2020
Annual Report

LENSAR
CATARACT LASER WITH AUGMENTED REALITY

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EXECUTIVE OFFICERS

Nicholas T. Curtis – *Chief Executive Officer*
Alan Connaughton – *Chief Operating Officer*
Thomas R. Staab, II – *Chief Financial Officer*

HEADQUARTERS

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

STOCK TRANSFER AGENT

Computershare
PO Box 505000
Louisville, KY 40233-5000
877-424-4271
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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, 2020

or

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

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

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, indicated 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. ☐

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

As of January 31, 2021, there were 10,932,703 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 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, 2020, 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 ongoing and global COVID-19 pandemic; the timing of and our ability to obtain and maintain regulatory approvals; our expectations about our ability to successfully develop and commercialize our next generation integrated cataract treatment system, ALLY, and the timing thereof; the sufficiency of our cash, cash equivalents and short-term investments; and the plans and objectives of management for future operations and capital expenditures are forward-looking statements. 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 generate revenue;
- our ability to maintain, grow market acceptance of and enhance our LENSAR Laser System, including the development of our next generation system, ALLY;
- the impact to our business, financial condition, results of operations and our suppliers as a result of the COVID-19 pandemic;
- 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 operation as a result of a material disruption to the supply or manufacture of our LENSAR Laser System;
- 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 ALLY 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, 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 including the following:

- We expect to incur operating losses for the foreseeable future and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.
- We principally derive 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, and the commercial success of our LENSAR Laser System will largely depend upon our ability to maintain and grow significant market acceptance for it.
- Our long-term growth depends in part on our ability to enhance our LENSAR Laser System.
- 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.
- COVID-19 and actions taken to control the spread of COVID-19 have had an adverse impact on our business, and we expect them to continue to do so.
- 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.
- If the supply or manufacture of our LENSAR Laser System or other products is materially disrupted, it may adversely affect our ability to manufacture products and could negatively affect our operating results.
- We compete and may 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 or approvals for our future products, including ALLY, or modifications to our current products, and failure to timely obtain necessary clearances or approvals for our future products or modifications to our current products would adversely affect our ability to grow our business.
- 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 an advanced femtosecond laser system for the treatment of cataracts and the management of pre-existing or surgically induced corneal astigmatism. Our LENSAR Laser System incorporates 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 with enhanced precision and the ability to do so consistently. Surgeons have used our laser system to perform more than 479,000 cataract procedures, including 97,071 procedures during the year ended December 31, 2020. As we continue to innovate, we are designing a next generation system, ALLY, which combines an enhanced femtosecond laser with a phacoemulsification system in a single, integrated cataract treatment system that is designed to allow surgeons to perform a femtosecond laser assisted cataract procedure in a single operating room using a single device. We expect this combination product to be a significant medical advancement and to provide improved efficiency and financial benefit to a surgeon's practice at a manufacturing cost less than that of our current system. We anticipate submitting an application for 510(k) clearance of ALLY to the U.S. Food and Drug Administration, or FDA, by the end of the first quarter of 2022 and, subject to FDA clearance, we expect to begin commercialization of ALLY in the latter half of 2022.

A cataract occurs when the normally clear lens of the eye becomes cloudy or opaque, causing a decrease in vision. The majority of patients suffering from cataracts also present with visually significant astigmatism, which is an imperfection in the symmetry of the cornea that results in decreased visual acuity. In 2020, Market Scope referenced data from a clinical study of 6,000 patients performed by Warren Hill, MD that estimates approximately 70% to 90% of cataract patients present with addressable astigmatism prior to cataract surgery. Currently, the only way to treat cataracts is to surgically remove the natural lens of the eye. The principal steps in the procedure include a corneal incision, called an anterior capsulotomy; cataract phacoemulsification including the fragmentation, aspiration and removal of the cataract; and implantation of an artificial intraocular lens, or IOL. IOLs contain corrective power to replace the optical power of the natural lens. A variety of IOLs exist, including a standard monofocal IOL, or premium IOLs, such as multifocal, accommodating or toric IOLs.

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. More recently, 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.

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 surgeons 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 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.

- ***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 is an advanced laser system that can be quickly integrated into a surgeon's existing practice and is easy to use. The LENSAR Laser System provides 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 are currently developing our proprietary, next generation integrated cataract treatment system, ALLY. ALLY is designed to combine our core femtosecond laser technology features with enhanced laser capabilities and a phacoemulsification system into a single unit and allow surgeons to perform a femtosecond laser assisted cataract procedure in a single operating room using this device. We anticipate submitting an application for 510(k) clearance to the FDA by the end of the first quarter of 2022 and, subject to FDA clearance, we expect to begin commercialization of ALLY in the latter half of 2022. If ALLY is cleared by the FDA, we believe its lower operating costs and combined functions will help drive broader penetration for us into the overall cataract surgery market and could create a paradigm shift in the treatment of cataracts and management of astigmatism in cataract surgery.

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. We have experienced considerable growth since we began commercializing our products in the United States in 2012, until 2020 when the COVID-19 pandemic resulted in the suspension of elective cataract surgery for approximately three months in all of our operating regions and decreased the number of new system placements. Although procedure volume has returned to pre-pandemic levels in the United States and Europe, the COVID-19 pandemic continues to negatively influence our ability to grow system sales and placements at historical levels. Our revenue decreased from $30.5 million for the year ended December 31, 2019 to $26.4 million for the year ended December 31, 2020, representing an annual revenue decline of 13.6% due to the impact of the COVID-19 pandemic on our operations. This decrease compares to a pre-COVID-19 annual revenue growth of 25.2% for fiscal 2019 as compared to $24.4 million for the year ended December 31, 2018. Our net losses were $19.8 million, $14.7 million, and $12.6 million for the years ended December 31, 2020, 2019 and 2018, respectively. Additionally, our installed base of LENSAR Laser Systems has increased from 207 as of December 31, 2019 to approximately 225 as of December 31, 2020.

Our Strengths

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

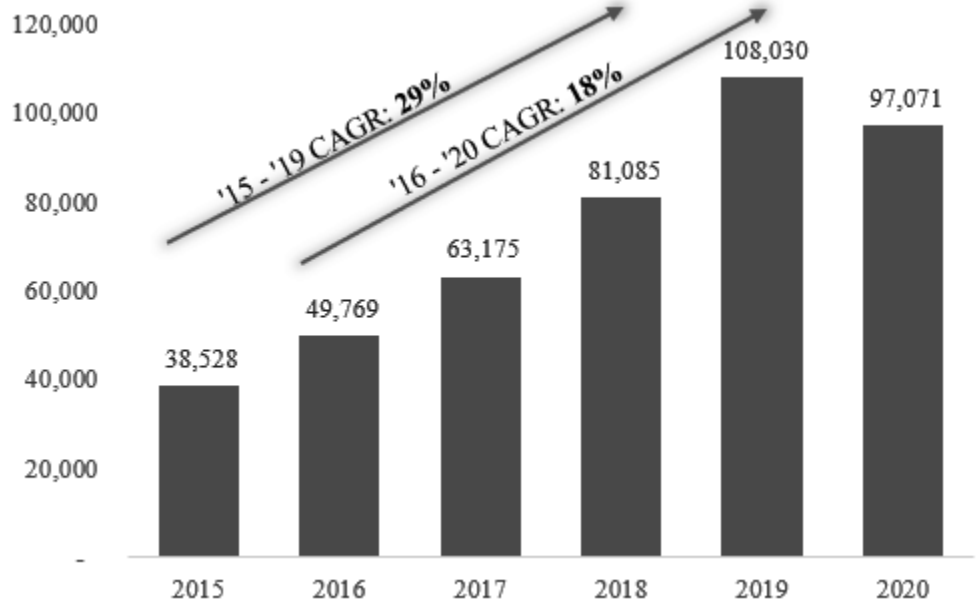
- ***Established large and growing market for cataract surgery.*** According to the 2020 Cataract Surgical Equipment Market Report, an estimated 29 million cataract/refractive lens surgical procedures were performed globally in 2019, with 4.3 million performed in the United States. We believe that growth in the

cataract market generally will continue to be driven by an aging population. Moreover, as IOL technology and advanced laser techniques demonstrate improved vision correction, we expect to see a greater portion of cataract surgeries transition to these advanced refractive cataract procedures.

- ***Disruptive technology platform providing improved visual outcomes.*** Our LENSAR Laser System was built specifically for laser refractive cataract surgery. Central to our LENSAR Laser System 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 system is 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 enable 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 LENSAR to rapidly take market share in a highly competitive market. Based on the 2020 Cataract Surgical Equipment Market Report, it was estimated that we would achieve 16% worldwide market share in femtosecond laser assisted cataract surgery in 2020. Additionally, when looking at the average procedures per installed device, each of our LENSAR Laser Systems averaged 430 procedures in 2020 compared to the estimated industry average of 232 procedures per year per installed device, based on a 2020 Cataract Surgical Equipment Market Report. Since commercial launch, we have continued to grow our annual number of procedures and revenue, with procedures increasing most recently from 63,175 in 2017 to 97,071 in 2020, representing a CAGR of 15.4%, and revenue increasing from $20.6 million in 2017 to $26.4 million in 2020, representing a CAGR of 6.4%. These growth rates compare to pre-COVID procedure and revenue growth representing CAGRs of 30.8% and 21.6% between 2017 and 2019, respectively. We believe that our improved patient outcomes, along with increased surgeon efficiencies and growing commercial presence, will enable us to continue to drive our commercial success. The following chart shows the number of procedures performed per year from 2015 to 2020:

LENSAR 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 management's calculations derived from the 2019 Market Scope Cataract Surgical Equipment Report, approximately 43% of patients receiving a standard cataract procedure fail to achieve their targeted visual outcome and must rely on glasses for distance or near vision or to correct visually significant astigmatism. 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 vison 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 current Streamline IV laser system encompasses improved innovations such as wireless capability, advanced imaging, iris registration, and other features to improve its effectiveness and enhance efficiency. We are currently focused on developing a proprietary next generation integrated cataract treatment system, known as ALLY, that is intended to further enhance the capabilities of our current femtosecond laser technology and combine it with an advanced phacoemulsification system. We are designing this compact, integrated cataract treatment system to operate anywhere 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 machines or patients. We believe this significant improvement in patient flow and efficiency will allow surgeons to offer this technology and its benefits to a broader base of patients. Moreover, by combining a femtosecond laser and phacoemulsification into a single system, we believe we can educate surgeons who currently rely solely on phacoemulsification on the benefits of adopting and integrating laser-assisted procedures into their practice.

- ***Innovative intellectual property protected by a comprehensive patent portfolio.*** As of December 31, 2020, we owned approximately 101 issued patents and 63 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, licensed and acquired significant

patent rights relating to our next generation integrated cataract treatment system. For example, we have filed one application, exclusively licensed two issued U.S. patents, four pending U.S. applications, one pending Patent Cooperation Treaty application and one pending foreign patent application. In addition, we have acquired through assignment one issued U.S. patent, one pending U.S. application which has received a Notice of Allowance, three pending U.S. patent applications and five pending foreign patent applications.

- ***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.

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 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 2020 Cataract Surgical Equipment Market Report, global estimated cataract/refractive lens exchange surgical procedures are expected to grow from 29 million in 2019 to 34 million in 2025. In the United States, cataract surgery is expected to increase from almost 4.3 million procedures in 2019 to approximately 5.1 million in 2025. By contrast, worldwide laser-assisted cataract surgery is expected to grow from an estimated 815,000 procedures in 2019 to an estimated one million procedures in 2025. There are approximately 10,000 ophthalmic surgeons in the United States focused on performing cataract procedures.

Current Cataract Treatment Alternatives

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.

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 2020, 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. More recently, 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 in order 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 round, 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. Many 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 Solution

We developed our LENSAR Laser System to provide an alternative laser cataract treatment that allows the surgeon to better address astigmatism, improve visual outcomes and to perform cataract surgery with enhanced precision and reproducibility.

Benefits of the LENSAR Laser System

Our system incorporates a range of proprietary technology features that are designed to provide surgeons the following key benefits:

- ***Advanced imaging***. Our proprietary Augmented Reality imaging and processing technology collects a broad spectrum of biometric data while taking a series of scans from multiple positions and different angles to capture the radius of corneal curvature, corneal thickness, anterior chamber depth, anterior and posterior lens apex and lens thickness, as well as various anterior segment measurements and location. Once collected, the system takes these two dimensional images and reconstructs them into a precise, three-dimensional model of each individual patient's eye that is then 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 advanced refractive procedures. For example, using patient-specific biometric data, the system is designed to provide the surgeon a concise view and choice of treatment parameters and algorithms based on cumulative treatment data or surgeon selectable preferences. Additionally, the system's technology, including cataract density imaging, has the ability to detect and compensate for lens tilt, and to identify and treat tissue specific densities in the patients' natural lens. These capabilities combine to enable the system to provide precise laser delivery; to produce easy to remove, free-floating capsulotomies; and to perform efficient lens fragmentation, while reducing the laser and phacoemulsification energy required to remove the cataract. The IntelliAxis IV technology allows for the precise placement of arcuate corneal incisions, as well as the proprietary refractive capsulorhexis that creates tabs on the exact axis of astigmatism 180 degrees apart to help produce proper toric IOL placement. These tabs can also be visualized by the surgeon postoperatively to help further ensure proper placement without rotation, which can diminish the effectiveness of the toric IOL. With these automated features, we believe surgeons can feel confident their treatment and execution will lead to better and more predictable outcomes.

- ***Efficient design***. We designed the ergonomics of the system to integrate seamlessly into a surgeon's existing surgical environment and to enable preferred patient positioning during treatment. In addition, the system has wireless capabilities that allow it to collect and transmit data quickly between itself and multiple pre-operative diagnostic devices, such as corneal topographers, for the surgeons use while examining patients in the office. The system uses this data, together with proprietary measurement and imaging technology, called iris registration, to automatically adjust to compensate for rotation of the eye and to place the AIs and capsulotomy in the desired locations, based on pre-programmable surgeon preferences. We believe this significantly improves the accuracy of the incisions, as the surgeon does not need to manually calculate and transpose data or manually mark the eye prior to treatment, and reduces treatment times. The system also includes expanded remote diagnostics that allows us to view and check various software and hardware performance metrics, which helps us increase system reliability and encourages surgeon confidence.

- ***Precision and reproducibility***. The system has multiple features specifically designed to enhance a surgeon's operating precision. The cloud-based or thumb-drive communication with pre-operative diagnostics, use of iris registration, and integrated surgeon's tables enhance procedure planning and treatments by storing surgeon specific treatment algorithms and eliminating the need to manually mark the eye with an ink pen. Additionally, our system has automated surface identification and utilizes Augmented Reality and wave tracing capability to accurately and efficiently provide the choice to the surgeon to automatically center the capsulotomy on the pupil center or the patient's optical axis. This is designed to result in 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.

Despite these benefits, many surgeons continue to rely on traditional cataract surgery procedures for a variety of reasons, including comfort with the process and the established reimbursement. Moreover, the use of our laser system requires a capital investment by the surgeon that may not be needed for traditional cataract surgery. In order to maintain and grow our market share, we must establish the ability to deliver improved visual outcomes relative to traditional cataract surgery and provide economic data that demonstrate the safety, efficacy and cost-effectiveness of our laser systems. We will also need to convince surgeons of the ease of use, reliability, precision and reproducibility afforded by our laser systems.

Improved Outcomes

We believe the cumulative effect of these technologies is an advanced laser system that can be quickly integrated into a surgeon's existing practice, is easy to use and provides surgeons the ability to deliver improved outcomes when addressing astigmatism in connection with cataract removal. Several recent studies support the ability to achieve targeted visual outcomes using our laser system. Key findings in these studies are summarized below:

- In January 2021, a peer-reviewed article was published in the American Journal of Ophthalmology on a prospective study to compare the accuracy of toric intraocular lens alignment and visual outcomes using femtosecond laser-assisted capsulotomy markings versus conventional or manual slit lamp-assisted markings. The study evaluated 57 eyes that received a toric IOL with 26 eyes undergoing femtosecond laser-assisted cataract surgery using the LENSAR Laser System with IntelliAxis Refractive Capsulorhexis to guide toric IOL alignment and 31 eyes undergoing manually marked slit lamp alignment. The study found that residual astigmatism after surgery of the LENSAR group was significantly lower than that in the manual group at 1 and 3 months ($P < .05$), whereas the misalignment of IOL of the LENSAR group was also significantly lower at 1 and 3 months ($P < .05$). One month after surgery, the residual astigmatism of 0.50 diopter or less in the manual group was 29.03% as contrasted to 80.77% of the LENSAR group ($P < .05$). At three months postop, 38.71% of the manual group, and 88.46% of the LENSAR group had no more than 0.50 diopter of residual astigmatism. Accordingly, the LENSAR group had statistically better visual outcomes in this study.

- At the 2019 Annual Meeting of the ASCRS, results were presented from a retrospective study designed to evaluate visual and refractive outcomes following toric IOL implantation guided by iris-registration guided femtosecond laser-assisted capsular marks. The study evaluated 60 eyes that had undergone femtosecond laser-assisted cataract surgery using the LENSAR Laser System and its IntelliAxis Refractive Capsulorhexis to guide toric IOL placement. The study demonstrated a reduction in mean corneal astigmatism from a mean of 2.11 diopters preoperatively to a mean of 0.15 diopters at between four and six weeks postoperatively. Moreover, 98% of eyes achieved postoperative astigmatism of 0.5 diopters or less, and 56% of eyes exhibited no residual astigmatism.

- Results from a separate retrospective study of 54 eyes that underwent femtosecond laser-assisted cataract surgery and toric IOL implantation using the LENSAR Laser System were presented at the 2019 AAO Annual Meeting. The purpose of the study was to evaluate the outcomes of toric IOL implantation based upon iris registration guided femtosecond laser assisted capsular marks. IOL placement was confirmed by an intraoperative wavefront aberrometer used to confirm IOL spherical power, placement of the toric and magnitude of cylinder. The study demonstrated a reduction in mean corneal astigmatism from a mean of 1.01 diopters preoperatively to a mean of 0.11 diopters at between four and six weeks postoperatively. Moreover, 95% of eyes achieved postoperative astigmatism of 0.5 diopters or less, 97.3% of eyes achieved a post-operative UDVA of 20/30 or better and 94.6% achieved a manifest refraction spherical equivalent, or MRSE, of less than 0.75 diopters. Notably, the aberrometer confirmed the IOL position and none of the IOLs required repositioning at the time of surgery.

- In another retrospective study presented at the AAO 2019 Meeting, of 115 eyes that underwent treatment with our laser system and implantation of a toric IOL, we observed a reduction in mean corneal astigmatism from 1.55 diopters preoperatively to 0.47 diopters postoperatively.

- Also presented at the 2019 AAO Annual Meeting were the results of a retrospective study of 590 eyes of patients that desired to be spectacle independent and underwent laser-assisted cataract surgery with a single surgeon using the LENSAR Laser System. Patients with a preoperative astigmatism of less than 0.5 diopters received no astigmatic treatment. Patients with preoperative astigmatism of greater than 0.5 diopters were considered for astigmatic treatment with arcuate keratotomy, or AK, and multifocal or toric IOL. Toric IOLs were used instead of multifocal in eyes where the astigmatism was too high to treat with AKs in the eye that would have received the multifocal IOL. Of the 590 eyes, 475 received a multifocal IOL with or without AK, and 115 eyes received a toric IOL. For the multifocal subgroup, approximately 91% of eyes were within 0.5 diopters of emmetropia, which occurs when the eye is without refractive error, 96.6% of eyes achieved a UDVA of 20/40 or better and 93.2% achieved uncorrected near vision acuity, or UNVA, of 20/40 or better. The multifocal group also achieved a mean MRSE of $-.04 \pm 0.35$, a postoperative UDVA. Similarly, eyes in

the toric subgroup achieved a significant decrease in mean corneal astigmatism from 1.55 diopters preoperatively to 0.47 diopters postoperatively. Additionally, 93.9% of eyes achieved a UDVA of 20/40 or better and 83.2% achieved UNVA of 20/40 or better.

- Lastly, in another retrospective study published in the Journal of Cataract Refractive Surgery in 2019, 189 eyes of 143 patients were analyzed to evaluate the outcomes of femtosecond laser-assisted arcuate keratotomy combined with cataract surgery in eyes with low to medium astigmatism. Each procedure was performed using the LENSAR Laser System and all eyes received the implantation of a non-toric monofocal or multifocal IOL. Results were analyzed at three months postoperatively and showed that 181 eyes (95.8%) demonstrated post-operative refractive astigmatism of 0.5 diopters or less and 170 eyes (90%) had a post-operative UDVA of 20/30 or better. Outcomes from the procedures were demonstrated to be stable for at least one year postoperatively.

Our Next Generation Integrated Cataract Treatment System—ALLY

We are designing our next generation system, ALLY, to dramatically advance the ability of surgeons to perform advanced refractive cataract procedures and improve visual outcomes by combining an enhanced version of our laser technology with a phacoemulsification system in a single, integrated cataract treatment system. We anticipate submitting an application for 510(k) clearance of ALLY to the FDA by the end of the first quarter of 2022 and, subject to FDA clearance, we expect to begin commercialization of ALLY in the latter half of 2022.

Currently, almost all cataract procedures, whether manual or laser-assisted, involve the use of a phacoemulsification system to fracture and remove the cataract. For 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 operating 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 are designing ALLY to seamlessly integrate an enhanced version of our femtosecond laser technology and an advanced phacoemulsification system into one unit that can allow the surgeon to switch seamlessly and quickly between femtosecond laser and phacoemulsification without movement of machines or patients. Importantly, this integrated cataract treatment system will be configured with the ergonomics to be used in an operating room or an in-office surgical suite, a trend in current ophthalmology practices. 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 we intend to incorporate into ALLY include a more versatile laser that uses pulse characteristics designed for tissue specific targeting with significantly faster speeds in different applications. We expect this combination product could be a considerable advancement and will provide significant administrative and financial benefit to a surgeon's practice at a cost less than the cost of our current system.

We believe several converging marketplace factors will encourage adoption of ALLY, if cleared by the FDA. 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 ALLY to assist surgeons in optimizing the accurate positioning using any of these lenses to correct astigmatism for better visual outcomes;

- continued pressure to lower, and the continued 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;

- the availability of a compact, integrated dual function system with a lower cost of goods that can be placed in the operating room, which we believe will encourage surgeons that currently rely solely on phacoemulsification to adopt and integrate laser-assisted procedures into their practice;

- given 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 touches of

the patient to treat and to complete the advanced cataract procedure, placing the system in the ambulatory surgery center, or ASC, operating room or in-office surgical suite; and

- lower technology acquisition cost and broad base procedure applications across all cataract procedures improve economics for the ASC, and the surgeon.

Our Products and Technology

LENSAR Laser System

Our current product portfolio consists of the Streamline IV LENSAR Laser System and its associated consumable components. The system itself is designed as a standalone console and consists of the following key components:

1. *Interactive graphic user interface.* Allows the physician to easily plan, customize and view custom surgery for each individual patient. Further allows easy adjustment of patient treatment moments before surgery.

2. *Deployable head.* Allows the patient to be presented to the system in multiple orientations in a multitude of different laser or operating room configurations.

3. *Scanning camera*. Allows the doctor to find all of the relevant unique eye surfaces automatically, with no manual, time-consuming or cumbersome adjustments.

4. *Seamless docking technology*. Allows for easy docking with force feedback technology to the patient's eye with minimal discomfort.

5. *Easy to use joystick*. Provides physician intuitive, simple control when docking the system to the patient's eye from multiple patient orientation to the system.

The consumable portion of the system consists of a disposable patient interface device, or PID, kit and 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 patients' 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 an active license. We 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.

ALLY

We are currently developing ALLY, our proprietary, next generation integrated cataract treatment system. ALLY is designed to combine our existing femtosecond laser technology with enhanced capabilities and a phacoemulsification system that together will allow surgeons to perform each of the critical steps in a cataract procedure in a single operating room using this device. We anticipate submitting an application for 510(k) clearance to the FDA by the end of the first quarter of 2022 and, subject to FDA clearance, we expect to begin commercialization of ALLY in the latter half of 2022.

Our market research supports the importance of this compact, dual function system. In February 2020, we engaged EyeQ Research, an independent third-party research firm, to conduct a survey to help evaluate and assess surgeon perceptions regarding a dual function system. EyeQ Research contacted over 250 surgeons in the United States in connection with the survey and excluded the results of those surgeons that did not meet certain eligibility criteria, which included, among other things, having performed less than 30 cataract procedures per month. This was a blind survey such that the surgeons contacted were unaware of our association and commissioning of the survey. The results from 122 surgeons, approximately 25% of which were not current users of femtosecond laser-assisted cataract surgery,

are reflected in the survey, with those surgeons possessing an average of 20 years in practice and an average monthly cataract surgery procedure volume of 55. Key findings from the survey are summarized below:

- 40% indicated that use of a dual function system would increase the number of femtosecond laser-assisted cataract surgery procedures they perform;
- 93% indicated that a dual function system would improve femtosecond laser assisted cataract surgery workflow;
- 89% indicated a preference to have the femtosecond laser in the same room as the phacoemulsification system;
- 83% would consider acquiring a dual function system when it is time to replace a femtosecond laser or phacoemulsification system;
- 83% would consider acquiring a dual function system as a new/additional femtosecond laser; and
- 42% indicated that it would be a barrier to acquiring a dual function system if the system was manufactured by a different supplier than their current femtosecond laser, and 55% indicated it would be a barrier if the dual function system was manufactured by a different supplier than their current phacoemulsification system.

We estimate that there are currently approximately 56,000 phacoemulsification systems installed globally, with an estimated 8,300 new phacoemulsification systems installed in 2019 growing to an anticipated 9,600 new units in 2024. According to the 2019 Cataract Surgical Equipment Market Report, there were an estimated 2,816 new femtosecond laser systems installed in 2019, of which 2,576 are in markets that we service. The number of total femtosecond laser systems installed is expected to grow to over 3,600 devices by 2024. We believe the expected growth in the phacoemulsification market, combined with the results from our blinded survey, suggest a significant market opportunity as surgeons replace, or add to, their phacoemulsification or femtosecond laser systems.

To help encourage and facilitate this transition to a dual function system, and to our ALLY system, in particular, we are focused on reducing the total the cost of the system, as compared to two separate systems, without compromising the capabilities or performance of either of the dual functions. With that in mind, we are designing ALLY to offer more functionality and better performance than the combined use of currently available separate systems but at a substantially lower cost of goods. If ALLY is cleared by the FDA, we believe its lower cost of goods and combined functions 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.

Technology

Our LENSAR Laser System has been built specifically for treating 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 through the use of 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 distributors in Germany, China, South Korea 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, 2020, consisted of approximately 35 commercial team professionals, including regional sales managers, clinical applications and outcomes specialists, field service, technical and customer support personnel. As of December 31, 2020, we had a total of approximately 225 systems installed in a total of 15 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.

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 in an effort 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.

Manufacturing

We currently manufacture our LENSAR Laser System at a facility in Orlando, Florida. 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 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 minimum purchase obligation of approximately $2.4 million at December 31, 2020. We expect to meet these requirements. We are also relying on a third party to develop and manufacture the phacoemulsification component of ALLY. We generally do not maintain large volumes of finished goods. As we approach our expected 510(k) submission for ALLY, we intend to have long-term supply agreements or sufficient supply of raw material inventory to adequately source the expected near-term demand of ALLY upon its commercial launch, if cleared. We strive to maintain enough inventory of our various component parts to avoid the impact of a potential short-term disruption in the supply.

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, 2020, we owned approximately 32 U.S. patents, 26 pending U.S. patent applications, 69 issued foreign patents, and 37 pending foreign patent applications, and we also exclusively licensed two U.S. patents, four pending U.S. patent applications, one pending Patent Cooperation Treaty application and one pending foreign patent. Our patents are expected to expire between 2021 and 2038. We have 69 issued foreign patents in a total of 10 countries and regions, including China, Macau, 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 provide significant protection for our current commercialized products.

Our material registered and unregistered trademarks include: LENSAR, ALLY, INTELLIAXIS, INTELLIAXIS REFRACTIVE CAPSULORHEXIS, STREAMLINE, CATARACT LASER UNIVERSITY, CLU CATARACT LASER UNIVERSITY, LENSAR CATARACT LASER WITH AUGMENTED REALITY AND 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 device. In addition to patent applications we have filed related to ALLY devices, we have pursued and consummated agreements with third parties to acquire and license patent rights, such as those described below, which provide important exclusivity with respect to our development and commercialization of ALLY devices. 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 and are required to make 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 royalty payments under the Patton License.

The Patton License will expire upon the last date on which a valid claim exists for any of the licensed patent rights or, if later, the final expiration of any pending but unissued patents owned or controlled by a Licensor or one of its affiliates either at the Effective Date or during the Term, as defined in the Patton License. We have the right to terminate the Patton License for any reason upon 60 days' prior written notice to the Licensors. Both we and the Licensors have the right to terminate the Patton License upon 30 days' prior written notice of an uncured material breach by the other party, or within 90 days of certain bankruptcy-related events involving the other party. Notwithstanding the foregoing, upon completion of the payment of all milestone payments required under the Patton License, the license granted to us will become fully paid up, irrevocable and perpetual for the term of the agreement.

Oertli Development Agreement

In January 2020, we entered into a development agreement with Oertli Instrumente AG, or the Oertli Agreement, pursuant to which we are collaborating in the development of a key component in our ALLY system. The Oertli 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 Oertli Agreement.

The Oertli Agreement will expire in January 2022. Both we and Oertli have the right to terminate the Oertli Agreement for any reason upon 60 days' prior written notice to the nonterminating party. Additionally, both we and Oertli have the right to terminate the Oertli Agreement upon 30 days' prior written notice of an uncured material breach by the other party. Pursuant to the Oertli Agreement, if the development project is successful, we will negotiate with Oertli to enter into a supply agreement, whereby Oertli will supply to us the key components, as well as phaco instruments and single use consumables for inclusion in the 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 have their own femtosecond lasers and phacoemulsification devices. Additionally, we compete with Ziemer Ophthalmic Systems AG, a private Swiss based company, in the femtosecond laser market. If ALLY were to be cleared for commercial use, we would also face competition from Beaver-Visitec International, Carl Zeiss AG, D.O.R.C. Holding B.V., KeraNova S.A., Lumenis, a division of XIO Group, and Oertli Instrumente AG in the standalone phacoemulsification market. 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 are a manufacturer and marketer of 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 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.

In the European Union, or EU, commercialization of medical devices is regulated by the European Union. The European Union has adopted specific directives regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices. Unlike EU regulations, directives must be implemented into the national laws of the EU Member States and national laws may vary from one member state to another.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I of Council Directive 93/42/EEC, or the Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement. To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The Notified Body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

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. All manufacturers placing medical devices into the market in the EU must comply with the EU Medical Device Vigilance System. Under this system, 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. An 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. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

In May 2017, the EU Medical Devices Regulation (Regulation 2017/745) entered into force, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU Member States, the regulations would be 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 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 Medical Devices Regulation was originally intended to become applicable three years after publication (in May 2020). However, in April 2020, to take the pressure off EU national authorities, notified bodies, manufacturers and other actors so they can focus fully on urgent priorities related to the COVID-19 pandemic, the Council of the EU and the European Parliament adopted Regulation 2020/561, extended the transition period by an additional year, until May 26, 2021. Devices lawfully placed on the market pursuant to the 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. Once applicable, the Medical Devices Regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen the rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market and these modifications may have an impact on the way we design and manufacture products and the way we conduct our business in 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.

Following the end of the "Brexit" Transition Period, beginning on January 1, 2021, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will be responsible for the UK medical device market. The new regulations will require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the

UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU notified bodies will remain valid until this time. 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 UK.

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 physician payment transparency laws 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 our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other national member state legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

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 ALLY 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 ALLY, 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 2020. Failure by physicians, hospitals, and other users of ALLY 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 ALLY, 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 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 ALLY 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, 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 is often accompanied by the implantation of an advanced IOL. We believe that the ability of our LENSAR Laser 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 ALLY 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. By way of example, the Tax Cuts and Jobs Act, or the Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a requirement commonly referred to as the "individual mandate".

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. In March 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and heard oral arguments in November 2020, though it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA in the future.

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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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.

Human Capital

LENSAR is 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 50% of employees have been with the Company five or more years, and over 20% have been with the Company 10 or more years. In 2020, we hired 16 new employees and experienced a full-time employee turnover rate of approximately 5%.

- ***Workforce Demographics*:** As of December 31, 2020, we had approximately 100 employees which 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 of LENSAR, 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 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 help to 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 with 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.

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 the previously planned 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, the 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 is 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

We expect to incur operating losses for the foreseeable 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, 2019 and 2020, we had net losses of $14.7 million and $19.8 million, respectively. As of December 31, 2020, we had an accumulated deficit of $58.0 million. We expect to continue to incur losses for the foreseeable future as we continue to build our commercial and clinical infrastructure, pursue development and FDA clearance of our proprietary, next generation integrated cataract treatment system, known as ALLY, and invest in research and development. In addition, as a result of becoming a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 principally derive our revenue from the sale or lease and use of our LENSAR Laser System, the associated procedure licenses and consumables used in each procedure and the commercial success of our LENSAR Laser System will largely depend upon our ability to maintain and grow significant market acceptance for it.

We principally derive 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 all of our revenue in the foreseeable future. Accordingly, our ability to increase revenue is highly dependent on our ability to market and sell or lease our LENSAR Laser System and market the associated consumables.

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 by surgeons, hospital outpatient surgical facilities, in-office surgical suites and ambulatory surgery centers, or ASCs. Our system is 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 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 ALLY or other 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, the use of our LENSAR Laser System or other future products;
- acceptance by cataract surgeons and others in the medical community of our LENSAR Laser System;
- the potential and perceived advantages and disadvantages of our LENSAR Laser System as compared to competing products;
- the willingness of patients to pay out-of-pocket for procedures in which our LENSAR Laser 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;
- the ease of use, reliability and convenience of our LENSAR Laser 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;
- the results of clinical trials and post-market clinical studies relating to the use of our LENSAR Laser 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 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 long-term growth depends in part on our ability to enhance our LENSAR Laser System.

We are currently focused on developing ALLY. ALLY will take considerable time and resources to develop, and we may not be able to complete development, obtain FDA clearance (or regulatory bodies' certification or approval) to market and ultimately commercialize ALLY on a timely basis, or at all. Moreover, we are developing ALLY as a dual-function device that can perform both phacoemulsification and laser-assisted surgery, and if approved, its commercial success will depend significantly on physicians' perception of the benefits of such a device and the extent to which government and other third-party payors cover and reimburse surgeons and other health care providers for procedures using ALLY. We are relying on a third party to develop and manufacture the phacoemulsification component of ALLY, and do not currently possess the internal resources or know-how to do so. Any adverse developments with that third-party supplier, including that third-party's failure to obtain 510(k) clearance for their phacoemulsification device, for which the phacoemulsification component of ALLY is using as a predicate, could in turn negatively impact our development of ALLY, our ability to obtain 510(k) clearance of ALLY or, even if clearance is obtained, the timing of any commercialization of ALLY.

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 ALLY 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;
- our ability to 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 ALLY 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.

COVID-19 and actions taken to control the spread of COVID-19 have had an adverse impact on our business, and we expect them to continue to do so.

The outbreak of a novel coronavirus, or COVID-19, has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets. COVID-19 and actions taken to control the spread of COVID-19 have significantly impacted our business, and we expect them to continue to do so. For example, many jurisdictions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19 by restricting non-essential activities, including the suspension or restriction of elective surgeries and various business operations. These types of orders and restrictions have resulted in a significant decrease in the number of and demand for non-essential or elective medical procedures, including cataract surgeries, since the outbreak of the pandemic. Additionally, some of our employees are still subject to remote working arrangements and restricted business-related travel. The respective commercial teams of certain of the third parties that act as our distributors in international markets have chosen or have been forced to take similar action, and those or other distributors may choose or be forced to take similar action in the future. Neither we, nor our distributors have significant experience operating with the majority of our respective work forces working from home, and this may disrupt standard operations for us or them, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our respective abilities to conduct business in the ordinary course. In addition, this may increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. While the implementation of these measures has not required material expenditures to date, the suspension of non-essential medical services has significantly impacted our revenues and cash flows and has significantly impacted our ability to operate our commercial operations. Furthermore, these developments, including their long-term impact on our suppliers, may adversely affect our development of ALLY or, if such conditions persist, the commercial success of ALLY. For example, the COVID-19 pandemic has resulted in, and may continue to result in, historically high unemployment rates, which typically result in lower rates of private health insurance. Even if procedures in which our LENSAR Laser Systems are used are covered or reimbursable by third-party payors, patients may not have adequate insurance coverage or other discretionary income to pay for a procedure in which one of our LENSAR Laser Systems is used, which would in turn adversely impact our future revenue and results of operations. Furthermore, industry meetings and conferences have moved to a virtual format, which severely limits our ability to meet and interact with surgeons and staff, display our technology, conduct user group meetings, and network as a means to market and sell our product.

The continued spread of COVID-19 has also led to extreme disruption and volatility in the global capital markets, which may increase the cost of, and adversely impact access to, capital and increases economic uncertainty. While we expect COVID-19 to continue to negatively impact our business, operations and revenue growth, given the rapid and evolving nature of the virus and the uncertainty about its impact on society and the global economy, we cannot predict with certainty the extent to which it will affect our operations, particularly if these impacts persist or worsen over an extended period of time. Furthermore, any similar pandemic, epidemic or outbreak of an infectious disease in the

markets in which we operate or in which we sell or lease our LENSAR Laser Systems may adversely affect our business.

In addition to the COVID-19 disruptions adversely impacting our business and financial results, they may also have the effect of heightening many of the other risks described in "Risk Factors," including risks relating to changes in consumer demand; our ability to maintain and grow significant market acceptance; our ability to enhance our LENSAR Laser System; 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.

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 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, such as those that have resulted from the COVID-19 pandemic, may cause individuals to be less willing to pay for advanced cataract procedures. Although we anticipate use of ALLY 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 LENSAR Laser System is 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 LENSAR Laser System. 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 as well as purchases of our consumables and licensed applications outside of the United States. For the year ended December 31, 2020, three customers each accounted for 12% of our revenue. As of December 31, 2020, two customers accounted for 11% and 10% of our accounts receivable, net. This customer concentration exposes us to a material adverse effect if either 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 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.

Subject to the duration and extent of the impact of the ongoing COVID-19 pandemic, 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. We also expect to continue to incur additional costs as a stand-alone public company. 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 of ALLY. 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 regulatory clearance of ALLY. We also expect the impact of the ongoing COVID-19 pandemic will negatively affect our capital requirements and the availability of funds to finance those requirements.

As of the date of this Annual Report, we expect our cash and cash equivalents, together with cash generated from the sale and lease of our products, to be sufficient to operate our business through the anticipated clearance and the commercial launch of ALLY, which is projected to occur in the latter half of 2022. However, if these amounts are insufficient to satisfy our liquidity requirements, we may seek additional funds from public and 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 LENSAR Laser Systems;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in procuring, manufacturing and selling our LENSAR Laser Systems;
- the costs of researching, developing and commercializing ALLY 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 international 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; and
- anticipated and unanticipated general and administrative expenses, including expenses related to operating as a public company and insurance expenses.

Such capital may not be available on favorable terms, or at all. 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.

If the supply or manufacture of our LENSAR Laser System or other products is materially disrupted, it may adversely affect our ability to manufacture products and could negatively affect our operating results.

We manufacture both our LENSAR Laser System 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 LENSAR Laser System 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 develop and manufacture the phacoemulsification component of ALLY. 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 delay in engaging additional or replacement suppliers for certain components. Our efforts to maintain an adequate supply of inventory may not be sufficient and, 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.

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 compete and may 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, a division of Bausch Health Companies Inc.; Johnson & Johnson; Carl Zeiss AG; and Zeimer. 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. 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 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, 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.

If one or more of these risks are realized, this could have a material adverse effect on our business, financial condition and results of operations.

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

Customers may lease our LENSAR Laser System or finance the laser through the product utilization, and we believe there has been an increase in demand for these types of customer leasing in recent years. 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 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. 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 procedures using ALLY 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 procedures using ALLY 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 ALLY generally rely on

third-party payors to pay for all or part of the costs and fees associated with the procedures using ALLY. 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 ALLY, ALLY may not be adopted or accepted by hospitals, healthcare facilities, physicians or other healthcare providers and the prices paid for a procedure using ALLY 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 ALLY 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 ALLY 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 ALLY consistently. Any perception by physicians and other healthcare providers that the reimbursement for procedures using ALLY 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 ALLY or other future products, may negatively affect the adoption and use of ALLY or other future products and technologies, and the prices paid for such products may decline.

The healthcare industry in the United States 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 ALLY 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 current LENSAR Laser System.

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, 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 ALLY 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, 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 could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, 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 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 LENSAR Laser System is used;
- adoption of our LENSAR Laser 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 competitor pricing;
- results of clinical research and trials on our products or competitive products;
- the mix of sales and leases of our LENSAR Laser Systems;
- timing of delivery of LENSAR Laser 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 LENSAR Laser 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 LENSAR Laser System;
- 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 or approval for our LENSAR Laser System.

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, with the exception of 2020 due to the impact of the COVID-19 pandemic on our operations, 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 that 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; and
- the need to hire, train and manage additional qualified personnel.

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. 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 and clinical personnel that are important to our R&D 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.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business and operating results.

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. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption and cyber-based attacks, including malicious software programs or other attacks, which have been attempted against us in the past. 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.

The failure to protect either our or our service providers' information technology infrastructure could disrupt our entire operation or result in decreased sales and leases of our products, increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property or sensitive or personal information, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. 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 data 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, or GDPR, and the California Consumer Privacy Act, or CCPA. These laws affect how we collect and use data of our employees, consultants, customers and other parties. 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 EEA GDPR applies to the EEA. We rely on transfer mechanisms permitted under these laws, including EU Standard Contract Clauses. If we cannot rely on existing mechanisms for transferring personal data from the EEA, the United Kingdom, or UK, or other jurisdictions, we could be prevented from transferring personal data of users or employees in those regions. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

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. Any failure by a third party to prevent security breaches could have adverse consequences for us. We will need to expend additional resources and make significant investments to comply with data privacy and security laws. Our failure to

comply with these laws or prevent security breaches of such data could result in significant liability under applicable laws, cause disruption to our business, harm our reputation and have a material adverse effect on our business.

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 representative of the results we would have achieved as a stand-alone public company during the periods presented and may not be a reliable indicator of our future results.

Our historical financial information included in this Annual Report may not necessarily reflect what our financial position, results of operations or cash flows would have been had we been an independent entity during the periods presented or those that we will achieve in the future. The costs and expenses reflected in our historical financial data 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 does not reflect changes that will occur 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 requirements. Accordingly, the historical financial information presented in this Annual Report 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 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 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 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 Distribution 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.

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 trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance 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 studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign regulatory authorities enforce these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future FDA (or foreign regulatory authorities) inspections. 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 or approvals; withdrawals or suspensions of current approvals, 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, including ALLY, or modifications to our current products, and failure to timely obtain necessary clearances, certifications or approvals for our 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 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 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.

We plan to submit a request for 510(k) clearance for ALLY. We have entered into a development agreement with Oertli pursuant to which we are collaborating in the development of a key component in our ALLY system. Our ability to receive 510(k) clearance on a timely basis, if at all, for ALLY is subject to our partner, Oertli, successfully receiving 510(k) clearance for their phacoemulsification device. If Oertli is delayed in its submission or is unsuccessful in obtaining clearance on its projected timelines, or at all, we could be delayed in our submission for 510(k) clearance of ALLY, and/or we may be required to find an alternative component from a different third party to replace the component Oertli is developing. We may be unable to identify a replacement supplier, and even if we are, the use of a 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 ALLY, if we are able to seek clearance of ALLY at all. Even if Oertli 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 ALLY as proposed.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory 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 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 policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

In order to sell our products in member countries of the EU our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the European Conformity mark, or CE Mark, to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. 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 of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited or licensed by a member state of the EU to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, 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. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

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. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our products, which would prevent us from selling them within the EU.

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, 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 or 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 may change its clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared 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 or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products. For example, the FDA recently announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. For more information, see "—Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained."

Our products must be manufactured in accordance with federal and state 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; 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 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 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 is an ophthalmic surgical laser indicated for, among other things, 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 approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. 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 or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

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

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA (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 or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance 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 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 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;
- 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 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 policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and

- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, disruptions caused by the COVID-19 pandemic 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 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 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 or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the 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 forthcoming steps that the FDA intends 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 plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include 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. In May 2019, the FDA solicited public feedback on these proposals. 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 finalized 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 will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain 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. For example, the results of the 2020 U.S. Presidential election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded or replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulatory framework governing our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

In the EU, in May 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745) entered into force, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU Member States, the regulations would be 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 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 Medical Devices Regulation was originally intended to become applicable three years after publication (in May 2020). However, in April 2020, to take the pressure off EU Member States' national authorities, notified bodies, manufacturers and other actors so they can focus fully on urgent priorities related to the COVID-19 pandemic, the Council of the EU and the European Parliament adopted Regulation 2020/561, extending the transition period by an additional year (until May 26, 2021). Devices lawfully placed on the market pursuant to postponing the date of

application of the 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. Once applicable, the Medical Devices Regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen the rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

The aforementioned EU rules are generally applicable in the EEA. Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market. These modifications may have an effect on the way we conduct our business in the EU and these modifications may have an impact on the way we design and manufacture products and the way we conduct our business in the EU.

Disruptions at the FDA and other government agencies 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 to review and clear 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory bodies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and cleared, certified or approved by necessary government agencies (or other regulatory bodies), which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

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

Enacted and future healthcare legislation may increase the difficulty and cost for us to commercialize ALLY 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.

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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 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 ALLY or any other products we may develop and obtain clearance for in the future.

We may be subject to certain federal and state 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 or federal 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 and state 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 other healthcare providers starting in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- 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.

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 regulations, including those laws that require the reporting of true, complete and accurate information to the FDA; (ii) manufacturing standards; (iii) federal and state 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.

Our intellectual property coverage includes protection provided by patents licensed through third parties, including patents that relate to combining a femtosecond laser and phacoemulsification system into a single device. Our licensors may not successfully prosecute the intellectual property applications, including patent applications, that we have licensed, may fail to maintain these patents, or may determine not to pursue litigation, or assist us in the pursuit of litigation against other companies that are infringing this intellectual property, or may pursue such litigation less aggressively than we would. If, in the future, we no longer have rights to one or more of these licensed patents or other licensed intellectual property, our intellectual property coverage may be compromised, which, in turn, could affect our ability to sell our products, or to protect our products and defend them against competitors. Without protection for the intellectual property we license, other companies might be able to offer similar products for sale, which could adversely affect our competitive business position and harm our business prospects.

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, 2020, we owned approximately 32 U.S. patents, 26 pending U.S. patent applications, 69 issued foreign patents, and 37 pending foreign patent applications, and we also exclusively licensed two U.S. patents, four pending U.S. patent applications, one pending Patent Cooperation Treaty application and one pending foreign patent application. 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 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.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention

earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

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.

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 the third party's 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 obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology 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 agreement 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 a development agreement with Oertli pursuant to which we are collaborating in the development of a key component in our ALLY system. Under this agreement, 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 agreement, we and Oertli are entitled to practice such jointly owned intellectual property in our respective sole discretion. Our agreement with Oertli does 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 agreement, 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 platform, 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. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. 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 $1.07 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
- general political and economic conditions, and other external factors, including the global impact of the COVID-19 pandemic.

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 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. As a public company, we are required to:

- prepare and distribute periodic public reports and other stockholder communications in compliance with our obligations under the federal securities laws and the listing rules of Nasdaq;
- create or expand the roles and duties of our board of directors and committees of the board of directors;
- institute more comprehensive financial reporting and disclosure compliance functions;

- supplement our internal accounting and auditing function, including hiring additional staff with expertise in accounting and financial reporting for a public company;
- establish formal closing procedures at the end of our accounting periods;
- develop our investor relations function;
- establish new internal policies, including those relating to disclosure controls and procedures; and
- involve and retain to a greater degree outside counsel and accountants in the activities listed above.

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.

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 needs for, subject to FDA clearance, the anticipated launch of ALLY in 2022.

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, 2021, there were approximately 123 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.

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. Selected Financial Data.

Not applicable.

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" section for a discussion of the uncertainties, risks and assumptions associated with these statements.

Spin-Off

On October 1, 2020, PDL completed a Spin-Off of LENSAR, Inc., its medical device business segment. The Spin-Off was in the form of a dividend involving the distribution of substantially all outstanding shares of LENSAR common stock owned by PDL to holders of PDL common stock. The Spin-Off created a separate, independent, publicly traded global 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. In connection with this Spin-Off, our stock began trading under the symbol "LNSR" on Nasdaq.

Our financial statements prior to October 1, 2020 were prepared on a stand-alone basis and were derived from PDL's consolidated financial statements and accounting records. Our financial statements reflect, in conformity with accounting principles generally accepted in the United States, our financial position, results of operations, and cash flows as the business was historically operated as part of PDL prior to the Spin-Off. The statements of operations include direct expenses for cost of revenue; research and development; selling, general and administrative expenses; and amortization, as well as allocated expenses for certain corporate support functions that were provided by PDL, such as administration and organizational oversight, including employee benefits, finance and accounting, treasury and risk management, professional and legal services, among others. These expenses were allocated to us on the basis of direct usage when identifiable, with the remainder allocated on a proportional basis of our expenses and expenses of PDL. Our management and PDL's management considered the basis on which the expenses have been allocated to be a reasonable reflection of utilization of services provided to or to the benefit received by us during the periods presented. These allocations may not be reflective of the expenses that would have been incurred had we operated as a separate, unaffiliated entity apart from PDL. Actual costs that would have been incurred if we had been a stand-alone, public company would depend on multiple factors, including the chosen organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

Transactions with PDL that were expected to be settled for cash are reflected in our balance sheet as of December 31, 2019. These transactions primarily included payables to PDL related to certain historical cross charge cost allocations. The cash flows related to payables due to PDL for these certain historical cross charge cost allocations are reflected in our statements of cash flows as operating activities. The cash flows, prior to our recapitalization related to the note payable due to PDL and our Series A Preferred Stock are reflected in our statements of cash flows as financing activities since these balances represent amounts financed by PDL. Transactions with PDL that were not historically settled in cash have been included in the balance sheets as a component of equity and are reflected in our statements of cash flows as financing activities. In July 2020, we entered into a contribution and exchange agreement with PDL, whereby we issued to PDL a total of 2.8 million shares of our common stock in exchange for the extinguishment of the $32.6 million outstanding, including accrued interest, we owed to PDL under the term loan facility we entered into with PDL in May 2017 and amended in July 2020, or the Credit Agreement. In July 2020, we issued to PDL a total of 3.4 million shares of our common stock in exchange for the extinguishment of all 30,000 shares of our Series A Preferred Stock, including any accrued and unpaid dividends thereon. We currently do not have any shares of Series A Preferred Stock outstanding. On September 10, 2020, we amended and restated our certificate of incorporation to effect a one-for-nine reverse stock split of our common stock. All issued and outstanding shares of common stock, other common stock share numbers, equity awards and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

In connection with the Spin-Off, we entered into several agreements with PDL that govern the future relationship between us and PDL and impose certain obligations on us following the Spin-Off and which may cause us to incur

new costs, including a Separation and Distribution Agreement, a Transition Services Agreement and a Tax Matters Agreement.

As an independent public company, we perform the functions described above using our own resources or purchased services. For an interim period, however, some of these functions may continue to be provided by PDL under the transition service agreements with PDL as described above in connection with the Spin-Off.

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 LENSAR Laser System incorporates 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 consists of the LENSAR Laser System with Streamline IV and IntelliAxis and its associated consumable components. The consumable portion of the system consists of a disposable patient interface device, or PID, kit and 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 an active license. We 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 are currently developing our proprietary, next generation integrated cataract treatment system, ALLY. ALLY is designed to combine our existing femtosecond laser technology with enhanced capabilities and a phacoemulsification system into a single unit and allow surgeons to perform each of the critical steps in a cataract procedure in a single operating room using this device. We expect this combination product will be a meaningful advancement and will provide significant administrative and financial benefit to a surgeon's practice at a cost less than the cost of our current system. We anticipate submitting an application for 510(k) clearance to the U.S. Food and Drug Administration, or FDA by the end of the first quarter of 2022 and, subject to FDA clearance, we expect to begin commercialization of ALLY by the end of 2022. If ALLY is cleared by the FDA, we believe its lower cost of goods and combined functions will help drive broader penetration for us into the overall cataract surgery market and could create a paradigm shift in the treatment of cataracts and management of astigmatism in cataract surgery.

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, 2020, consisted of approximately 35 commercial professionals, including regional sales managers, clinical applications and outcomes specialists, field service, technical and customer support personnel. We currently manufacture our LENSAR Laser System 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 a potential short-term disruption in the supply chain.

Our revenue decreased from $30.5 million for the year ended December 31, 2019 to $26.4 million for the year ended December 31, 2020, representing a decline of 13.6%, due to the impact of the COVID-19 pandemic as discussed below. Our net losses were $14.7 million and $19.8 million for the years ended December 31, 2019 and 2020, respectively. Additionally, our installed base of LENSAR Laser Systems has increased from 207 as of December 31,

2019 to approximately 225 as of December 31, 2020. Although our installed base of LENSAR Laser Systems increased, the decrease in revenue was primarily driven by the impact of the COVID-19 pandemic resulting in a suspension of approximately three months of cataract procedures in all of our operating markets as well as a proportional decline in LENSAR Laser System sales and leases relative to 2019.

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 trials;
- uncertainty of regulatory actions and marketing approvals;
- 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; 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 of our ALLY laser system, the number of laser systems we manufacture, sell, and lease on an annual basis, the availability of capital and direction from regulatory agencies, 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.

On March 11, 2020, the World Health Organization declared a global pandemic, as the outbreak of a novel strain of coronavirus spread throughout the world. The outbreak of COVID-19 has significantly disrupted our business operations and adversely impacted our business, as non-essential medical procedures, including cataract surgeries, were suspended or significantly decreased in many geographic areas in which we operate for approximately three months. Actions taken to mitigate coronavirus have had, and are expected to continue to have, an adverse impact on the geographical areas in which we operate, and we are making adjustments intended to assist in protecting the safety of our employees and communities while continuing our business activities where possible and legally permitted. To date, implementation of these measures has not required material expenditures, but the temporary suspension of non-essential medical services significantly impacted our revenues and cash flows as well as increasing our inventories, and the pandemic continues to disrupt our commercial operations. During the second quarter of 2020, we made lease concessions to several customers related to the effects of the COVID-19 pandemic, which adversely impacted revenue recognized during the period. In return for these concessions, the related contracts were extended by the same number of months waived. Although procedure volume has returned to pre-pandemic levels in the United States and Europe, the COVID-19 pandemic continues to negatively influence our ability to grow system placements at historical levels. We have also experienced minor supply chain disruptions as a result of COVID-19. We are continuing to monitor

developments with respect to the outbreak and its potential impacts on our operations and those of our employees, distributors, partners, suppliers, and regulators.

As a result of these and other factors, our historical results are not necessarily indicative of future performance, and any interim results we previously presented 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 PID 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 LENSAR Laser 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 LENSAR laser systems. For the year ended December 31, 2020, approximately 85% of our revenue was attributable to recurring sources, compared to 79% for the year ended December 31, 2019.

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 and equipment overhead, 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 the 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 and legal fees, marketing, insurance, travel and other expenses.

We are continuing to grow our sales efforts of the LENSAR Laser System in the United States. We expect our selling, general and administrative expenses to continue to increase in association with our planned growth. Additionally, if we receive regulatory clearance for ALLY, we anticipate additional increases in selling, general and administrative expenses as we prepare for and launch ALLY. We also expect to incur additional expenses as a result of operating as a public company, including expenses necessary to comply with the rules and regulations applicable to companies listed on a national securities exchange and those of the SEC, as well as increased expenses for director and officer insurance, investor relations and professional services.

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 laser system, ALLY, which is designed to combine our existing femtosecond laser technology with a phacoemulsification system into an integrated cataract treatment system.

As we continue to advance the development of ALLY, we expect our research and development expenditures to increase from current levels, as we anticipate that the planned development of ALLY will consume significant capital resources.

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.

Interest Expense

Prior to the Spin-Off, interest expense primarily consisted of interest expense associated with the Series A Preferred Stock and a note payable to PDL. The Series A Preferred Stock was classified as a liability on our balance sheet and related dividends were recorded as interest expense using the effective interest method. In July 2020, we entered into a contribution and exchange agreement with PDL, whereby we issued to PDL a total of 2.8 million shares of our common stock in exchange for the extinguishment of the $32.6 million, including accrued interest, we owed to PDL under the Credit Agreement. In July 2020, we issued to PDL a total of 3.4 million shares of our common stock in exchange for the extinguishment of all 30,000 shares of our Series A Preferred Stock, including any accrued and unpaid dividends thereon. We currently do not have any shares of Series A Preferred Stock outstanding.

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 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, 2020 and 2019

(Dollars in thousands)	2020	2019	Change from Prior Year %
Revenue:			
Product	$ 19,831	$ 23,254	(14.7)%
Lease	3,601	4,181	(13.9)%
Service	2,950	3,093	(4.6)%
Total revenue	$ 26,382	$ 30,528	(13.6)%
Cost of revenue (excluding intangible amortization):			
Product	$ 8,303	$ 12,030	(31.0)%
Lease	1,136	2,264	(49.8)%
Service	2,868	3,005	(4.6)%
Total cost of revenue	$ 12,307	$ 17,299	(28.9)%

Revenue

Total revenue for the year ended December 31, 2020 was $26.4 million, a decrease of 13.6% when compared to total revenue of $30.5 million for the year ended December 31, 2019. The decrease was primarily driven by the impact of

the COVID-19 pandemic and the associated decline in elective surgical procedures and sales of LENSAR Laser Systems.

Product revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $3.4 million, or 14.7%. The decrease was primarily attributable to a decrease of $2.4 million related to net sales of LENSAR Laser Systems. Furthermore, Product revenue declined due to a decrease in procedures performed. The number of procedures performed decreased by 10% for the year ended December 31, 2020 as compared to the year ended December 31, 2019, primarily driven by the impact of the COVID-19 pandemic and the associated decline in elective surgical procedures.

Service revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $0.1 million primarily due to decreased sales of our extended warranty services due to the impact of the COVID-19 pandemic.

Geographically, the decrease in product and service revenue was primarily attributable to lower international net revenues due to decreased sales volume. Changes in price did not have a material impact. Our international sales represented 49% and 59% of product and service revenues for the years ended December 31, 2020 and 2019, respectively. The decline was primarily driven by a decrease in product sales, specifically systems, PIDs and procedure licenses, and was comprised of a $4.8 million decrease in South Korea, which was partially offset by a $0.5 million increase in Asia, excluding South Korea, and a $0.7 million increase in the United States.

Lease revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $0.6 million, or 13.9%, primarily related to the impact of the COVID-19 pandemic, including approximately $0.3 million of lease concessions made in the period ended December 31, 2020.

Cost of Revenue

Total cost of revenue for the year ended December 31, 2020 was $12.3 million, a decrease of 28.9% when compared to total cost of revenue of $17.3 million for the year ended December 31, 2019.

Cost of product revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $3.7 million or 31.0%. The decrease was primarily attributable to a decrease in the number of LENSAR Laser Systems that were sold in the year ended December 31, 2020 as compared to the year ended December 31, 2019. In addition, there was a decrease in the number of PIDs sold in the year ended December 31, 2020 as compared to the year ended December 31, 2019 due to the COVID-19 pandemic.

Cost of service revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $0.1 million or 4.6%. This decrease was primarily attributable to a decrease in service, maintenance, and warranty costs associated with lower sales volume. Although more systems were under service contracts, fewer service requests were made due to the COVID-19 pandemic.

Cost of lease revenue for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased by $1.1 million, or 49.8%. This decrease was primarily attributable to a decrease in rental depreciation as LENSAR Laser Systems reached the end of their depreciable life but were still active under lease arrangements in the field.

Operating Expenses

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2020 were $23.8 million, an increase of $6.6 million, or 38.6%, compared to $17.1 million for the year ended December 31, 2019. The increase was primarily due to a $6.4 million increase in personnel expense primarily due to stock-based compensation expense and a $1.0 million increase in professional services fees. The increase was partially offset by a decrease in trade show and travel expenses as a result of travel restrictions and cancellations related to the COVID-19 pandemic. Selling, general and administrative expenses included $3.4 million and $4.4 million of expenses allocated from PDL for corporate support functions for the years ended December 31, 2020 and 2019, respectively. As we get closer to submitting the application for 510(k) clearance of ALLY to the U.S. Food and Drug

Administration, currently expected by the end of the first quarter of 2022, and the projected commercial launch of ALLY in the latter half of 2022, we expect selling, general and administrative expense to increase from current levels.

Research and Development. Research and development expenses were $7.6 million for the year ended December 31, 2020, which was consistent with the year ended December 31, 2019. Research and development expenses in the year ended December 31, 2020 primarily consisted of expenses related to developing ALLY. There was an increase of $1.7 million in consulting expenses and supplies and an increase of $1.1 million increase in personnel expense primarily due increases in headcount and stock-based compensation expense offset by a decrease of $3.5 million in non-recurring project costs related to intellectual property purchased in the year ended December 31, 2019.

Amortization of Intangible Assets. Amortization of intangible assets was approximately $1.2 million for the year ended December 31, 2020, which was consistent with the year ended December 31, 2019.

Other Income (Expense)

Interest expense decreased by $0.7 million, or 33.0%, to $1.3 million for the year ended December 31, 2020 from $2.0 million for the year ended December 31, 2019. The decrease was attributable to a recapitalization of the Company in the third quarter of 2020, resulting in the elimination of interest expense related to our Series A Preferred Stock and outstanding note from PDL.

Income Taxes

Prior to the Spin-Off, we were included in the consolidated federal tax return of PDL. The provision for income taxes for the year ended December 31, 2019 was calculated by using a "separate return" method. Under this method, we were assumed to file a separate return with the applicable tax authority(ies). The provision was the amount of tax payable or refundable on the basis of a hypothetical, current-year separate return. Deferred taxes were provided on temporary differences and on any attributes being carried forward that could be claimed on the hypothetical return. The need for a valuation allowance was assessed on a separate company basis and on projected separate return assets.

Subsequent to the Spin-Off, we are no longer included in the consolidated federal tax return of PDL and will file a tax return for the period following the Spin-Off as a separate company. The provision for income taxes for the year ended December 31, 2020 reflects the impact of the Spin-Off and our status as a separate company for federal and state income tax filing purposes.

We maintain a full valuation allowance against our deferred tax assets.

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, 2020 and 2019.

	Year Ended December 31,	
(Dollars in thousands)	**2020**	**2019**
Net loss	$ (19,774)	$ (14,657)
Add: Interest expense	1,340	2,001
Less: Interest income	(68)	(58)
Add: Depreciation expense	1,309	2,639
Add: Amortization expense	1,256	1,227
EBITDA	(15,937)	(8,848)
Add: Stock-based compensation expense	9,026	918
Adjusted EBITDA	$ (6,911)	$ (7,930)

EBITDA is defined as net loss before interest expense, income tax expense, interest income, 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.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2020 and 2019, we had net losses of $19.8 million and $14.7 million, respectively, and, as of December 31, 2020, we had an accumulated deficit of $58.0 million. We expect to continue to incur losses and operating cash outflows for the foreseeable future as we continue to build our commercial and clinical infrastructure, pursue development and FDA clearance of our proprietary, next generation integrated cataract treatment system, known as ALLY, and invest in research and development. In addition, as a stand-alone public company, we will incur significant legal, accounting and other expenses that we did not incur as a subsidiary of PDL.

As discussed above, we also expect the ongoing COVID-19 pandemic will negatively affect our capital requirements and more operating capital may be needed to fund our operations.

In May 2017, we entered into a credit agreement with PDL whereby, we had drawn the full amount of $32.6 million under the Credit Agreement prior to the contribution and exchange agreement we entered into with PDL in July 2020. Under the contribution and exchange agreement with PDL, we issued to PDL a total of 2.8 million shares of our common stock in exchange for the extinguishment of the $32.6 million outstanding, including accrued interest, we owed to PDL under the Credit Agreement.

We issued 30,000 shares of Series A Preferred Stock to PDL in May 2017. The Series A Preferred Stock had an aggregate liquidation preference of $30.0 million, plus all accrued and unpaid dividends, whether or not declared. In July 2020, we exchanged all 30,000 shares of our Series A Preferred Stock, including any accrued and unpaid dividends thereon, for a total of 3.4 million shares of our common stock. We currently do not have any shares of Series A Preferred Stock outstanding.

In July 2020, we issued an additional 0.7 million shares of our common stock to PDL in exchange for $8.0 million.

On August 4, 2020, PDL committed that through August 5, 2021 it would provide financial support to us of up to $20.0 million to fund our operating, financing and investing activities. This obligation was fulfilled on August 24, 2020 in connection with the receipt of a capital contribution of $29.0 million from PDL. We issued 0.7 million shares of common stock to PDL in exchange for $8.3 million. The remaining $20.7 million was a cash contribution from PDL.

On September 29, 2020, we issued an additional 9,000 shares of additional common stock to PDL in exchange for $0.1 million cash.

Historically, PDL, as our former parent, provided us cash management and other treasury services. Following the Spin-Off, PDL no longer provides such services and our primary sources of liquidity are our cash on hand, cash from the sale and lease of our systems and the sale of our consumables. We may raise additional capital from equity or debt financings or from other sources. As of December 31, 2020, we expect our cash and cash equivalents, together with

cash generated from the sale and lease of our products, to be sufficient to operate our business through the anticipated clearance and launch of ALLY, which is projected to occur in the latter half of 2022.

As we get closer to the commercial launch of ALLY later in 2022, we expect selling, general and administrative expenses to increase from current levels. Clearance of ALLY and its subsequent launch in 2022 is contingent on the regulatory review and discretion of the FDA and is not entirely within our control.

Our liquidity needs will be largely determined by the success of our operations regarding the successful commercialization of our existing products and the progression, anticipated clearance and launch of ALLY in the future. We will need to raise additional capital through equity or debt financings or from other sources to continue our operations beyond 2022. 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. 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.

However, if these sources are insufficient to satisfy our liquidity requirements, we may seek additional funds from public and private stock offerings, borrowings under credit facilities or other sources. Such capital may not be available on favorable terms, or at all. 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. Additionally, the extent and duration of the impact the COVID-19 pandemic 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. We also expect to incur additional costs as a stand-alone public company. 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 of ALLY, our next generation integrated 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 on our business; the timing, scope and magnitude of our commercial and development activities; and the timing of regulatory clearance of ALLY.

Cash Flows

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

	Year Ended December 31,	
(Dollars in thousands)	**2020**	**2019**
Net cash used in operating activities	$ (13,791)	$ (12,589)
Net cash used in investing activities	(326)	(2,089)
Net cash provided by financing activities	50,001	15,949
Net increase in cash, cash equivalents and restricted cash	$ 35,884	$ 1,271

Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $13.8 million, consisting primarily of a net loss of $19.8 million and an increase in net operating assets of $6.2 million, partially offset by non-cash charges of $12.2 million. The increase in net operating assets was primarily due to changes in inventory and accounts receivable, net. Non-cash charges consisted of depreciation, amortization, and stock-based compensation.

Net cash used in operating activities for the year ended December 31, 2019 was $12.6 million, consisting primarily of a net loss of $14.7 million and an increase in net operating assets of $2.4 million, partially offset by non-cash charges of $4.4 million. The increase in net operating assets was primarily due to purchases of inventory offset by changes in accrued liabilities. Non-cash charges consisted of depreciation, amortization, and stock-based compensation.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was $0.3 million, which consisted primarily of capital expenditures for property and equipment.

Net cash used in investing activities for year ended December 31, 2019 was $2.1 million, which consisted primarily of $1.7 million costs to acquire intangible assets and $0.4 million of capital expenditures for property and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $50.0 million, primarily due to capital contributions of $20.7 million, sale of common stock of $16.4 million, proceeds of $12.4 million from the note due to PDL and a $2.4 million contributions from PDL, partially offset by a $1.9 million distributions to PDL.

Net cash provided by financing activities for the year ended December 31, 2019 was $15.9 million, primarily due to the proceeds of $13.2 million from the loan due to PDL and a $3.8 million contributions from PDL, partially offset by a $1.1 million payment of contingent consideration.

Off Balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

Contractual Obligations

The following table summarizes our contractual obligations and commercial commitments as of December 31, 2020:

	Payments Due by Period				
(Dollars in thousands)	Less than 1 year	1-3 years	3-5 years	Thereafter	Total
Operating leases [1]	$ 522	$ 1,089	$ 1,149	$ 1,160	$ 3,920
Purchase obligations [2]	2,388	—	—	—	2,388
Total contractual obligations	$ 2,910	$ 1,089	$ 1,149	$ 1,160	$ 6,308

[1] Amounts represent the lease for the LENSAR corporate office and manufacturing facility in Orlando, Florida.

[2] Consists of a $2.4 million minimum purchase obligation for inventory components for the manufacture and supply of certain components. LENSAR expects to meet these requirements.

Some of the amounts included in this table 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 reflected in the table. Furthermore, the table excludes contingent milestone and royalty payments we could be required to pay in connection with the exclusive license of certain intellectual property.

Critical Accounting Policies and Use of 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 on accounting estimates and judgments on our financial condition and results of operations due to COVID-19 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.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

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 distinct performance obligations are satisfied.

We principally derive our revenue from the sale and lease of the LENSAR Laser System 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 LENSAR Laser System surgical application in connection with a surgery procedure. Without separately procuring procedure licenses granted by us, either together with the purchase of the LENSAR Laser 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 LENSAR Laser 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 products or service is separately identifiable from other promises in the contract.

For contracts involving the sale or lease of the LENSAR Laser System, our performance obligations generally include the LENSAR Laser 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 LENSAR Laser System.

We have determined that the LENSAR Laser 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 LENSAR Laser 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 LENSAR Laser 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 LENSAR Laser 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. LENSAR Laser 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. LENSAR Laser System sales to distributors are recognized as revenue upon shipment.

PID and procedure licenses. The LENSAR Laser 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, which represent a one-time right to utilize the LENSAR Laser System surgical software application, at the point in time when control of the procedure license is transferred to the customer. Control transfers at the time a customer receives the license key. 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. 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 judgement.

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.

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, over 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 impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates. We have not recorded any impairment to our intangible assets for the years ended December 31, 2020 and 2019.

Stock-based compensation

Prior to the Spin-Off, we had an equity incentive plan under which we grant phantom stock units, or PSUs, to LENSAR directors and employees. PSUs are awards in the form of phantom shares, denominated in a hypothetical equivalent number of shares of LENSAR common stock and with the value of each PSU equal to the fair value of LENSAR common stock at the date of grant.

Stock-based compensation is measured at the grant date based on the fair value of the award and is expensed over the requisite service period. The holders of the phantom stock units had the right to receive cash upon settlement. Awards of phantom stock were accounted for as a liability under ASC Topic 718 and changes in the fair value of the Company's liability were recognized as compensation cost over the remaining requisite service period. Changes in the fair value of the liability that occurred after the requisite service period were recognized as compensation cost during the period in which the changes occurred. We remeasured the liability for the outstanding awards at the end of

each reporting period and the compensation cost was based on the change for each reporting period. Forfeitures were accounted for as they occur.

On July 9, 2020, the Board of Directors approved the LENSAR Inc. 2020 Incentive Award Plan (the "2020 Plan"). Under the 2020 Plan, the Company is authorized to issue up to 3,333 shares in the form of stock options, restricted stock, restricted stock unit awards and other stock-based awards. The amount and terms of grants are determined by the Company's Board of Directors or a duly authorized committee thereof.

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.

Common stock valuation

Prior to the Spin-Off, the estimated fair value of our common stock was determined by our board of directors, with input from management. In the absence of a public trading market for the common stock, we developed an estimate of the fair value of the common stock based on the information known on the reporting date, upon a review of any recent events and their potential impact on the estimated fair value, and valuations from an independent third-party valuation firm.

In determining the fair value of our common stock, we established the enterprise value of our company using generally accepted valuation methodologies including discounted cash flow analysis, comparable public company analysis and comparable acquisitions analysis. We then allocated the equity value among the securities that comprised the capital structure of LENSAR using the Black Scholes Option-Pricing model after deducting the liquidation preference of the Series A Preferred Stock. Under the Option-Pricing model, the common stock was modeled as a call option that gave its owner the right but not the obligation to buy the underlying enterprise value at a predetermined or exercise price. Common stock was considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock was liquidated.

The Black-Scholes Option-Pricing model requires the use of highly subjective and complex assumptions which impact the fair value of the common stock, including the option's expected term and the implied volatility of the underlying stock. Because we had not operated as a stand-alone public company, there was a lack of company-specific historical and implied volatility data, and therefore we have estimated stock price volatility based upon an index of the historical volatilities of a group of comparable publicly-traded medical device and pharmaceutical peer companies. We estimated the expected term using our expected time to a liquidity event. We also considered the fact that the stockholders could not freely trade the common stock in the public markets. Accordingly, the estimated fair value reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

The assumptions used in calculating the fair value of stock-based awards represent our best estimates, however the estimates involve inherent uncertainties and judgment and the use of different values could produce materially different results.

Following the Spin-Off, our board of directors determines the fair value of our common stock based on the closing price as reported on the date of grant on Nasdaq.

Income Taxes

We are subject to U.S. federal, state, and local corporate income taxes at the entity level. Prior to the Spin-Off, our losses were included with PDL's consolidated U.S. federal and state income tax returns. Income taxes as presented in our financial statements for periods prior to the Spin-Off have been prepared on the separate return method as if we were a taxpayer separate from PDL. Subsequent to the Spin-Off, income taxes as presented in our financial statements reflect our status as a separate company, filing federal and state income tax returns on a stand-alone basis.

The provision for income taxes is determined using the asset and liability approach. Under this method, we recognize deferred tax assets and liabilities for the temporary differences between the financial reporting and tax basis of assets and liabilities. Deferred tax assets and liabilities are measured using the enacted tax rates that apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

We recognize 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. We adjust 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.

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, 2020.

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

We had cash and cash equivalents of $40.6 million as of December 31, 2020. 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 statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. 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, 2020.

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 LENSAR Laser System's ability to operate for lack of payment

and, in the case of notes receivable, repossess the LENSAR Laser System if scheduled payments lapse. As of December 31, 2020, two customers accounted for 11% and 10% of our accounts receivable, net.

Inflationary factors, such as increases in our costs of revenues and operating expenses, may adversely affect our operating results. Although we do not believe inflation has had a material impact on our financial condition, results of operations or cash flows to date, 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 currently have very infrequent and 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, 2020.

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, 2020 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, 2020, 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Amendment to Bylaws

On March 9, 2021, the Board further amended and restated the Company's amended and restated bylaws (as further amended and restated, the "Amended and Restated Bylaws"), effective immediately, to revise Section 2.4(ii) to include the assumed anniversary date of the preceding year's annual meeting of stockholders for purposes of the Company's first annual meeting of stockholders following the initial registration statement of the Company's common stock pursuant to the Exchange Act, which date shall be deemed to be May 20, 2021.

The foregoing description of the Amendment is qualified by reference to the Amended and Restated Bylaws, a copy of which is attached hereto as Exhibit 3.2.

Annual Meeting Date

Our annual meeting of stockholders is scheduled for May 18, 2021.

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 2021 (the "2021 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

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
2.1+	Separation and Distribution Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	2.1	10/2/2020	
3.1	Amended and Restated Certificate of Incorporation of LENSAR, Inc.	Form 8-K	001-39473	3.1	10/2/2020	
3.2	Amended and Restated Bylaws of LENSAR, Inc.					*
3.3	Amended and Restated Bylaws of LENSAR, Inc. (redlined version of amended section)					*
4.1	Form of Certificate of Common Stock	Form 10/A	001-39473	4.1	09/14/2020	
4.2	Description of Registered Securities					*
10.1+	Transition Services Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	10.1	10/2/2020	
10.2	Tax Matters Agreement between PDL BioPharma, Inc. and LENSAR, Inc.	Form 8-K	001-39473	10.2	10/2/2020	
10.3#	2020 Incentive Award Plan	Form 10	001-39473	10.4	08/26/2020	
10.4#	Form of Restricted Stock Agreement pursuant to 2020 Incentive Award Plan	Form 10	001-39473	10.5	08/26/2020	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.5#	Form of Stock Option Agreement pursuant to 2020 Incentive Award Plan					*
10.6#	2020 Employee Stock Purchase Plan	Form 10/A	001-39473	10.5	09/14/2020	
10.7#	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	
10.8#	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	
10.9#	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	
10.10#	Form of Indemnification Agreement between LENSAR, Inc. and its directors and officers	Form 10	001-39473	10.9	08/26/2020	
10.11†	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	
10.12†	Development Agreement, dated January 29, 2020, by and between LENSAR, Inc. and Oertli Instrumente AG	Form 10	001-39473	10.11	08/26/2020	
10.13+	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	
10.14#	Non-Employee Director Compensation Program, as amended					*
21.1	Subsidiaries of the Registrant					*
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					*
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	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase					*
101.LAB	XBRL Taxonomy Extension Label Linkbase					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					*

+ 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 11, 2021

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

Date: March 11, 2021

/s/ THOMAS R. STAAB, II
Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 Curtis **Nicholas Curtis**	Chief Executive Officer and Director (*principal executive officer*)	March 11, 2021
/s/ Thomas R. Staab, II **Thomas R. Staab, II**	Chief Financial Officer (*principal financial officer and principal accounting officer*)	March 11, 2021
/s/ William Link, PhD **William Link, PhD**	Chairperson of the Board of Directors	March 11, 2021
/s/ Richard Lindstrom, MD **Richard Lindstrom, MD**	Director	March 11, 2021
/s/ John McLaughlin **John McLaughlin**	Director	March 11, 2021
/s/ Elizabeth G. O'Farrell **Elizabeth G. O'Farrell**	Director	March 11, 2021
/s/ Aimee Weisner **Aimee Weisner**	Director	March 11, 2021
/s/ Gary Winer **Gary Winer**	Director	March 11, 2021

LENSAR, Inc.
INDEX TO FINANCIAL STATEMENTS

As of December 31, 2020 and 2019 and for the Years Ended December 31, 2020 and 2019

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, 2020 and 2019, and the related statements of operations, of changes in stockholders' equity (deficit) and of cash flows for 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, 2020 and 2019, 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 audit 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.

/s/ PricewaterhouseCoopers LLP
Tampa, Florida
March 11, 2021

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,	
	2020	**2019**
Revenue		
Product	$ 19,831	$ 23,254
Lease	3,601	4,181
Service	2,950	3,093
Total revenue	26,382	30,528
Cost of revenue (exclusive of amortization)		
Product	8,303	12,030
Lease	1,136	2,264
Service	2,868	3,005
Total cost of revenue	12,307	17,299
Operating expenses		
Selling, general and administrative expenses	23,768	17,147
Research and development expenses	7,553	7,569
Amortization of intangible assets	1,256	1,227
Operating loss	(18,502)	(12,714)
Other income (expense)		
Interest expense	(1,340)	(2,001)
Other income, net	68	58
Net loss attributable to common stockholders	$ (19,774)	$ (14,657)
Net loss per share attributable to common stockholders		
Basic and diluted	$ (4.28)	$ (13.70)
Weighted-average number of shares used in calculation of net loss per share:		
Basic and diluted	4,621	1,070

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,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 40,599	$ 4,615
Accounts receivable, net of allowance of $19 and $0, respectively	2,012	3,384
Notes receivable, net of allowance of $9 and $0, respectively	444	502
Inventories	13,473	8,064
Prepaid and other current assets	1,857	618
Total current assets	58,385	17,183
Property and equipment, net	832	720
Equipment under lease, net	3,583	1,431
Notes and other receivables, long-term, net of allowance of $9 and $0, respectively	452	827
Intangible assets, net	12,110	13,366
Other assets	3,758	1,009
Total assets	$ 79,120	$ 34,536
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,481	$ 1,577
Accrued liabilities	4,570	4,778
Deferred revenue	923	777
Other current liabilities	493	697
Total current liabilities	8,467	7,829
Long-term operating lease liabilities	3,314	333
Note payable due to related party	—	20,200
Series A Preferred Stock	—	36,417
Other long-term liabilities	129	310
Total liabilities	11,910	65,089
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Common stock, par value $0.01 per share, 150,000 and 1,070 shares authorized at December 31, 2020 and 2019, respectively; 10,933 and 1,070 shares issued and outstanding at December 31, 2020 and 2019, respectively	109	11
Additional paid-in capital	125,094	7,621
Accumulated deficit	(57,993)	(38,185)
Total stockholders' equity (deficit)	67,210	(30,553)
Total liabilities and stockholders' equity (deficit)	$ 79,120	$ 34,536

The accompanying notes are an integral part of these financial statements

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

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (19,774)	$ (14,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,309	2,639
Amortization of intangible assets	1,256	1,227
Non-cash operating lease cost	505	537
Provision for bad debts	22	(78)
Write-down of inventory	8	—
Loss on disposal of property and equipment	27	—
Stock-based compensation expense	9,045	102
Changes in operating assets and liabilities:		
Accounts receivable, net	1,332	14
Prepaid and other current assets	(1,239)	(51)
Inventories	(8,697)	(4,773)
Accounts payable	910	127
Accrued liabilities	871	1,929
Other	634	395
Net cash used in operating activities	(13,791)	(12,589)
Cash flows from investing activities		
Acquisition of intangibles	—	(1,700)
Purchase of property and equipment	(366)	(389)
Proceeds from sale of property and equipment	40	—
Net cash used in investing activities	(326)	(2,089)
Cash flows from financing activities		
Contributions from PDL	2,366	3,826
Distributions to PDL	(1,862)	(31)
Proceeds from notes payable due to related party	12,400	13,225
Payment of contingent consideration	—	(1,071)
Sale of common stock to PDL	16,431	—
Capital contribution from PDL	20,666	—
Net cash provided by financing activities	50,001	15,949
Net increase in cash, cash equivalents and restricted cash	35,884	1,271
Cash, cash equivalents and restricted cash at beginning of the year[(1)]	4,715	3,444
Cash, cash equivalents and restricted cash at end the year[(2)]	$ 40,599	$ 4,715

The accompanying notes are an integral part of these financial statements

(1) Includes restricted cash of $100 as of December 31, 2019 and 2018, respectively.
(2) Includes restricted cash of zero and $100 as of December 31, 2020 and 2019, respectively.

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

	Year Ended December 31,	
	2020	2019
Supplemental cash flow information		
Cash paid for interest	$ 478	$ 473
Supplemental schedule of non-cash investing and financing activities		
Transfer from Inventories to Equipment under lease, net	$ 3,280	$ 745
Phantom stock liability settled with common stock	$ 783	$ 784
Modification of phantom stock-based awards	$ 306	$ —
Common stock issued to extinguish Series A Preferred Stock	$ 37,246	$ —
Common stock issued to extinguish note payable due to related party	$ 32,633	$ —

The accompanying notes are an integral part of these financial statements

LENSAR, Inc.
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2018	1,070	$ 11	$ 3,052	$ (23,528)	$ (20,465)
Contributions from PDL	—	—	3,928	—	3,928
Distributions to PDL	—	—	(143)	—	(143)
Settlement of phantom stock-based awards	—	—	784	—	784
Net loss	—	—	—	(14,657)	(14,657)
Balance as of December 31, 2019	1,070	11	7,621	(38,185)	(30,553)
Impact of adoption of ASC 326	—	—	—	(34)	(34)
Impact from recapitalization transactions	6,221	62	69,817	—	69,879
Sale of common stock to PDL	1,496	15	16,416	—	16,431
Capital contribution from PDL	—	—	20,666	—	20,666
Issuance of common stock, net of cancellations	2,146	21	(21)	—	—
Stock-based compensation under the 2020 Plan	—	—	8,849	—	8,849
Contributions from PDL	—	—	2,518	—	2,518
Distributions to PDL	—	—	(1,861)	—	(1,861)
Settlement of phantom stock-based awards	—	—	783	—	783
Modification of phantom stock-based awards	—	—	306	—	306
Net loss	—	—	—	(19,774)	(19,774)
Balance as of December 31, 2020	10,933	$ 109	$ 125,094	$ (57,993)	$ 67,210

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 astigmatisms to achieve improved vision outcomes for patients. The Company's revenue is derived from the sale and lease of the LENSAR Laser System, 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.

In September 2020, the Company's former parent entity, PDL BioPharma, Inc. ("PDL") announced its plans to pursue a separation and distribution of its medical device segment, which was solely comprised of its majority-owned subsidiary, LENSAR. On October 1, 2020, the previously planned spin-off was completed in the form of a dividend involving the distribution of substantially all outstanding shares of LENSAR common stock owned by PDL to holders of PDL common stock ("Spin-Off" or the "Distribution"). The Distribution was made to PDL's stockholders of record as of the close of business on September 22, 2020 (the "Record Date") and such stockholders received 0.075879 shares of LENSAR common stock for one PDL common share held as of close of business on the Record Date. Prior to the Distribution, PDL owned approximately 81.5% of LENSAR common stock. Following the completion of the distribution, PDL does not own any equity interest in LENSAR. LENSAR became an independent public company whose stock is listed and trading under the symbol "LNSR" on the Nasdaq Stock Market ("Nasdaq").

On September 10, 2020, the Company amended its amended and restated certificate of incorporation to effect a one-for-nine reverse stock split of the Company's common stock. The par value of the Company's common stock and the total number of shares of common stock that the Company is authorized to issue remained unchanged.

All issued and outstanding shares of common stock, other common stock share numbers, equity awards and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

The Company has incurred recurring losses and operating cash outflows since its inception and as of December 31, 2020 had an accumulated deficit of $57,993. The Company expects to continue to incur losses and cash outflows from operating activities for the foreseeable future. In addition, the Company's results of operations, financial condition and cash flows have been adversely affected by the COVID-19 pandemic. The extent to which the COVID-19 outbreak will further negatively impact the Company's business or operating results cannot be determined with certainty at this time. In geographies in which the Company or its customers, partners and service providers operate, health concerns as well as political or governmental developments in response to COVID-19 could result in further economic, social or labor instability or prolonged contractions in the industries in which the Company's customers or partners operate, slow the sales process, result in customers not purchasing or renewing the Company's products or failing to make payments, and could otherwise have a material adverse effect on the Company's business and results of operations and financial condition.

During the year ended December 31, 2020, PDL and the Company entered into a series of recapitalization transactions and capital contribution transactions as described below. Management believes the Company's cash and cash equivalents on hand provides sufficient liquidity to meet the Company's obligations for a period of at least twelve months from the date of issuance of the 2020 financial statements. The Company anticipates submitting an application for 510(k) clearance of ALLY, its next generation integrated cataract treatment system, to the United States Food and Drug Administration ("FDA") by the end of the first quarter of 2022. As the Company gets closer to the commercial launch of ALLY later in 2022, it expects selling, general and administrative expenses to increase from current levels. Clearance of ALLY and its subsequent launch in 2022 is contingent on the regulatory review and discretion of the FDA and is not entirely within the Company's control.

The Company's liquidity needs will be largely determined by the success of its operations regarding the successful commercialization of its existing products and the progression, clearance and launch of ALLY in the future. The

Company will need to raise additional capital through equity or debt financings or from other sources to continue its operations beyond 2022. 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.

Description of the Recapitalization Transactions and Capital Contributions

On July 10, 2020, the Company amended and restated its certificate of incorporation to, among other things, (a) increase the number of shares of common stock ($0.01 par value per share) the Company is authorized to issue to 150,000 shares and (b) issue to PDL a total of 3,415 shares of the Company's common stock in exchange for the extinguishment of all 30 shares of the Company's Series A Preferred Stock, including any accrued and unpaid dividends thereon (the "Series A Preferred Stock Recapitalization"). As of December 31, 2020, the Company does not have any shares of Series A Preferred Stock outstanding.

On July 13, 2020, the Company and PDL entered into a contribution and exchange agreement whereby the Company issued to PDL a total of 2,806 shares of the Company's common stock in exchange for the extinguishment of the $32,600 outstanding that the Company owed PDL under the loan agreement (the "Note Payable Recapitalization").

The Series A Preferred Stock Recapitalization, together with the Note Payable Recapitalization, is defined as the "Recapitalization Transactions". The Recapitalization Transactions resulted in the issuance of 6,221 shares of common stock with a fair value of $67,188 to extinguish an aggregate of $69,879 carrying value of liabilities recognized for the Series A Preferred Stock inclusive of accumulated dividend and loans outstanding under the loan agreement inclusive of accrued interest, resulting in an approximate $2,691 extinguishment gain recorded in additional paid-in capital during the year ended December 31, 2020. The estimated fair value of the common stock was determined by the board of directors, with input from management. In the absence of a public trading market for the common stock, the Company developed an estimate of the fair value of the common stock based on the information known as of the date of the Recapitalization Transactions, upon a review of any recent events and their potential impact on the estimated fair value, and valuations from an independent third-party valuation firm. Valuations of the Company's common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. In evaluating the fair value of common stock, the Company first established the enterprise value of the Company using generally accepted valuation methodologies including discounted cash flow analysis, comparable public company analysis and comparable acquisitions analysis. Then the Company allocated the equity value among the fully diluted shares outstanding as a result of the Recapitalization Transactions.

On July 21, 2020, the Company issued an additional 740 shares of common stock to PDL in exchange for $8,000 in cash (the "Capital Contribution").

On August 4, 2020, PDL committed that through August 5, 2021 it would provide financial support of up to $20,000 to support the operating, investing and financing activities of the Company. On August 24, 2020, the Company received cash of $29,000 from PDL (the "Additional Capital Contribution"). The Company issued 747 shares of common stock to PDL in exchange for $8,334. The remaining $20,666 was a cash contribution from PDL. In connection with the Additional Capital Contribution, PDL's financial support under its commitment on August 4, 2020 was fulfilled.

On September 29, 2020, the Company issued an additional nine shares of additional common stock to PDL in exchange for $97 in cash.

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").

Prior to the Spin-Off, these financial statements were prepared on a stand-alone basis derived from the consolidated financial statements and accounting records of PDL and are presented as if LENSAR had been operating as a stand-alone company for all years presented. These financial statements exclude the assets, liabilities, revenue and expenses directly attributable to LENSAR's wholly-owned subsidiary, PDL Investment Holdings, LLC ("PDLIH"). On August 20, 2020, the Company distributed 100% of its ownership interest in its wholly owned subsidiary, PDLIH, to PDL. This distribution does not result in U.S. Federal or State income tax effects due to an election made by the Company and PDL following the Company's separation from PDL under Internal Revenue Code ("IRC") Section 336(e), which provides for a recharacterization of the distribution of stock as a deemed sale of assets for tax purposes. This election was made following the Spin-Off of all outstanding shares of LENSAR common stock owned by PDL to holders of PDL common stock. For periods following the Spin-Off, these financial statements were prepared on a stand-alone basis from the Company's accounting records.

During the periods prior to the Spin-Off presented in these financial statements, the operations of the Company were included in the consolidated U.S. federal and state income tax returns filed by PDL. Income tax expense and other income tax related information contained in the financial statements for those periods are presented on a separate return basis as if the Company had filed its own tax returns. For income tax purposes, LENSAR and PDL jointly made an election under IRC Section 336(e), which provides for a recharacterization of the Distribution of stock as a deemed sale of assets. This election was made following the Spin-Off and is effective as of October 2, 2020. As a result of this election, LENSAR's research and development credits and net operating losses remain with PDL, and LENSAR recorded a tax-basis step up adjustment to reflect the fair value of all assets and liabilities on the date of the Spin-Off for tax purposes. In periods following the Spin-Off, LENSAR will file federal and state tax returns separate from PDL. The deferred income taxes of the Company as presented in these financial statements for periods prior to the Spin-Off, including tax attributes such as net operating losses or credit carryforwards, may not be indicative of the deferred tax assets available to the Company. For periods following the Spin-Off, tax attributes and deferred tax assets are indicative of LENSAR's status as a separate Company for federal and state tax return filing purposes. See Note 14, *Income Taxes*, for more information.

Prior to the Spin-Off, the assets, liabilities, revenue and expenses directly attributable to the Company's operations have been reflected in these financial statements on a historical cost basis, as included in the consolidated financial statements of PDL. The statements of operations include expenses for certain corporate support functions that were provided by PDL such as administration and organizational oversight; including employee benefits, finance and accounting, treasury and risk management, professional and legal services, among others. These expenses have been allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on a proportional basis of expenses of the Company and PDL. Management of the Company and PDL considered the basis on which the expenses have been allocated to be a reasonable reflection of the utilization of services provided to or the benefit received by the Company during the periods presented. These allocations may not be reflective of the expenses that would have been incurred had the Company operated as a separate, unaffiliated entity apart from PDL. Actual costs that would have been incurred if LENSAR had been a stand-alone, public company would depend on multiple factors, including the chosen organizational structure and strategic decisions made in various areas, including information technology and infrastructure. Following its separation on October 1, 2020, the Company performs these functions using its own resources or purchased services. For an interim period in 2021, however, some of these functions will continue to be provided by PDL as the Company entered into a transition service agreement with PDL in connection with the separation.

The Company was historically funded as part of PDL's treasury program prior to the Spin-Off. Cash and restricted cash managed through bank accounts legally owned by PDL at the corporate level were not attributable to the Company for any of the periods presented. Only cash and restricted cash legally owned by the Company are reflected in the balance sheets. All significant transactions between the Company and PDL were considered to be effectively settled for cash at the time the transaction is recorded, unless otherwise noted. Such transfers of cash to and from PDL

have been included in these financial statements as a component of equity in the balance sheets and as a financing activity in the statements of cash flows, unless otherwise noted.

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, cost allocations from PDL, 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 full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, reserves and allowances, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on domestic and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future 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, 2020 and 2019, 100% and 98% 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, by policy, limits the amount of credit exposure in any one financial instrument.

Restricted Cash

Restricted cash primarily consists of funds reserved for bank business credit card service. The Company had $0 and $100 restricted cash as of December 31, 2020 and 2019, respectively. Restricted cash balances are included in Other assets within the Company's balance sheets.

Accounts Receivable

The Company had $37 and zero for allowance for credit losses as of December 31, 2020 and 2019, 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.

As a result of the impact of COVID-19 as discussed above, the Company determined certain impairment triggers had occurred during the three months ended March 31, 2020 related to the Company's finite-lived tangible and intangible assets. Accordingly, the Company analyzed undiscounted cash flows at the asset group level for certain finite-lived tangible and intangible assets as of March 31, 2020. Based on that undiscounted cash flow analysis, the Company determined that estimated undiscounted future cash flows substantially exceeded their net carrying values, and,

therefore, as of March 31, 2020, the Company's finite-lived tangible and intangible assets were not impaired. The Company did not record any impairment of its intangible assets for the years ended December 31, 2020 and 2019.

Property and Equipment

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

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

Equipment Under Lease

Equipment under lease is related to LENSAR laser 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.

Note Payable Due to Related Party

Amounts loaned to the Company from PDL related to funding the Company's operations and were carried at the principal amount borrowed and accrued interest using the effective interest method. Balances that were due to PDL were to be cash settled and have been included in the balance sheets. Cash proceeds received from PDL to fund the Company's operations have been classified in the statements of cash flows as financing activities.

Series A Preferred Stock

The Company assessed the preferred stock's provisions including redemption rights, dividends, voting rights and covenants to determine the classification of redeemable preferred stock. The Company's preferred stock was mandatorily redeemable with cumulative dividends at a fixed rate and was to be cash settled at redemption. Therefore, LENSAR's preferred stock was classified as a liability in the balance sheets and accreted to the redemption value at redemption using the effective interest method. Refer to Note 10, *Series A Preferred Stock*.

Revenue Recognition

The reported results reflect the application of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not substantially completed as of the date of adoption. ASC Topic 340-40, *Contracts with customers* ("ASC 340") was adopted on the same date and using the same methodology as ASC 606.

Policy Elections and Practical Expedients Taken

Upon the Company's adoption of ASC 606, the Company applied 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, 2020 and 2019 were $90 and $100, respectively.

General

In accordance with ASC 606, 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 LENSAR 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.

LENSAR principally derives its revenue from the sale and lease of the LENSAR Laser System 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 LENSAR Laser System and the sale of other related products and services. For bundled packages, which include the sale or lease of a LENSAR Laser 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 LENSAR Laser 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 LENSAR Laser 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 sales are recognized as Product revenue when the Company transfers control of the system. This usually occurs after the customer signs a contract, LENSAR installs the system, and LENSAR performs the requisite training for use of the system for direct customers. LENSAR Laser System sales to distributors are recognized as revenue upon shipment as they do not require training and installation.
>
> *PID and Procedure Licenses*. The LENSAR Laser System requires 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 LENSAR Laser 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 LENSAR Laser 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 6, *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, 2020, three customers each accounted for 12% of the Company's revenue, respectively, and two customers accounted for 11% and 10% of the Company's accounts receivable, net as of December 31, 2020, respectively. For the year ended December 31, 2019, two customers accounted for 26% and 11% of the Company's revenue, respectively, and one customer accounted for 25% of the Company's accounts receivable, net as of December 31, 2019.

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, prototyping, testing, materials, travel expenses, and depreciation.

In September 2019, LENSAR exclusively licensed certain intellectual property from a third-party for $3,500 in cash for use in research and development activities. The amount was immediately expensed and is included in research and development expense in the statements of operations for the year ended December 31, 2019 because it had no alternative future use. The cash consideration transferred has been classified in the statements of cash flows as an operating activity.

Asset Acquisitions

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. Contingent consideration in asset acquisitions payable in the form of cash is recognized when payment becomes probable and reasonably estimable, unless the contingent consideration meets the definition of a derivative, in which case the amount becomes part of the asset acquisition cost when acquired. Upon recognition of the contingent consideration payment, the amount is included in the cost of the acquired asset or group of assets.

Income Taxes

The Company is subject to U.S. federal, state, and local corporate income taxes at the entity level. Prior to the Spin-Off, the Company's losses were included with PDL's consolidated U.S. federal and state income tax returns. Income

taxes as presented in the Company's financial statements for periods prior to the Spin-Off have been prepared on the separate return method as if the Company were a taxpayer separate from PDL. Subsequent to the Spin-Off, income taxes as presented in the Company's financial statements reflect our status as a separate Company, filing federal and state income tax returns on a stand-alone basis.

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 adopted ASC Topic 842, *Leases*, on January 1, 2019 using the modified retrospective method for all leases not substantially completed as of the date of adoption. The cumulative impact of the adoption of ASC 842 was not material, therefore, the Company did not record any adjustments to retained earnings. As a result of adopting ASC 842, the Company recorded operating lease right-of-use ("ROU") assets of $1,390 and operating lease liabilities of $1,424, primarily related to the corporate office lease, based on the present value of the future lease payments on the date of adoption. Changes to lessor accounting focused on conforming with certain changes made to lessee accounting and the recently adopted revenue recognition guidance. The adoption of ASC 842 did not materially change how the Company accounts for lessor arrangements.

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 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 Other current 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 LENSAR Laser 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 LENSAR Laser 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 4, *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, 2020 and 2019, 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 13, *Stock-Based Compensation,* for a discussion of stock-based compensation plans.

Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASC 326"). The new guidance amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in more timely recognition of losses. The Company adopted ASU No. 2016-13 on January 1, 2020 using a modified retrospective approach. The adoption resulted in a $34 adjustment to the Company's accumulated deficit opening balance within the balance sheets. As a consequence of adopting ASU 2016-13, the Company's accounts and notes receivable accounting policy has been updated.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software*. The new guidance reduces complexity for the accounting for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The Company adopted ASU No. 2018-15 on January 1, 2020 using the prospective transition option. The adoption did not have a material impact on the financial statements.

In April 2020, the FASB issued a staff question-and-answer document, "Topic 842 and Topic 840: Accounting for Lease Concessions Related to the Effects of the COVID-19 Pandemic" (the "COVID-19 Q&A"), to address certain frequently-asked questions pertaining to lease concessions arising from the effects of the COVID-19 pandemic. Existing lease guidance requires entities to determine if a lease concession was a result of a new arrangement reached with the lessee (which would be addressed under the lease modification accounting framework) or if a lease concession was under the enforceable rights and obligations within the existing lease agreement (which would not fall under the lease modification framework). The COVID-19 Q&A clarifies that entities may elect to not evaluate whether lease-related relief granted in light of the effects of COVID-19 is a lease or obligations of the lease. This election is available for concessions that result in the total payments required by the modified contract being substantially the same or less than the total payments required by the original contract.

The Company elected to account for lease concessions related to the effects of the COVID-19 pandemic in accordance with the COVID-19 Q&A. LENSAR entered into agreements with 23 customers through which LENSAR agreed to waive monthly rental fees ranging from one to three months. A total of $335 in lease revenue was not recognized during the year ended December 31, 2020 related to the waived lease payments. There were no concessions provided for any non-lease components of the lease arrangements. In return for these concessions the related contracts were extended by the same number of months waived. No amounts of accounts receivable or notes receivable were deemed

uncollectible due to COVID-19 as of December 31, 2020; however, the Company considered the effects of COVID-19 in estimating its credit losses for the period.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12 ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC Topic 740, *Income Taxes*, and also clarifies and amends existing guidance to improve consistent application. The amendments in ASU 2019-12 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements and related disclosures and does not expect the adoption of ASU 2019-12 to have a material impact.

Note 3. Asset Acquisitions

In January 2018, LENSAR entered into an agreement with a domestic distributor to purchase assets used in the distributors' laser-assisted cataract surgery business. The transaction was closed on January 8, 2018 as the acquisition date. The assets purchased include equipment, inventory and the distributor's customer relationships. No workforce was transferred as part of the transaction. The transaction was accounted for as an asset acquisition as the acquired assets did not constitute a business under U.S. GAAP. In connection with the acquisition, the Company contingently agreed to make payments related to milestones based on future operating performance during the 12 months following the close of the acquisition date, for a total value of up to $1,929 at the acquisition date. The Company's payments for the contingent consideration were $1,071 during the year ended December 31, 2019. The contingent liability was paid in full as of December 31, 2019.

In December 2018, LENSAR entered into an agreement with a medical technology company to license certain patents and to obtain an option to purchase the medical technology company's assets. The transaction was closed on April 9, 2019 as the acquisition date. LENSAR had 120 days to exercise the option and three months thereafter to negotiate the terms of the final purchase agreement. In April 2019, LENSAR entered into an agreement with the medical technology company to purchase patents, intellectual property, and products. The assets purchased included patents, patent applications, intellectual property, and prototypes. No workforce was transferred as part of the transaction. The Asset Assignment Agreement also provides for an additional $300 in contingent consideration if certain patents are revived. The full contingent consideration was included in the purchase price at the time of the acquisition. The contingent consideration was paid during 2019. The transaction was accounted for as an asset acquisition as the acquired assets did not constitute a business under U.S. GAAP.

The following table summarizes the identifiable assets acquired:

	Amount
Intangible assets	$ 2,300
Total identifiable assets	$ 2,300

The following table summarizes the purchase price:

	Amount
Consideration paid for the License and Option Agreement	$ 300
Cash consideration paid at closing	1,700
Contingent consideration	300
Total consideration	$ 2,300

Note 4. 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, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
United States	$ 11,604	$ 10,918
South Korea	3,077	7,876
Europe	3,588	3,448
Asia (excluding South Korea)	4,193	3,664
Other	319	441
Total[1]	$ 22,781	$ 26,347

1 The table above does not include lease revenue of $3,601 and $4,181 for the years ended December 31, 2020 and 2019, respectively. Refer to Note 6, *Leases*.

Contract Balances

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

		As of December 31,	
	Classification	2020	2019
Accounts receivable, current	Accounts receivable, net	$ 2,012	$ 3,384
Notes receivable, current	Notes receivable, net	$ 444	$ 502
Notes receivable, long-term	Notes and other receivables, long-term, net	$ 452	$ 827
Contract liability, current	Deferred revenue	$ 923	$ 777
Contract liability, non-current	Other long-term liabilities	$ 128	$ 118

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 creditworthiness, 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 January 1, 2020	$ —
Impact of adoption of ASC 326	15
Change in provision for credit losses	24
Write-offs	(20)
Accounts receivable, allowance for credit losses as of December 31, 2020	$ 19

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 5.75%.

The Company recorded interest income on notes receivable during the years ended December 31, 2020 and 2019 of $54 and $53 in other income, net in its statements of operations.

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

	Amount
Notes receivable, allowance for credit losses as of January 1, 2020	$ —
Impact of adoption of ASC 326	19
Change in provision for credit losses	(1)
Write-offs	—
Notes receivable, allowance for credit losses as of December 31, 2020	$ 18

Maturities of notes receivables, net under extended payment terms with a significant financing component as of December 31, 2020 are as follows:

Fiscal Year	Amount
2021	$ 483
2022	350
2023	126
2024	—
2025	—
Thereafter	—
Total undiscounted cash flows	959
Present value of notes receivable	914
Difference between undiscounted and discounted cash flows	$ 45

Contract Liabilities—The Company's contract liabilities consist of deferred revenue related to services and products sold to customers for which the performance obligation has not been completed by the Company. The Company classifies deferred revenue 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, 2018	$ 994
Billings not yet recognized as revenue	739
Beginning contract liabilities recognized as revenue	(838)
Contract liabilities at December 31, 2019	895
Billings not yet recognized as revenue	880
Beginning contract liabilities recognized as revenue	(724)
Contract liabilities at December 31, 2020	$ 1,051

Transaction Price Allocated to Future Performance Obligations

At December 31, 2020, 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 $7,505. The Company expects to satisfy its remaining performance obligations over the next four years, with $4,187 to be satisfied in the next twelve months, $2,274 to be satisfied in the next two years, and $1,044 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, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Beginning balance	$ 190	$ 80
Additions	379	452
Amortization	(460)	(342)
Ending balance	$ 109	$ 190

Note 5. Inventories

Inventory balances were as follows:

	As of December 31,	
	2020	2019
Finished Goods	$ 10,551	$ 3,156
Work-in-progress	319	1,170
Raw Materials	2,603	3,738
Total	$ 13,473	$ 8,064

Write downs of inventories to net realizable value for the years ended December 31, 2020 and 2019 were immaterial.

Note 6. Leases

Lessee Arrangements

The Company has an operating lease for a corporate office. On August 20, 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 6.9 years as of December 31, 2020, and contains an option to extend the lease for five years.

The components of lease expense are as follows:

	Year Ended December 31,	
	2020	2019
Operating lease cost	$ 543	$ 576
Short-term lease cost	9	8
Total lease cost	$ 552	$ 584

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

	Year Ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 413	$ 575
Right-of-use-assets obtained in exchange for lease obligations:		
Operating leases	$ 3,320	$ 1,390

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	2020	2019
Operating lease ROU assets	Other assets	$ 3,668	$ 853
Operating lease liabilities, current	Other current liabilities	$ 493	$ 555
Operating lease liabilities, long-term	Long-term operating lease liabilities	3,314	333
Total operating lease liabilities		$ 3,807	$ 888
Weighted-average remaining lease term		6.9 years	1.6 years
Weighted-average discount rate		10.00%	6.04%

Maturities of operating lease liabilities as of December 31, 2020 are as follows:

Fiscal Year	Amount
2021	$ 522
2022	537
2023	552
2024	567
2025	582
Thereafter	1,160
Total operating lease payments	3,920
Less: imputed interest	(113)
Total operating lease liabilities	$ 3,807

Lessor Arrangements

The Company has operating leases for the LENSAR Laser System, 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, 2020 and 2019 was as follows:

	Year ended December 31,	
	2020	2019
Lease revenue	$ 3,601	$ 4,181

Equipment under lease is as follows:

	As of December 31,	
	2020	2019
Equipment under lease	$ 9,343	$ 6,749
Less accumulated depreciation	(5,760)	(5,318)
Equipment under lease, net	$ 3,583	$ 1,431

Depreciation expense on equipment under lease amounted to $1,037 and $2,252 for the years ended December 31, 2020 and 2019, respectively.

Maturities of operating lease payments as of December 31, 2020 are as follows:

Fiscal Year	Amount
2021	$ 4,187
2022	2,274
2023	1,044
2024	—
2025	—
Thereafter	—
Total undiscounted cash flows	$ 7,505

Note 7. Property and Equipment

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

	As of December 31,	
	2020	2019
Leasehold improvements	$ 112	$ 107
Manufacturing equipment	269	203
Computer and office equipment	107	98
System and laser	1,452	1,304
Furniture and fixtures	50	50
Transportation equipment	38	76
Total	2,028	1,838
Less accumulated depreciation	(1,876)	(1,543)
Construction in progress	680	425
Property and equipment, net	$ 832	$ 720

Depreciation expense on property and equipment amounted to $272 and $387 for the years ended December 31, 2020 and 2019, 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 $680 and $425 as of December 31, 2020 and 2019, respectively.

Note 8. Intangible Assets

In April 2019, LENSAR acquired certain intellectual property from a third-party for $2,000 in cash and contingent obligations to pay a $300 milestone payment and royalties upon the completion of certain events. The $300 milestone payment was paid prior to December 31, 2019. See Note 3, *Asset Acquisitions*, for more information.

The components of intangible assets were as follows:

	As of December 31, 2020			As of December 31, 2019		
	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	$ (1,326)	$ 2,966	$ 4,292	$ (951)	$ 3,341
Acquired technology [1,3]	11,500	(2,508)	8,992	11,500	(1,741)	9,759
Acquired trademarks [1]	570	(418)	152	570	(304)	266
	$ 16,362	$ (4,252)	$ 12,110	$ 16,362	$ (2,996)	$ 13,366

1 Certain intangible assets were established upon PDL's acquisition of LENSAR in May 2017. They are being amortized on a straight-line basis over a weighted-average 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 LENSAR 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 LENSAR 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.

Amortization expense for the years ended December 31, 2020 and 2019 was $1,256 and $1,227, respectively.

Based on the intangible assets recorded at December 31, 2020, 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
2021	$ 1,240
2022	1,149
2023	1,097
2024	1,085
2025	1,074
Thereafter	6,465
Total remaining estimated amortization expense	$ 12,110

Note 9. Accrued Liabilities

Accrued liabilities consist of the following:

	As of December 31,	
	2020	2019
Compensation	$ 2,971	$ 3,972
Professional services	1,271	498
Warranty	79	58
Other	249	250
Total	$ 4,570	$ 4,778

Note 10. Series A Preferred Stock

The Company authorized and issued 30 shares of Series A preferred stock, par value $0.01, to PDL in May 2017. The Series A preferred stock has an aggregate liquidation preference of $30,000 ("stated value"), plus all accumulated and unpaid dividends (whether or not declared). Dividends on each share of preferred stock initially accrued on an annual

basis at a rate of 15.00% per annum of the stated value, and subsequently decreased to 5.0% per annum of the stated value effective January 1, 2019 as amended in December 2018.

Dividends were to be payable when and if declared by the board of directors. No dividends were declared by the board of directors from the time of issuance to the Series A Preferred Stock Recapitalization.

The Series A Preferred Stock was accounted for as a liability on the Company's balance sheets because it was mandatorily redeemable. Upon completion of the Series A Preferred Stock Recapitalization, the Company does not currently have any shares of Series A Preferred Stock outstanding. See Note 1, *Overview and Basis of Presentation*, for more information on the Series A Preferred Stock Recapitalization. Interest expense recognized on the Series A Preferred Stock was $829 and $1,528 for the years ended December 31, 2020 and 2019, respectively.

Note 11. Commitments and Contingencies

Purchase Obligation

LENSAR entered into various supply agreements for the manufacture and supply of certain components. The supply agreements commit LENSAR to a minimum purchase obligation of approximately $2,388 over the next 12 months. LENSAR expects to meet these requirements. LENSAR made purchases of $1,936 and $9,600 under these supply agreements during the year ended December 31, 2020 and 2019, respectively.

Royalty and Milestone Payments

In connection with the exclusive license of certain intellectual property (refer to Note 2, *Summary of Significant Accounting Policies*, Research and Development) the Company could be required to make milestone payments in the amount of $2,400, which are contingent upon the regulatory approval and commercialization of the next generation integrated cataract treatment system. In addition, the Company acquired certain intellectual property, which if used in the development of the next generation system could result in additional royalty payments at a rate of 3%.

Legal Matters

The medical device market in which LENSAR 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 12. Stockholders' Equity (Deficit)

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, 2020 and 2019.

Note 13. Stock-Based Compensation

Phantom Stock Plan

LENSAR had a phantom stock plan under which it granted phantom stock units ("PSUs") to LENSAR directors and employees. In connection with the Company's issuance of restricted stock awards under the 2020 Plan (as defined below), all remaining outstanding awards under the Phantom Stock Plan were cancelled, and no further awards are outstanding under such plan. As such, the liability recorded for unvested phantom stock units was remeasured at fair value immediately prior to the modification on July 22, 2020, which resulted in a decrease in fair value of $108. The fair value of $306 was reclassified from Accrued liabilities to Additional paid-in capital on the modification date. The

fair value of the underlying common stock was determined using preliminary valuation techniques with the most reliable information currently available.

The total shares authorized for grant were 0 and 1,560 as of December 31, 2020 and 2019, respectively.

The estimated fair value of the common stock underlying the PSUs was determined by the board of directors, with input from management. In the absence of a public trading market for the common stock, the Company developed an estimate of the fair value of the common stock based on the information known on the reporting date, upon a review of any recent events and their potential impact on the estimated fair value, and valuations from an independent third-party valuation firm. Valuations of the Company's common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. In evaluating the PSUs, the Company first established the enterprise value of the Company using generally accepted valuation methodologies including discounted cash flow analysis, comparable public company analysis and comparable acquisitions analysis. Prior to the Recapitalization Transactions, the Company then allocated the equity value among the securities that comprised the capital structure of the Company using the Black Scholes Option-Pricing model after deducting the liquidation preference. Under the Option-Pricing model, the common stock was modeled as a call option that gives its owner the right but not the obligation to buy the underlying enterprise value at a predetermined or exercise price. Common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock is liquidated. After the Recapitalization Transactions, the Company then allocated the equity value among the fully diluted shares outstanding as a result of the Recapitalization Transactions.

The fair value of the Company's common stock, as used for purposes of determining the fair value of the PSUs, was estimated using the following assumptions:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.1 - 0.2%	1.6%
Expected term (years)	0.11 - 0.25	3
Expected volatility	55 - 70%	60%
Dividends	0.0%	0.0%
Marketability discount	4 - 8%	23%

Expected term: As its share-based compensation awards were generally non-transferrable and represented in substance a liquidation interest in the Company, the Company estimated the expected term input to the Black-Scholes model to be equivalent to the Company's expected time to a liquidity event.

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 time to liquidity of the Company's common stock.

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 over the time to liquidity 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.

Marketability discount: The estimated fair value reflected a non-marketability discount to reflect the fact that the stockholders could not freely trade the common stock in the public markets and was based on the anticipated likelihood and timing of a liquidity event.

As of December 31, 2020 and 2019, the Company's liabilities related to the PSU recorded in liabilities were zero and $1,179, respectively. The fair value of the PSUs as of December 31, 2019 was $14.94. The following table summarizes the phantom share activity during the years ended December 31, 2020 and 2019:

	2020		2019	
	Number of Units	Weighted-average grant-date fair value per share	Number of Units	Weighted-average grant-date fair value per share
Non-vested at beginning of year	43	$ 6.39	109	$ 6.39
Granted	—	$ —	6	$ 10.80
Vested	(6)	$ 6.39	(71)	$ 6.75
Forfeited	—	$ —	(1)	$ 6.39
Cancelled	(37)	$ 6.39	—	$ —
Non-vested at end of year	—	$ —	43	$ 6.39

During the year ended December 31, 2020, six shares were transferred from PDL to settle vested shares. As of December 31, 2020, zero units are vested but unsettled.

Stock-Based Incentive Plans

The 2020 Plan

On July 9, 2020, the Board of Directors approved the LENSAR Inc. 2020 Incentive Award Plan (the "2020 Plan"). Under the 2020 Plan, the Company is authorized to issue up to 3,333 shares in the form of stock options, restricted stock, restricted stock unit awards and other stock-based awards. 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 generally satisfy the tax liability in cash or in stock.

Restricted Stock Awards

On July 22, 2020, the Board of Directors approved the grants of 1,847 shares of restricted stock in connection with the proposed Spin-Off to certain individuals under the 2020 Plan in consideration of future services to be rendered to the Company. The aggregate grant date fair value of these restricted stock awards was determined to be $19,951 or $10.80 per share based on the fair value of the underlying common stock using preliminary valuation techniques with the most reliable information currently available. The vesting schedule of the restricted stock awards is (i) 40% vest on the later of three months following the completion of the proposed Spin-Off or six months following the grant date (provided the proposed Spin-Off has occurred prior to such date), (ii) 30% vest 18 months following grant date, and (iii) 30% vest 36 months following grant date.

On October 1, 2020, the Board of Directors modified certain July 22, 2020 restricted stock awards to waive the excess share forfeiture restriction. A total of 18 shares of restricted stock awards were released under this waiver. The incremental fair value of the modified awards was not material and the vesting schedule did not change.

On October 6, 2020, the Board of Directors approved grants of four shares of restricted stock to certain individuals under the 2020 Plan in consideration of future services to be rendered to the Company. The aggregate grant date fair value of these restricted stock awards was determined to be $46 or $10.90 per share based on the fair value of the underlying common stock as determined as the closing market price as quoted by Nasdaq. The vesting schedule of the restricted stock awards is (i) 40% vest on January 22, 2021, (ii) 30% vest on January 22, 2022, and (iii) 30% vest on July 22, 2023.

On December 7, 2020, the Board of Directors modified certain July 22, 2020 restricted stock awards to board members and executives to amend and extend the vesting schedules applicable to the July 22, 2020 restricted stock awards. In order to comply with tax laws and to recognize the individuals' agreement to the extension to the vesting schedule of the July 22, 2020 restricted stock awards, each individual was issued an additional restricted stock award, which represents 20% of the total number of shares subject to the July 22, 2020 restricted stock award, totaling 305 additional shares of restricted stock. The aggregate grant date fair value of the additional restricted stock awards was determined to be $2,201 or $7.22 per share based on the fair value of the underlying common stock as determined as the closing market price as quoted by Nasdaq. No additional incremental fair value of the modified restricted stock awards will be recorded as the fair value of common stock on the date of modification was less than the grant date fair value. The modified and newly granted restricted stock awards provide for vesting in quarterly installments over the three-year period following the modification date.

The following table summarizes the restricted stock award activity under the 2020 Plan for the year ended December 31, 2020:

	2020	
	Number of Units	Weighted-average grant-date fair value per share
Non-vested at beginning of year	—	$ —
Granted	2,174	$ 10.30
Vested	(96)	$ 10.19
Cancelled	(28)	$ 10.89
Non-vested at end of year	2,050	$ 10.30

Prior to the Spin-off, the estimated fair value of the common stock was determined as described above. After the Spin-off, the fair value of common stock was determined as the closing market price as quoted by Nasdaq.

The total fair value of restricted stock awards vested during the years ended December 31, 2020 and 2019 was $970 and zero, respectively.

The weighted-average grant date fair value for restricted stock awards granted under the 2020 Plan for the year ended December 31, 2020 was $10.30. No awards were granted under the 2020 Plan during the year ended December 31, 2019.

At December 31, 2020, there was approximately $13,231 of total unrecognized compensation expense related to restricted stock awards, which is expected to be recognized over a weighted-average period of 1.3 years. The unrecognized compensation expense is expected to be amortized as follows:

	Year Ended December 31,		
	2021	2022	2023
Unrecognized stock-based compensation expense	$ 5,733	$ 4,701	$ 2,797

The amounts included in this table are based on restricted stock awards outstanding at December 31, 2020 and assumes the requisite service period is fulfilled for all restricted stock awards outstanding. Actual stock-based compensation expense in future periods may vary from those reflected in the table.

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 IRC.

As of December 31, 2020, no shares of common stock have been issued to employees participating in the 2020 ESPP and 340 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, the 2020 ESPP and the Phantom Stock Plan in the Company's statements of operations:

	Year Ended December 31,	
	2020	2019
Cost of revenue—product	$ 303	$ 29
Cost of revenue—service	165	17
Selling, general and administrative expenses	7,529	696
Research and development expenses	876	76
Total	$ 8,873	$ 818

PDL Equity Incentive Plan

PDL had equity incentive plans under which it granted equity awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance share and performance unit awards, deferred compensation awards and other stock-based or cash-based awards. As of December 31, 2020 and 2019, PDL granted awards to one LENSAR employee which consisted of restricted stock awards. There were no other grants to LENSAR employees of any other award types under PDL's equity incentive plan.

Restricted Stock Awards

PDL granted restricted stock awards to an employee of LENSAR pursuant to a stockholder approved stock-based incentive plan. As LENSAR received the employee's services in consideration for these awards, stock-based compensation expense for the awards granted to the LENSAR employee has been reflected in the statements of operations. As the stock-based compensation plans are PDL's plans and the awards were settled by PDL, the offset to the expense was recognized through additional paid-in capital on the balance sheets. Stock-based compensation expense related to the PDL awards for the years ended December 31, 2020 and 2019 was approximately $153 and $100 recorded in selling, general and administrative expense, respectively.

Restricted stock has the same rights as other issued and outstanding shares of PDL's common stock, including, in some cases, the right to accrue dividends, which are held in escrow until the award vests. The compensation expense related to these awards was determined using the fair market value of PDL's common stock on the date of the grant, and the compensation expense was recognized ratably over the vesting period. The restricted stock award granted to the LENSAR employees vested over one to two years and compensation expense associated with these awards was recognized on a straight-line basis over the vesting period.

The total fair value of restricted stock awards vested during the years ended December 31, 2020 and 2019 was approximately $180 and $100, respectively.

The weighted-average grant date fair value for restricted stock awards granted under PDL's 2005 Amended and Restated Equity Incentive Plan for the years ended December 31, 2020 and 2019 was $3.07 and $3.46, respectively.

At December 31, 2020, there was $0 total unrecognized compensation expense related to restricted stock awards.

Note 14. Income Taxes

Prior to the Spin-off, the Company was included in the consolidated federal tax return of PDL. The provision for income taxes for the year ended December 31, 2019 was calculated by using a "separate return" method. Under this method, the Company was assumed to file a separate return with the applicable tax authority(ies). The provision was the amount of tax payable or refundable on the basis of a hypothetical, current-year separate return. Deferred taxes were provided on temporary differences and on any attributes being carried forward that could be claimed on the hypothetical return. The need for a valuation allowance was assessed on a separate company basis and on projected separate return assets.

Subsequent to the Spin-Off, the Company is no longer included in the consolidated federal tax return of PDL and will file a tax return for the period following the Spin-Off as a separate company. The provision for income taxes for the year ended December 31, 2020 reflects the impact of the Spin-Off and the Company's status as a separate company for federal and state income tax filing purposes.

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

	Years Ended December 31,	
	2020	2019
United States	$ (19,774)	$ (14,657)
Foreign	—	—
Total	$ (19,774)	$ (14,657)

The provision for income taxes for the years ended December 31, 2020 and 2019 consisted of the following:

	Year Ended December 31,	
	2020	2019
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,	
	2020	2019
Tax at U.S. statutory rate on income before income taxes	$ (4,153)	$ (3,078)
Change in valuation allowance	1,573	2,218
State taxes	(210)	543
Accrued preferred dividend	—	321
(Income)/Loss taxable in period under the separate return method	2,719	—
Other	71	(4)
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,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 496	$ 38,781
Intangible assets	6,541	3,827
Stock-based compensation	1,886	340
Other	170	1,724
Total deferred tax assets	9,093	44,672
Valuation allowance	(9,084)	(44,465)
Total deferred tax assets, net of valuation allowance	9	207
Deferred tax liabilities:		
Other	(9)	(207)
Total deferred tax liabilities	(9)	(207)
Net deferred tax assets	$ —	$ —

The deferred tax assets associated with net operating losses included in the table above for the year ended December 31, 2019 reflected net operating losses as if the Company was a taxpayer separate from PDL on the "separate return method" of accounting for an entity that files as part of a consolidated group. The deferred tax assets associated with net operating losses included in the table above for the year ended December 31, 2020 reflect the net operating losses the Company expects to generate on its separate federal and state income tax returns subsequent to the Spin-Off.

As of December 31, 2020 and 2019, the Company maintained federal net operating loss carryforwards of $2,046 and $158,297, respectively. As of December 31, 2020 and 2019, the Company also maintained state net operating loss carryforwards of $1,558 and $131,761, respectively. As of December 31, 2020 and 2019, the Company had $0 and $2,234 of R&D credits. The Company eliminated the December 31, 2019 tax return attributes at the time the separation was executed. The federal net operating losses generated during the period ended December 31, 2020 after the Spin-Off may only be utilized to offset 80% of taxable income annually and may be carried forward indefinitely. The state net operating losses generated during the period ended December 31, 2020 after the Spin-Off will begin to expire in the year 2028 if not utilized.

As of December 31, 2020, the Company determined that it was more likely than not that certain federal and state deferred tax assets would not be realized in the near future and maintained a $9,084 valuation allowance against deferred tax assets. The net change in total valuation allowance between the years ended December 31, 2020 and 2019, was a decrease of $35,381; however, the deferred tax assets the Company maintained at December 31, 2019 were indicative of the "separate return method" as the Company was part of the PDL federal consolidated group at that time, and the tax return attributes were eliminated following the Spin-Off.

A reconciliation of the Company's unrecognized tax benefits, excluding accrued interest and penalties, is as follows:

	Year Ended December 31,	
	2020	2019
Balance at the beginning of the year	$ 2,255	$ 2,255
Decreases related to prior year tax positions	—	—
Increases related to tax positions from prior fiscal years	—	—
Increases related to tax positions taken during current fiscal year	—	—
Decreases related to the Spin-Off	(2,255)	—
Balance at the end of the year	$ —	$ 2,255

The Company periodically evaluates its exposures associated with its tax filing positions. At this time, the Company does not anticipate a material change in the unrecognized tax benefits that would affect the effective tax rate or deferred tax assets or valuation allowances over the next 12 months.

The U.S. federal income tax returns for which the Company filed as part of the PDL consolidated group are subject to examination for tax years 2017 forward. The Company's income tax returns for periods separate from our consolidation with PDL are subject to examination by U.S. federal, state and local tax authorities for tax years 2009 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, 2020 and 2019.

In response to the COVID-19 pandemic, many governments have enacted or are contemplating measures to provide aid and economic stimulus. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted on March 27, 2020 in the U.S., includes measures to assist companies, including temporary changes to income and non-income-based tax laws. The Company will monitor additional guidance and impact that the CARES Act and other potential legislation may have on its income taxes.

Note 15. 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,	
	2020	2019
Net loss attributable to common stockholders	$ (19,774)	$ (14,657)
Weighted average number of shares of common stock	4,621	1,070
Basic and diluted net loss per share	$ (4.28)	$ (13.70)

The Company applied the two-class method for calculating net loss per share. The two-class method is an allocation of losses between the holders of common stock and the Company's participating securities. Net loss attributable to common stockholders is computed by deducting the dividends accumulated for the period on the Series A preferred stock from the Company's net loss. Interest expense on the Series A preferred stock is calculated using the effective interest method. The adjustment, if any, to the net loss is the portion of the cumulative dividends in excess of the interest expense on the Series A preferred stock. There were no adjustments for cumulative dividends in excess of the interest expense on the Series A preferred stock for the years ended December 31, 2020 and 2019.

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. The Company's shares eligible for phantom stock awards (non-vested shares or non-settled awards) were held by PDL and were outstanding. If equity settlement was elected by the award holder, shares of LENSAR common stock were transferred from PDL's ownership to award owners. These shares were included in the Company's computation of weighted-average shares outstanding in the determination of basic net loss per share attributable to common stockholders.

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. For the year ended December 31, 2020, the Company excluded 2,050 shares underlying restricted stock awards, from its net loss per diluted share calculations because their effect was anti-dilutive. Under the 2020 Plan, there were zero outstanding restricted stock awards in 2019.

Note 16. Related Party Transactions

In the ordinary course of business prior to the Spin-Off, the Company entered into transactions with PDL.

Corporate Allocations

The Company's Financial Statements include expenses of $3,387 and $4,371 for the years ended December 31, 2020 and 2019, respectively, allocated to the Company by PDL for corporate support functions that are provided by PDL such as administration and organizational oversight; including employee benefits, finance and accounting, treasury and risk management, professional and legal services, among others. Allocated costs are included within selling, general and administrative expenses in the accompanying statements of operations. A portion of these allocated costs related to certain cross charges that have historically been cash settled and included in our statements of cash flows as operating activities. As of December 31, 2020 and 2019, $0 and $142, respectively, related to the allocation of corporate costs are included in other current liabilities as those amounts are to be cash settled.

Note Payable to Related Party

In May 2017, the Company entered into a loan agreement with PDL. Under the loan agreement, the maximum aggregate principal amount that LENSAR could draw from the loan agreement was $25,600. On April 15, 2020, the Company and PDL, upon mutual agreement, increased the credit limit that LENSAR could draw from PDL under the loan agreement by $7,000 to a total of $32,600. LENSAR drew an additional $12,400 under the loan agreement during the nine months ended September 30, 2020. Immediately before the Note Payable Recapitalization, the Company had drawn the full amount under the amended loan agreement. The interest expense incurred during the years ended December 31, 2020 and 2019 was $511 and $473, respectively, and is included in interest expense.

As of December 31, 2020 the Company does not have a Note payable due to related party. See Note 1, *Overview and Basis of Presentation*, for more information on the Note Payable Recapitalization.

Series A Preferred Stock

Refer to Note 10, *Series A Preferred Stock*.

Agreements with PDL

In connection with the completion of the Spin-Off, the Company entered into several agreements with PDL, each dated September 30, 2020, that, among other things, provide a framework for the Company's relationship with PDL after the Distribution, including the following (collectively, the "Spin Agreements"):

- Separation and Distribution Agreement: The Separation and Distribution Agreement set forth the agreements between PDL and the Company regarding the principal transactions necessary to separate the Company from PDL. It also set forth other agreements that govern certain aspects of the relationship with PDL after the completion of the Spin-Off. In general, neither the Company nor PDL will make any representations or warranties regarding the transactions contemplated by the Separation and Distribution Agreement or the respective businesses, assets, liabilities, condition or prospects of PDL or the Company.
- Transition Services Agreement: The Transition Services Agreement provides that for a limited time, PDL is to provide services (through various separate work streams) to LENSAR on an interim basis, ranging in duration from two to nine months, with the majority of such services being provided for a duration of six months. The support functions include accounting and other financial functions. The agreed upon charges for such services are either (i) generally intended to allow PDL to recover all out-of-pocket costs and expenses, along with a pre-determined mark-up of such out-of-pocket costs and expenses or (ii) where available, a benchmark market based rate for the service.
- Tax Matters Agreement: The Tax Matters Agreement generally governs the respective rights, responsibilities and obligations of LENSAR and PDL with respect to tax liabilities and benefits, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and certain other matters regarding taxes.

Note 17. Subsequent Events

In March 2021, the Company granted 166,396 option awards to eligible employees under the 2020 Plan in consideration of future services to be rendered to the Company. In general, the requisite service period begins on the grant date; however, for certain employees who were not eligible to participate in the Phantom Stock Plan or other incentive programs, the requisite service period for new hire option awards began on the date of hire. The aggregate grant date fair value of these option awards was determined to be $880 based on estimating the fair value of stock options using the Black-Scholes option pricing model. The vesting schedule of the option awards is (i) 25% vest one year after the inception of the requisite service period and (ii) 75% vest monthly thereafter over the following 36 months. The option awards have a contractual term of 10 years and an exercise price of $8.27, which was the closing price on the grant date as quoted by Nasdaq.

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