares calculations were:

	Year Ended December 31,	
	2022	2021
Restricted stock awards and units	929	1,142
Outstanding stock options	1,149	491
Total	2,078	1,633

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