UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended June 30, 2022
or

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

Commission File Number: 001-39473

LENSAR, INC.

(Exact name of registrant as specified in its charter)

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

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

(888) 536-7271
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

As of July 31, 2022, there were 11,020,965 shares of the registrant's Common Stock outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly 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 Quarterly Report, including without limitation statements regarding our business model and strategic plans for our products, technologies and business, including our implementation thereof; the impact on our business, financial condition and results of 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 system, the ALLY™ Adaptive Cataract Treatment System ("ALLY System"), and the timing thereof; the sufficiency of our cash and cash equivalents; and the plans and objectives of management for future operations and capital expenditures are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I. Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II. Item 1A. "Risk Factors" in this Quarterly Report. These risks and uncertainties include, but are not limited to:

- our history of operating losses and ability to achieve or sustain profitability;
- our ability to maintain, grow market acceptance of and enhance our LENSAR Laser System, and to develop, receive regulatory clearance or certification of and successfully commercialize our next generation system, the ALLY System;
- the impact to our business, financial condition, results of operations and our suppliers and distributors 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 operations as a result of a material disruption to the supply or manufacture of our systems or necessary component parts for such 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 our ALLY System or our other future products, or changes in such coverage or reimbursement;
- the impact to our business, financial condition and results of operations of product liability suits brought against us;
- risks related to government regulation applicable to our products and operations; and

- risks related to our intellectual property and other intellectual property matters.

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

You should read this Quarterly Report and the documents that we reference in this Quarterly 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.

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

RISK FACTOR SUMMARY

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

- We expect to incur operating losses for the foreseeable future and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.
- We have historically derived our revenue principally from the sale or lease of our LENSAR Laser System and the associated procedure licenses and sale of consumables used in each procedure involving our LENSAR Laser System. The commercial success of our ALLY System will depend upon receipt of regulatory clearances or certifications and our ability to maintain and grow significant market acceptance for it.
- Our growth depends on our ability to gain regulatory clearances or certifications and meet production goals for our ALLY 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 impeded global supply chains and have had an adverse impact on our business, and we expect this situation to continue, and potentially worsen.
- 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 systems or other products associated with the systems is materially disrupted, including supply chain shortages and price increases resulting from the COVID-19 pandemic, 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, certifications or approvals for our future products, including our ALLY System, or modifications to our current products, and failure to timely obtain necessary clearances, certifications or approvals for our ALLY System and future products or modifications to our current products would adversely affect our ability to grow our business.
- If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

PART I – FINANCIAL INFORMATION

Item 1.Financial Statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue				
Product	$ 5,733	$ 6,056	$ 12,702	$ 11,214
Lease	1,415	1,140	2,814	2,251
Service	890	726	1,862	1,500
Total revenue	8,038	7,922	17,378	14,965
Cost of revenue (exclusive of amortization)				
Product	1,765	2,366	4,459	4,456
Lease	484	268	958	519
Service	897	830	2,377	1,638
Total cost of revenue	3,146	3,464	7,794	6,613
Operating expenses				
Selling, general and administrative expenses	7,569	5,518	13,847	11,553
Research and development expenses	3,834	3,006	8,622	5,752
Amortization of intangible assets	287	309	596	622
Operating loss	(6,798)	(4,375)	(13,481)	(9,575)
Other income				
Other income, net	39	13	48	31
Net loss	$ (6,759)	$ (4,362)	$ (13,433)	$ (9,544)
Net loss per share:				
Basic and diluted	$ (0.67)	$ (0.47)	$ (1.34)	$ (1.03)
Weighted-average number of shares used in calculation of net loss per share:				
Basic and diluted	10,073	9,296	10,020	9,242

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

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 25,196	$ 31,637
Accounts receivable, net of allowance of $25 and $47, respectively	2,760	4,638
Notes receivable, net of allowance of $181 and $61, respectively	164	350
Inventories	5,856	6,488
Prepaid and other current assets	1,230	1,700
Total current assets	35,206	44,813
Property and equipment, net	680	756
Equipment under lease, net	7,161	6,690
Notes and other receivables, long-term, net of allowance of $1 and $2, respectively	29	121
Intangible assets, net	12,674	10,870
Other assets	2,950	3,215
Total assets	$ 58,700	$ 66,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,191	$ 2,694
Accrued liabilities	4,372	4,604
Contingent consideration	1,200	—
Deferred revenue	937	904
Operating lease liabilities	521	512
Total current liabilities	11,221	8,714
Long-term operating lease liabilities	2,540	2,803
Other long-term liabilities	37	69
Total liabilities	13,798	11,586
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 10,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, par value $0.01 per share, 150,000 shares authorized at June 30, 2022 and December 31, 2021; 11,021 and 10,990 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	110	110
Additional paid-in capital	135,819	132,363
Accumulated deficit	(91,027)	(77,594)
Total stockholders' equity	44,902	54,879
Total liabilities and stockholders' equity	$ 58,700	$ 66,465

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

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (13,433)	$ (9,544)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,110	670
Amortization of intangible assets	596	622
Non-cash operating lease cost	260	258
Provision for expected credit losses	125	5
Write-down of inventory	—	4
Loss on disposal of property and equipment	—	120
Stock-based compensation expense	3,244	3,750
Changes in operating assets and liabilities:		
Accounts receivable	1,871	(691)
Prepaid and other current assets	470	423
Inventories	(818)	(840)
Accounts payable	1,497	326
Accrued liabilities	(232)	(1,236)
Other	(87)	52
Net cash used in operating activities	(5,397)	(6,081)
Cash flows from investing activities		
Purchase of property and equipment	(56)	(134)
Net cash used in investing activities	(56)	(134)
Cash flows from financing activities		
Payment of contingent consideration	(1,200)	—
Proceeds from issuance of common stock under employee stock purchase plan	212	170
Net cash (used in) provided by financing activities	(988)	170
Net decrease in cash and cash equivalents	(6,441)	(6,045)
Cash and cash equivalents at beginning of the period	31,637	40,599
Cash and cash equivalents at end of the period	$ 25,196	$ 34,554

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

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

	Six Months Ended June 30,	
	2022	2021
Supplemental cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ 10	$ 19
Supplemental schedule of non-cash investing and financing activities		
Transfer from Inventories to Equipment under lease, net	$ 1,416	$ 1,860
Transfer from Inventories to Property and equipment, net	$ 34	$ —
Accounts payable for purchases of Property and equipment	$ —	$ 51

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

LENSAR, Inc.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2021	10,990	$ 110	$ 132,363	$ (77,594)	$ 54,879
Stock-based compensation	—	—	1,607	—	1,607
Restricted stock awards cancelled	(5)	—	—	—	—
Net loss	—	—	—	(6,674)	(6,674)
Balance as of March 31, 2022	10,985	$ 110	$ 133,970	$ (84,268)	$ 49,812
Issuance of common stock under the 2020 ESPP	37	—	212	—	212
Restricted stock awards cancelled	(1)	—	—	—	—
Stock-based compensation	—	—	1,637	—	1,637
Net loss	—	—	—	(6,759)	(6,759)
Balance as of June 30, 2022	11,021	$ 110	$ 135,819	$ (91,027)	$ 44,902

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2020	10,933	$ 109	$ 125,094	$ (57,993)	$ 67,210
Stock-based compensation	—	—	2,301	—	2,301
Net loss	—	—	—	(5,182)	(5,182)
Balance as of March 31, 2021	10,933	109	127,395	(63,175)	64,329
Issuance of common stock under the 2020 ESPP	24	1	169	—	170
Stock-based compensation	—	—	1,491	—	1,491
Net loss	—	—	—	(4,362)	(4,362)
Balance as of June 30, 2021	10,957	$ 110	$ 129,055	$ (67,537)	$ 61,628

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

Note 1. Overview and Basis of Presentation

Overview and Organization

LENSAR, Inc. ("LENSAR" or the "Company") is a global medical device business focused on the design, development and commercialization of advanced technology for the treatment of cataracts and management of astigmatism to achieve improved visual outcomes for patients. LENSAR is a public company whose stock is listed and trading under the symbol "LNSR" on The Nasdaq Stock Market LLC ("Nasdaq"). The Company's revenue is derived from the sale and lease of LENSAR's laser systems, which may include equipment, a consumable referred to as the Patient Interface Device ("PID"), procedure licenses, training, installation, limited warranty and maintenance agreements through extended warranty. LENSAR has developed its next-generation ALLY™ Adaptive Cataract Treatment System ("ALLY System"), the first platform to integrate its proprietary imaging with a dual-pulsed femtosecond laser and phacoemulsification technology in a single, compact system. The ALLY System, now cleared by the U.S. Food and Drug Administration ("FDA"), enables cataract surgeons to complete the femtosecond-laser-assisted cataract surgery ("FLACS") procedure in a single, sterile environment. This clearance is the first stage of a planned, two step commercial release strategy. The Company expects to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. The Company's ability to place systems in 2022 has been limited by supply chain constraints that have delayed the delivery of certain ALLY System raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. As the second stage of the commercial release strategy, the Company plans to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as the predicate device. LENSAR was recently informed by the third party that it has withdrawn its 510(k) submission for its standalone phacoemulsification device and plans to resubmit the application at a later date. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, LENSAR is unable to submit its second 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, the Company will deliver the ALLY System to surgeons in the initial launch and the subsequent 2023 rollout with the phacoemulsification features remaining disabled and/or removed.

The Company has incurred recurring losses and operating cash outflows since its inception and, as of June 30, 2022, had an accumulated deficit of $91,027. 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, including supply chain shortages and price increases. The extent to which the COVID-19 outbreak, and current or future variants, will further negatively impact the Company's business or operating results cannot be determined with certainty at this time. 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. The Company has also experienced some supply chain disruptions, and increased costs of various component parts needed for the development of the ALLY System as a result of COVID-19, including increasing lead times required for the ordering of component parts to meet targeted production goals and unpredictability with respect to the availability and delivery timing of these parts. To date, the Company has maintained sufficient inventory to mitigate significant adverse impact from such disruptions and unavailability in the near-term and to facilitate the initial launch of the ALLY System assuming regulatory clearance; however, the Company is continuing to monitor developments with respect to such disruptions and their potential impact on the Company's business, results of operations and financial condition. If these supply chain shortages and disruptions continue or worsen, or the Company is unable to find suitable alternative component parts, there is no guarantee the Company will be able to meet customer demand for the ALLY System following its initial launch. In addition, pricing increases in component parts for the ALLY System may necessitate an increase in overall cost to customers, which in turn may have an adverse impact on customer demand.

Management believes the Company's cash and cash equivalents on hand provide sufficient liquidity to meet the Company's projected obligations for a period of at least twelve months from the date of issuance of these condensed financial statements. As the Company gets closer to the planned commercial launch of the ALLY System, anticipated to be in the third quarter of 2022, it expects annual revenue and selling, general and administrative expenses to increase from current levels. In addition, the successful commercialization of the ALLY System depends in part on the Company's ability to produce the ALLY System in sufficient quantities and within requested timelines to satisfy customer demand.

The Company expects cash and cash equivalents, together with cash generated from the sale and lease of products, to be sufficient to operate into 2024. 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, additional regulatory clearances and launch of the ALLY System in the future. Such success will depend on the availability of the necessary component parts for the ALLY System. The Company expects it will need to raise additional capital through equity or debt financings or from other sources to continue its operations beyond 2024. The Company may issue securities, including common stock, preferred stock, warrants, and/or debt securities through private placement transactions or registered public offerings in the future. The Company's ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of the Company's control and the Company may be unable to raise financing when needed, or on terms favorable to the Company. If the necessary funds are not available from these sources, the Company may have to delay, reduce or suspend the scope of its sales and marketing efforts, research and development activities, or other components of its operations.

Basis of Presentation

These condensed financial statements of the Company are unaudited and 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") for interim financial information and, therefore, omit or condense certain footnotes and other information normally included. The condensed financial statements include all adjustments (consisting only of normal recurring adjustments), that management of the Company believes are necessary for a fair statement of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year. The December 31, 2021 condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The accompanying unaudited condensed financial statements and related financial information should be read in conjunction with the Company's annual audited financial statements and the related notes thereto for the fiscal year ended December 31, 2021, included in the Annual Report on Form 10-K (the "Annual Report") as filed with the SEC.

Note 2. Summary of Significant Accounting Policies

Other than policies noted below, there have been no significant changes to the significant accounting policies disclosed in Note 2, *Summary of Significant Accounting Policies*, of the annual audited financial statements included in the Annual Report.

Accounting Estimates

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

The COVID-19 pandemic continues to directly and indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, reserves and allowances. The Company continues to monitor developments that are highly uncertain, including supply chain disruptions and price increases, as well as the economic impact on domestic and international suppliers, customers, and markets. The Company assessed certain accounting matters that require consideration of forecasted financial information, including, but not limited to, its current expected credit losses, the carrying value of the Company's intangible assets and other long-lived assets, and valuation allowances in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of June 30, 2022 and through the date of this report. As a result of these assessments, there were no impairments or material increases in expected credit losses or valuation allowances that impacted the Company's condensed financial statements as of and for the three and six months ended June 30, 2022 and 2021. However, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the condensed financial statements in future reporting periods.

As of the date of issuance of these unaudited condensed interim 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.

(Dollars and shares in thousands)

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.

Income Taxes

Income tax expense/(benefit) from continuing operations for the three and six months ended June 30, 2022 and 2021 was $0 in each period, which resulted primarily from maintaining a full valuation allowance against the Company's deferred tax assets.

Recently Issued Accounting Pronouncements Not Yet Adopted

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

Note 3. Revenue from Contracts with Customers

Disaggregation of Revenue

The following table summarizes the Company's product and service revenue disaggregated by geographic region, which is determined based on customer location, for the three and six months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
United States	$ 4,097	$ 3,942	$ 8,067	$ 7,380
South Korea	662	1,190	2,096	2,188
Europe	956	921	2,575	1,810
Asia (excluding South Korea)	771	633	1,551	1,175
Other	137	96	275	161
Total[1]	$ 6,623	$ 6,782	$ 14,564	$ 12,714

[1] The table above does not include lease revenue of $1,415 and $1,140 for three months ended June 30, 2022 and 2021, respectively, and $2,814 and $2,251 for the six months ended June 30, 2022 and 2021, respectively. Substantially all lease revenue originates from the United States. Refer to Note 5, *Leases*.

(Dollars and shares in thousands)

Contract Balances

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

	Classification	As of June 30, 2022	As of December 31, 2021
Accounts receivable, current	Accounts receivable, net	$ 2,760	$ 4,638
Notes receivable, current	Notes receivable, net	$ 164	$ 350
Notes receivable, long-term	Notes and other receivables, long-term, net	$ 29	$ 121
Contract liability, current	Deferred revenue	$ 937	$ 904
Contract liability, non-current	Other long-term liabilities	$ 37	$ 66

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

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

	Amount
Accounts receivable, allowance for credit losses as of December 31, 2021	$ 47
Provision for credit losses	(6)
Write-offs	(16)
Accounts receivable, allowance for credit losses as of June 30, 2022	$ 25

Accounts receivable, allowance for credit losses as of December 31, 2020	$ 19
Provision for credit losses	8
Write-offs	—
Accounts receivable, allowance for credit losses as of June 30, 2021	$ 27

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 three months ended June 30, 2022 and 2021 of $3 and $9, respectively, and during the six months ended June 30, 2022 and 2021 of $8 and $19, respectively, in other income, net in the statement of operations.

(Dollars and shares in thousands)

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

	Amount
Notes receivable, allowance for credit losses as of December 31, 2021	$ 63
Provision for credit losses	130
Write-offs	(11)
Notes receivable, allowance for credit losses as of June 30, 2022	$ 182

Notes receivable, allowance for credit losses as of December 31, 2020	$ 18
Provision for credit losses	(3)
Write-offs	—
Notes receivable, allowance for credit losses as of June 30, 2021	$ 15

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 condensed balance sheets.

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

	Amount
Contract liabilities as of December 31, 2021	$ 970
Billings not yet recognized as revenue	637
Beginning contract liabilities recognized as revenue	(633)
Contract liabilities as of June 30, 2022	$ 974

Contract liabilities as of December 31, 2020	$ 1,051
Billings not yet recognized as revenue	713
Beginning contract liabilities recognized as revenue	(622)
Contract liabilities as of June 30, 2021	$ 1,142

Transaction Price Allocated to Future Performance Obligations

At June 30, 2022, the revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more was approximately $4,830. The Company expects to satisfy its remaining performance obligations by December 31, 2026, with $2,433 to be satisfied by December 31, 2022, $1,907 to be satisfied by December 31, 2023, $309 to be satisfied by December 31, 2024 and $181 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.

Note 4. Inventories

Inventory balances were as follows:

	As of June 30, 2022	As of December 31, 2021
Finished Goods	$ 1,884	$ 4,319
Work-in-process	273	173
Raw Materials	3,699	1,996
Total	$ 5,856	$ 6,488

(Dollars and shares in thousands)

Note 5. Leases

Lessor Arrangements

The Company has operating leases for the LENSAR Laser System. The Company's leases have remaining lease terms of less than one year to four years. Lease revenue for the three and six months ended June 30, 2022 and 2021 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Lease revenue	$ 1,415	$ 1,140	$ 2,814	$ 2,251

Note 6. Intangible Assets

The components of intangible assets were as follows:

	As of June 30, 2022			As of December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:						
Customer relationships [1,2]	$ 4,292	$ (1,860)	$ 2,432	$ 4,292	$ (1,685)	$ 2,607
Acquired technology [1,3,4]	13,900	(3,658)	10,242	11,500	(3,275)	8,225
Acquired trademarks [1]	570	(570)	—	570	(532)	38
	$ 18,762	$ (6,088)	$ 12,674	$ 16,362	$ (5,492)	$ 10,870

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

2 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.

4 In 2019, LENSAR acquired certain intellectual property from a third-party. In connection with the agreement, milestone payments of $2,400 were contingent upon regulatory approval and commercialization of the ALLY System. Refer to Note 8, *Commitments and Contingencies*, for further discussion about the contingent consideration. The intangible assets are being amortized on a straight-line basis over a period of 15 years.

Amortization expense for three months ended June 30, 2022 and 2021 was $287 and $309, respectively, and for the six months ended June 30, 2022 and 2021 was $596 and $622, respectively.

Based on the intangible assets recorded at June 30, 2022, and assuming no subsequent additions to or impairment of the underlying assets, the remaining amortization expense is expected to be as follows:

Fiscal Year	Amount
Remainder of 2022	2,953
2023	1,097
2024	1,085
2025	1,074
2026	1,064
2027	1,055
Thereafter	4,346
Total remaining estimated amortization expense	$ 12,674

(Dollars and shares in thousands)

Note 7. Accrued Liabilities

Accrued liabilities consist of the following:

	As of June 30, 2022	As of December 31, 2021
Compensation	$ 2,320	$ 3,375
Professional services	1,173	526
Customer advances	395	159
Warranty	21	45
Other	463	499
Total	$ 4,372	$ 4,604

Note 8. Commitments and Contingencies

Purchase Obligation

LENSAR is a party to various supply agreements for the manufacture and supply of certain components. The supply agreements commit LENSAR to a minimum purchase obligation of approximately $7,815 by December 31, 2023. LENSAR expects to meet these requirements.

Royalty and Milestone Payments

In connection with the acquisition of certain intellectual property, the Company paid a $1,200 milestone payment, which was contingent upon regulatory clearance of the ALLY System. The Company could also be required to make an additional milestone payment in the amount of $1,200, which is contingent upon the commercialization of the ALLY System. The payment is considered probable and reasonably estimable, as such the contingent consideration is recorded as a current liability on the Company's balance sheet. In addition, the Company acquired certain intellectual property, which would result in additional royalty payments at a rate of 3% of certain revenue generated from the ALLY System.

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 9. Stockholders' Equity

Preferred Stock

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

Common Stock

The Company has a single class of common stock in which stockholders are entitled to one vote for each share of common stock. No cash dividend was declared on common stock during the three and six months ended June 30, 2022 and 2021.

(Dollars and shares in thousands)

Note 10. Stock-Based Compensation

Stock-Based Incentive Plans

The 2020 Plan

In July 2020, the Board of Directors approved the LENSAR Inc. 2020 Incentive Award Plan (the "2020 Plan"). The 2020 Plan provides for the grant of stock options, restricted stock, restricted stock unit awards and other stock-based awards to recipients. The amount and terms of grants are determined by the Company's Board of Directors or a duly authorized committee thereof. Participants must pay the Company, or make provisions to pay, any required withholding taxes by the date of the event creating the tax liability. Participants may satisfy the tax liability in cash or in stock. A total of 3,333 shares of common stock were initially reserved for issuance pursuant to the 2020 Plan. The number of shares available for issuance under the 2020 Plan includes an annual increase on the first day of each fiscal year beginning fiscal 2021, equal to the lesser of (i) 5% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as determined by the Board of Directors. As of June 30, 2022 the Company has reserved 4,429 shares of common stock for issuance under the 2020 Plan.

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

	Number of Shares
Balance at December 31, 2021	1,082
Authorized	549
Granted/Awarded	(660)
Cancelled	40
Balance at June 30, 2022	1,011

Stock Options

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

(Dollars and shares in thousands)

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

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	653	$ 7.57	9.3	$ —
Options granted	574	$ 6.20		
Options exercised	—	$ —		
Options cancelled	(34)	$ 6.87		
Outstanding at June 30, 2022	1,193	$ 6.93	9.2	$ 215
Vested and expected to vest at June 30, 2022	1,193	$ 6.93	9.2	$ 215
Vested and exercisable at June 30, 2022	311	$ 7.54	8.8	$ —

The weighted average grant date fair value of options granted during the three and six months ended June 30, 2022 was $4.48 and $3.90, respectively. The total fair value of options vested during the three and six months ended June 30, 2022 was approximately $503 and $1,050, respectively. Total unrecognized compensation expense of $3,490 related to stock options will be recognized over a weighted average period of 2.9 years.

The Company estimated the fair value of stock-options using the Black-Scholes option pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following assumptions for the three and six months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.5 - 3.0%	1.1%	1.5 - 3.0%	0.6 - 1.1%
Expected term (years)	6	6	6	6
Expected volatility	70%	73%	70%	72 - 73%
Dividends	0.0%	0.0%	0.0%	0.0%

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

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

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

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

Restricted Stock Awards

Restricted stock has the same rights as other issued and outstanding shares of the Company's common stock. The compensation expense related to these awards is determined using the fair market value of the Company's common stock on the date of the grant. Under the

(Dollars and shares in thousands)

Company's restricted stock plans, restricted stock awards typically vest over three years and compensation expense associated with these awards is recognized on a straight-line basis over the vesting period.

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

	Restricted Stock Awards Outstanding	
	Number of Units	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2021	1,332	$ 10.29
Restricted stock awards granted	—	$ —
Restricted stock awards vested	(478)	$ 10.33
Restricted stock awards cancelled	(6)	$ 10.81
Non-vested at June 30, 2022	848	$ 10.27

The total fair value of restricted stock awards vested during the three and six months ended June 30, 2022 was approximately $1,421 and $4,933, respectively. At June 30, 2022 there was approximately $5,129 of total unrecognized compensation expense related to restricted stock awards, which is expected to be recognized over a weighted-average period of 1.1 years. The number of restricted stock awards that are expected to vest are as follows: 113 in the quarter ending September 30, 2022; 113 in the quarter ending December 31, 2022; 237 in the quarter ending March 31, 2023; 136 in the quarter ending June 30, 2023; 174 in the quarter ending September 30, 2023; and 75 in the quarter ending December 31, 2023. These are based on restricted stock awards outstanding at June 30, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual vesting in future periods may vary from those reflected above.

Restricted Stock Units

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

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

	Restricted Stock Units Outstanding	
	Number of Units	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2021	—	$ —
Restricted stock units granted	86	$ 6.33
Restricted stock units vested	—	$ —
Restricted stock units cancelled	—	$ —
Non-vested at June 30, 2022	86	$ 6.33

At June 30, 2022 there was approximately $482 of total unrecognized compensation expense related to restricted stock units, which is expected to be recognized over a weighted-average period of 2.7 years.

2020 Employee Stock Purchase Plan

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

(Dollars and shares in thousands)

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 June 30, 2022, 94 shares of common stock have been issued to employees participating in the 2020 ESPP and 246 shares were available for future issuance under the 2020 ESPP. The grant date fair value of the shares to be issued under the Company's 2020 ESPP was estimated using the Black-Scholes valuation model.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue – product	$ 54	$ 47	$ 106	$ 122
Cost of revenue – service	32	27	62	68
Selling, general and administrative expenses	1,397	1,223	2,774	3,207
Research and development expenses	154	133	302	353
Total	$ 1,637	$ 1,430	$ 3,244	$ 3,750

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

Fiscal Year	Amount
2022	$ 3,263
2023	4,218
2024	981
2025	625
2026	14
Thereafter	—
Total unrecognized stock-based compensation expense	$ 9,101

The amounts included in this table are based on restricted stock awards, restricted stock units, and stock options outstanding at June 30, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual stock-based compensation expense in future periods may vary from those reflected in the table.

Note 11. 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (6,759)	$ (4,362)	$ (13,433)	$ (9,544)
Weighted average number of shares of common stock	10,073	9,296	10,020	9,242
Basic and diluted net loss per share	$ (0.67)	$ (0.47)	$ (1.34)	$ (1.03)

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

As the Company has reported a net loss for all periods presented, basic and diluted net loss per share attributable to common stockholders are the same for those periods. The Company excluded 934 shares of underlying unvested restricted stock awards and units and 1,193 outstanding stock options for the three and six months ended June 30, 2022 and 1,573 shares of underlying unvested restricted stock awards and 629 outstanding stock options for the three and six months ended June 30, 2021 from its net loss per diluted share calculations because their effect was anti-dilutive.

(Dollars and shares in thousands)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Restricted stock awards and units	995	1,417	1,033	1,431
Outstanding stock options	1,140	537	1,096	328
Total	2,135	1,954	2,129	1,759

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this Quarterly Report, as well as the audited financial statements and the related notes thereto, and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in the Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly 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 Factor Summary" and "Risk Factors" sections for a discussion of the uncertainties, risks and assumptions associated with these statements.

Overview

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

Our current product portfolio 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 kit, or PID kit, and the system also requires a procedure license. Each procedure on each system requires the use of a PID kit. The PID kit includes a suction ring, vacuum filter and fluidic connection that are designed to facilitate placement of the laser while minimizing a patient's discomfort, intraocular pressure and trauma to the retina and maintaining corneal integrity. The procedure license is downloaded onto the system as required or as purchased by the customer. The system will not perform a procedure without a valid license. We sell licenses individually and also offer licenses in a subscription package with minimum monthly obligations and the ability to increase procedure numbers as the practice grows to address occasional increases in demand. We believe this structure allows the surgeon to implement a budget while also providing us with a predictable revenue stream.

We are focused on continuous innovation and are launching our proprietary next generation ALLY™ Adaptive Cataract Treatment System, or ALLY System. The ALLY System, now cleared by the U.S. Food and Drug Administration, or FDA, enables cataract surgeons to complete the femtosecond-laser-assisted cataract surgery, or FLACS, procedure seamlessly in a single, sterile environment. This clearance is the first stage of a planned, two step commercial release strategy. We expect to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. Our ability to place systems in 2022 has been limited by supply chain constraints that have delayed the delivery of certain ALLY raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. As the second stage of the commercial release strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as the predicate device. LENSAR was recently informed by the third party that it has withdrawn its 510(k) submission for its standalone phacoemulsification device and plans to resubmit the application at a later date. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, LENSAR is unable to submit its second 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, we will deliver the ALLY System to surgeons in the initial launch and the subsequent 2023 rollout with the phacoemulsification features remaining disabled and/or removed. We believe the ALLY System's enhanced efficiencies and potential for combined functions in the future 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 believe 2022 is a transition year for the Company, as we have transitioned from manufacturing and selling our LENSAR Laser System and are focusing on our ALLY System. We also intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory clearance in that region, among other factors. In addition, based on inventory of our LENSAR Laser System, our future revenue and cash flows will depend on, among other factors, our installed base of systems and the timing of and applicable clearances for our ALLY System.

We have built and are continuing to grow our commercial organization, which includes a direct sales force in the United States and distributors in Germany, China, South Korea and other targeted international markets. We believe there is significant opportunity for us to expand our presence in these countries and other markets and regions. In the United States, we sell our products through a direct sales organization that, as of June 30, 2022, consisted of approximately 45 commercial professionals, including regional sales managers,

clinical applications and outcomes specialists, field service, marketing, technical and customer support personnel. We manufacture our systems at a facility in Orlando, Florida. We purchase custom and off-the-shelf components from a number of suppliers, including some single-source suppliers. We purchase the majority of our components and major assemblies through purchase orders with limited long-term supply agreements and generally do not maintain large volumes of finished goods. We strive to maintain enough inventory of our various component parts to avoid the impact of potential disruptions in the supply chain; however, availability of these components can be outside of our control, especially with the impact of the COVID-19 pandemic on the global supply chain of certain products, including increasing lead times required for the ordering of component parts to meet targeted production goals, unpredictability with respect to suppliers' ability to fulfill orders in the requested quantities within the agreed timeframe and the ability to find alternative component parts.

Our revenue increased from $7.9 million for the three months ended June 30, 2021 to $8.0 million for the three months ended June 30, 2022, representing an increase of 1%, primarily due to increased procedure volume. Our net losses were $6.8 million and $4.4 million for the three months ended June 30, 2022 and 2021, respectively. The increase in net loss is primarily due to pre-production inventory for the ALLY System, which was recorded as research and development expenses through April 30, 2022, when future commercialization of our ALLY System was considered probable and the future economic benefit was expected to be realized. Our installed base of LENSAR Laser Systems is approximately 260 as of June 30, 2022.

Our revenue increased from $15.0 million for the six months ended June 30, 2021 to $17.4 million for the six months ended June 30, 2022, representing an increase of 16.1%, primarily due to increased procedure volume. Our net losses were $13.4 million and $9.5 million for the six months ended June 30, 2022 and 2021, respectively. The increase in net loss is primarily due to pre-production inventory for the ALLY System, which was recorded as research and development expenses through April 30, 2022, when future commercialization of our ALLY System was considered probable and the future economic benefit was expected to be realized.

Factors to Consider

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

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

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

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

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. Actions taken to mitigate coronavirus have had, and are expected to continue to have, an impact on the geographical areas in which we operate, and we are continually making adjustments intended to assist in protecting the safety of our employees and communities and maintaining appropriate inventories and component parts to continue our business activities where possible and legally permitted. In response, we have increased safety stock of certain critical components and are continuously evaluating our supply chain to identify potential gaps and take steps intended to ensure business continuity.

Although procedure volume in 2021 and the first half of 2022 has returned to pre-pandemic levels, the COVID-19 pandemic continues to influence our operations, particularly as it relates to building inventory for our existing commercially-available products and the ALLY System. We have experienced some supply chain disruptions and unavailability of various component parts needed for our systems, including increasing lead times required for the ordering of component parts to meet targeted production goals and unpredictability with respect to our suppliers' ability to fulfill orders in the requested quantities, within the agreed timeframe as well as an increase of costs associated with certain raw materials and component parts. To date, we have maintained sufficient inventory to mitigate significant adverse impact from such disruptions and unavailability in the near-term and to meet the expected needs of our initial launch of the ALLY System; however, we are continuing to monitor developments with respect to the outbreak and its potential impact on our operations and to our employees, distributors, partners, suppliers, and regulators. The lingering impacts of COVID-19 into 2022 have impeded global supply chains, resulted in longer lead times and delays in procuring component parts and raw materials, and resulted in inflationary cost increases in certain raw materials, labor and transportation. In particular, a global semiconductor supply shortage resulting from the COVID-19 pandemic is having wide-ranging effects across multiple industries, and we are seeing more significant disruptions in the supply of, timing of delivery of and fluctuations in pricing for various component parts needed for our products, including the integrated circuits used in our systems. These broad-based inflationary impacts have negatively impacted the Company's financial condition, results of operations and cash flows since 2020 and these supply chain constraints may result in future impacts to our business. We expect these inflationary impacts to continue for the foreseeable future.

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

Components of Our Results of Operations

Revenue

Total revenue comprises product revenue, service revenue and lease revenue. We derive product revenue from the sale of our laser systems and sales of our PIDs and procedure licenses to our surgeon customers and to our distributors outside the United States. A PID and procedure license, which may also be referred to as an application license, is required to perform each procedure using our laser system. A procedure license represents a one-time right to utilize the system surgical application in connection with a surgery procedure. Service revenue is derived from the sale of extended warranties for our laser systems that provide additional maintenance and service beyond our standard limited warranty. In some situations, we lease our laser systems to surgeons, primarily through non-cancellable leases with a fixed lease payment. We consider all components of our revenue to be recurring source revenue, with the exception of sales of our systems. For the three and six months ended June 30, 2022, approximately 99% and 94% of our revenue, respectively, was attributable to recurring sources, compared to 90% for the three and six months ended June 30, 2021.

Cost of Revenue

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

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

Selling, General and Administrative Expense

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

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

Research and Development Expense

Our research and development expenses consist primarily of engineering, product development, clinical studies to develop and support our products, personnel costs, such as salaries and wages, including stock-based compensation and benefits, regulatory expenses, and other costs associated with products and technologies that are in development. Currently, our research and development expense primarily consists of costs associated with the continued development of our next generation system, the ALLY System, which is designed to combine our existing femtosecond laser technology with a phacoemulsification system into an integrated cataract treatment system. The Company recognized pre-launch inventory costs as research and development expenses through April 30, 2022, when future commercialization of our ALLY System was considered probable and the future economic benefit was expected to be realized.

Amortization of Intangible Assets

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

Seasonality

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

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2022 and 2021

(Dollars in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change from Prior Year (%)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change from Prior Year (%)
Revenue						
Product	$ 5,733	$ 6,056	(5)%	$ 12,702	$ 11,214	13%
Lease	1,415	1,140	24%	2,814	2,251	25%
Service	890	726	23%	1,862	1,500	24%
Total revenue	$ 8,038	$ 7,922	1%	$ 17,378	$ 14,965	16%
Cost of revenue (exclusive of amortization)						
Product	$ 1,765	$ 2,366	(25)%	$ 4,459	$ 4,456	0%
Lease	484	268	81%	958	519	85%
Service	897	830	8%	2,377	1,638	45%
Total cost of revenue	$ 3,146	$ 3,464	(9)%	$ 7,794	$ 6,613	18%

Revenue

Three Months Ended June 30, 2022 compared with Three Months Ended June 30, 2021

Total revenue for the three months ended June 30, 2022 increased by $0.1 million, or 1%, compared to the three months ended June 30, 2021.

Product revenue for the three months ended June 30, 2022 decreased by $0.3 million, or 5%, compared to the three months ended June 30, 2021. The decrease was primarily attributable to a decrease in system sales of $0.7 million as we completed placement of the last new LLSs in inventory as part of our operational transition to the ALLY's commercial launch in the third quarter of 2022. This decrease was partially offset by increased procedure volume, which resulted in an increase of $0.4 million, during the three months ended June 30, 2022.

Service revenue for the three months ended June 30, 2022 increased by $0.2 million, or 23%, compared to the three months ended June 30, 2021.

The increase in product and service revenue combined was primarily attributable to increased net revenues in most of our operating regions, as procedure volume exceeded the second quarter of 2021. Our U.S. sales represented 62% and 58% of product and service revenue for the three months ended June 30, 2022 and 2021, respectively.

Lease revenue for the three months ended June 30, 2022 increased by $0.3 million, or 24%, compared to the three months ended June 30, 2021.

Six Months Ended June 30, 2022 compared with Six Months Ended June 30, 2021

Total revenue for the six months ended June 30, 2022 increased by $2.4 million, or 16%, compared to the six months ended June 30, 2021.

Product revenue for the six months ended June 30, 2022 increased by $1.5 million, or 13%, compared to the six months ended June 30, 2021. The increase was primarily attributable to increased procedure volume, which resulted in an increase of $1.9 million, offset by a decrease in system sales of $0.4 million as we completed placement of the last new LLSs in inventory as part of our operational transition to the ALLY's commercial launch in the third quarter of 2022.

Service revenue for the six months ended June 30, 2022 increased by $0.4 million, or 24%, compared to the six months ended June 30, 2021 primarily due to the increased number of systems installed.

The increase in product and service revenue combined was primarily attributable to increased net revenues in most of our operating regions as procedure volume exceeded the first half of 2021. Our U.S. sales represented 55% and 58% of product and service revenue for the six months ended June 30, 2022 and 2021, respectively.

Lease revenue for the six months ended June 30, 2022 increased by $0.6 million, or 25%, compared to the six months ended June 30, 2021.

Cost of Revenue

Three Months Ended June 30, 2022 compared with Three Months Ended June 30, 2021

Total cost of revenue for the three months ended June 30, 2022 decreased by $0.3 million, or 9%, compared to the three months ended June 30, 2021.

Cost of product revenue for the three months ended June 30, 2022 decreased by $0.6 million, or 25%, compared to the three months ended June 30, 2021. The lower cost of product revenue was attributable to the decreased number of sales of LENSAR Laser Systems in the 2022 period, which have a lower gross margin than procedure licenses. This decrease was partially offset by increased procedure volume between the periods. We expect cost of product revenue to fluctuate in future periods as supply chain challenges have resulted in higher costs of ALLY pre-launch inventory, which has been charged to research and development expenses through April 2022, as well as availability of systems which have a higher cost of sales.

Cost of service revenue for the three months ended June 30, 2022 increased by $0.1 million, or 8%, compared to the three months ended June 30, 2021 primarily due to higher service costs.

Cost of lease revenue for the three months ended June 30, 2022 increased by $0.2 million, or 81%, compared to the three months ended June 30, 2021. Cost of lease revenue increased primarily due to depreciation of newly leased systems.

Six Months Ended June 30, 2022 compared with Six Months Ended June 30, 2021

Total cost of revenue for the six months ended June 30, 2022 increased by $1.2 million, or 18%, compared to the six months ended June 30, 2021.

Cost of product revenue for the six months ended June 30, 2022 was consistent with the six months ended June 30, 2021, attributable to the decreased number of sales of LENSAR Laser Systems in the 2022 period, which have a lower gross margin than procedure licenses, offset by increased procedure volume between the periods. We expect cost of product revenue to fluctuate in future periods as supply chain challenges have resulted in higher costs of ALLY pre-launch inventory, which has been charged to research and development expenses through April 2022, as well as availability of systems which have a higher cost of sales.

Cost of service revenue for the six months ended June 30, 2022 increased by $0.7 million, or 45%, compared to the six months ended June 30, 2021 primarily due to higher service costs.

Cost of lease revenue for the six months ended June 30, 2022 increased by $0.4 million, or 85%, compared to the six months ended June 30, 2021. Cost of lease revenue increased primarily due to depreciation of newly leased systems.

Operating Expenses

Three Months Ended June 30, 2022 compared with Three Months Ended June 30, 2021

Selling, General and Administrative. Selling, general and administrative expenses for the three months ended June 30, 2022 were $7.6 million, an increase of $2.1 million, or 37%, compared to $5.5 million for the three months ended June 30, 2021. The increase was due primarily to increases in sales and marketing expenses of $0.9 million, which was primarily the result of increased trade show and travel activity, and $0.7 million of increased professional fees. We expect selling, general and administrative expense to increase from current levels as we begin the planned commercial launch of the ALLY System, anticipated in the third quarter of 2022.

Research and Development. Research and development expenses for the three months ended June 30, 2022 were $3.8 million, an increase of $0.8 million, or 28%, compared to $3.0 million for the three months ended June 30, 2021. The increase was primarily attributable to increased expenses for the continued development of the ALLY System. Inventory costs for the manufacture of ALLY Systems totaled approximately $1.0 million and $1.1 million during the three months ended June 30, 2022 and 2021, respectively.

Amortization of Intangible Assets. Amortization of intangible assets was $0.3 million for the three months ended June 30, 2022, consistent with the three months ended June 30, 2021.

Six Months Ended June 30, 2022 compared with Six Months Ended June 30, 2021

Selling, General and Administrative. Selling, general and administrative expenses for the six months ended June 30, 2022 were $13.8 million, an increase of $2.3 million, or 20%, compared to $11.6 million for the six months ended June 30, 2021. The increase was due to increases in sales and marketing expenses of $1.3 million, which was primarily the result of increased trade show and travel activity and $0.7 million of increased professional fees. We expect selling, general and administrative expense to increase from current levels as we begin the planned commercial launch of the ALLY System, anticipated in the third quarter of 2022.

Research and Development. Research and development expenses for the six months ended June 30, 2022 were $8.6 million, an increase of $2.9 million, or 50%, compared to $5.8 million for the six months ended June 30, 2021. The increase was primarily attributable to increased expenses for the continued development of the ALLY System, as well as inventory costs for the manufacture of ALLY Systems, which amounted to approximately $3.4 million and $1.6 million during the six months ended June 30, 2022 and 2021, respectively.

Amortization of Intangible Assets. Amortization of intangible assets was $0.6 million for the six months ended June 30, 2022, consistent with the six months ended June 30, 2021.

Non-GAAP Financial Measures

We prepare and analyze operating and financial data and non-GAAP measures to assess the performance of our business, make strategic and offering decisions and build our financial projections. The key non-GAAP measures we use, EBITDA and Adjusted EBITDA, are reconciled to net loss below for the three and six months ended June 30, 2022 and 2021.

	Three Months Ended June 30,		Six Months Ended June 30,	
(Dollars in thousands)	2022	2021	2022	2021
Net loss	$ (6,759)	$ (4,362)	$ (13,433)	$ (9,544)
Less: Interest income	(39)	(13)	(48)	(31)
Add: Depreciation expense	569	342	1,110	670
Add: Amortization expense	287	309	596	622
EBITDA	(5,942)	(3,724)	(11,775)	(8,283)
Add: Stock-based compensation expense	1,637	1,430	3,244	3,750
Adjusted EBITDA	$ (4,305)	$ (2,294)	$ (8,531)	$ (4,533)

EBITDA is defined as net loss before interest expense, interest income, income tax expense, depreciation and amortization expenses. EBITDA is a non-GAAP financial measure. EBITDA is included in this filing because we believe that EBITDA provides meaningful supplemental information for investors regarding the performance of our business and facilitates a meaningful evaluation of actual results on a comparable basis with historical results. Adjusted EBITDA is also a non-GAAP financial measure. We believe Adjusted EBITDA, which excludes stock-based compensation expense, provides meaningful supplemental information for investors when evaluating our results and comparing us to peer companies as stock-based compensation expense is a significant non-cash charge due to the recapitalization of the Company. We use these non-GAAP financial measures in order to have comparable financial results to analyze changes in our underlying business from quarter to quarter. However, there are a number of limitations related to the use of non-GAAP measures and their nearest GAAP equivalents. For example, other companies may calculate non-GAAP measures differently, or may use other measures to calculate their financial performance and, therefore, any non-GAAP measures we use may not be directly comparable to similarly titled measures of other companies.

Liquidity and Capital Resources

Overview

For the six months ended June 30, 2022 and 2021, we had net losses of $13.4 million and $9.5 million, respectively, and as of June 30, 2022, we had an accumulated deficit of $91.0 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 and pursue further regulatory clearances of our ALLY System.

As discussed above, the ongoing COVID-19 pandemic has negatively affected our capital requirements and more operating capital may be needed to fund our operations in the future.

Our primary sources of liquidity are our cash and cash equivalents, cash from the sale and lease of our systems and the sale of our consumables. We may raise additional capital from equity or debt financings or from other sources. As of June 30, 2022, 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 into 2024. The Company expects to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. The Company then plans a full commercial launch of the ALLY System in 2023. The Company expects it will need to raise additional capital through equity or debt financings or from other sources to continue its operations beyond 2024.

As we begin the commercial launch of the ALLY System in the third quarter of 2022, we expect selling, general and administrative expenses to increase from current levels. The successful commercialization of the ALLY System depends in part on the Company’s ability to produce the ALLY System in sufficient quantities and within requested timing to satisfy customer demand. Ongoing supply chain disruptions and unavailability of various parts needed to manufacture the ALLY System may have an adverse impact on the Company’s ability to meet customer demand for the ALLY System following initial launch.

Our liquidity needs will be largely determined by the success of our operations regarding the successful commercialization of our existing products and the launch of the ALLY System in the future.

We believe 2022 is a transition year for the Company, as we have transitioned from manufacturing and selling our LENSAR Laser System and are focusing on our ALLY System. We also intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory clearance in that region, among other factors. In addition, based on inventory of our LENSAR Laser System, our future revenue and cash flows will depend on, among other factors, our installed base of systems and the timing of and applicable clearances for our ALLY System.

We expect we will need to raise additional capital through equity or debt financings, borrowings under credit facilities or from other sources to continue our operations beyond 2024. We may issue securities, including common stock, preferred stock, warrants, and/or debt securities through private placement transactions or registered public offerings in the future. If we issue equity securities to raise additional capital, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. In addition, if we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Our ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of our control and we may be unable to raise financing when needed, or on terms favorable to us. If the necessary funds are not available from these sources, we may have to delay, reduce or suspend the scope of our sales and marketing efforts, research and development activities, or other components of our operations. Any of these events could adversely affect our ability to achieve our business and financial goals or to achieve or maintain profitability and could have a material adverse effect on our business, financial condition and results of operations. Additionally, the extent and duration of the impact 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. 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, development, and launch of the ALLY System, 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 and supply chain issues on our business; and the timing, scope and magnitude of our commercial and development activities.

Our material contractual obligations and commercial commitments at June 30, 2022 primarily consist of $3.1 million in operating lease payments for our facility lease and $7.8 million in minimum purchase obligations for inventory components for the manufacture and supply of certain components within the next 24 months. Our contractual obligations have increased due to supply chain issues that have necessitated us to enter into longer-term and more expensive per unit contracts to build and source inventory to satisfy the expected commercial demand for the ALLY System, if approved by regulatory authorities or certified by notified bodies in the applicable regions. LENSAR expects to meet these requirements through cash and cash equivalents and cash provided by operations. Some of these amounts are based on management’s estimates and assumptions about these obligations, including their duration, timing, anticipated actions by third parties and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those described. Furthermore, we could be required to pay contingent milestone and royalty payments in connection with the acquisition of certain intellectual property. The Company could be required to make a milestone payment in the amount of $1.2 million, which is contingent upon the commercialization of the ALLY System, in addition to the milestone payment of $1.2 million in contingent consideration paid in June 2022 in connection with the FDA clearance of the ALLY System. The payment is considered probable and reasonably estimable, as such the contingent consideration is recorded as a current liability on the Company’s balance sheet. In addition, the Company acquired certain intellectual property, which would result in additional royalty payments at a rate of 3% of certain revenue generated from the ALLY System.

We currently have an effective shelf registration statement on Form S-3 (No. 333-255136) filed with the SEC on April 8, 2021 (the “Registration Statement”) under which we may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, depositary shares, warrants, purchase contracts and units of up to $100.0 million in the aggregate. We also simultaneously entered into a sales agreement with SVB Leerink LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $35.0 million of our common stock from time to time in “at-the-market” (“ATM”) offerings under the

Registration Statement. Any sales by us pursuant to the Registration Statement, including any sales pursuant to the ATM offering, will be subject to any limits imposed under applicable law, including General Instructions I.B.1 and I.B.6 of Form S-3.

Cash Flows

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

	Six Months Ended June 30,	
(Dollars in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (5,397)	$ (6,081)
Net cash used in investing activities	(56)	(134)
Net cash (used in) provided by financing activities	(988)	170
Net decrease in cash and cash equivalents	$ (6,441)	$ (6,045)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2022 was $5.4 million, consisting primarily of a net loss of $13.4 million and an increase in net operating assets of $2.7 million and non-cash charges of $5.3 million. The increase in net operating assets was primarily due to changes in accounts receivable, inventories and accounts payable. Non-cash charges primarily consisted of depreciation, amortization, and stock-based compensation.

Net cash used in operating activities for the six months ended June 30, 2021 was $6.1 million, consisting primarily of a net loss of $9.5 million and a decrease in net operating assets of $2.0 million, partially offset by non-cash charges of $5.4 million. The decrease in net operating assets was primarily due to changes in accounts receivable, inventories and accrued liabilities. Non-cash charges primarily consisted of depreciation, amortization, and stock-based compensation.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 was $56,000, which consisted primarily of capital expenditures for property and equipment.

Net cash used in investing activities for the six months ended June 30, 2021 was $0.1 million, which consisted primarily of capital expenditures for property and equipment.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2022 was $1.0 million, primarily due to the payment of $1.2 million in contingent consideration due to regulatory approval of the ALLY System offset from proceeds from the sale of common stock under the employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2021 was $0.2 million, primarily due to proceeds from the sale of common stock under the employee stock purchase plan.

Stock-Based Incentive Plan

The 2020 Incentive Award Plan provides for the grant of stock options, restricted stock, restricted stock unit awards and other stock-based awards to recipients. During 2021, we granted stock options to directors, employees, and non-employees. During the six months ended June 30, 2022, we granted stock options and restricted stock units to employees and non-employees. We intend to grant stock options and restricted stock units as part of our overall compensation package to directors and employees.

At June 30, 2022, there was approximately $5.1 million, $0.5 million, and $3.5 million of total unrecognized compensation expense related to restricted stock awards, restricted stock units and stock options, respectively, which is expected to be recognized over a

weighted-average period of 1.1 years, 2.7 years and 2.9 years, respectively. Total unrecognized stock-based compensation expense is expected to be amortized as follows:

(Dollars in thousands)	Amount
2022	$ 3,263
2023	4,218
2024	981
2025	625
2026	14
Thereafter	—
Total unrecognized stock-based compensation expense	$ 9,101

The amounts included in this table are based on restricted stock awards, restricted stock units, and stock options outstanding at June 30, 2022 and assumes the requisite service period is fulfilled for all awards outstanding. Actual stock-based compensation expense in future periods may vary from those reflected in the table.

Off Balance Sheet Arrangements

As of June 30, 2022, we did not have any off-balance sheet arrangements, as defined under Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with U.S. Generally Accepted Accounting Principles, or GAAP, and the discussion and analysis of our financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. The impact 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.

There have been no significant and material changes in our critical accounting estimates during the three months ended June 30, 2022, as compared to those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Annual Report.

Recently Issued Accounting Standards

See Note 2, *Summary of Significant Accounting Policies*, to our unaudited condensed financial statements included in this Quarterly Report for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of June 30, 2022.

Item 3.Quantitative and Qualitative Disclosures About Market Risk.

We had cash and cash equivalents of $25.2 million as of June 30, 2022. Our cash and cash equivalents are held in deposit demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. Management has reviewed the financial 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 June 30, 2022.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of accounts receivable and notes receivable. We limit our credit risk with respect to accounts receivable and notes receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers. We do have the ability to disable the system's ability to operate for lack of payment and, in the case of notes receivable, repossess the system if scheduled payments lapse. As of June 30, 2022, two customers accounted for 17% and 11% 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 limited exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Item 4. 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 Quarterly 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 June 30, 2022.

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 June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1.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 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 Quarterly Report, including our unaudited condensed 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, 2020 and 2021, we had net losses of $19.8 million and $19.6 million, respectively, and for the six months ended June 30, 2021 and 2022, we had net losses of $9.5 million and $13.4 million, respectively. As of June 30, 2022, we had an accumulated deficit of $91.0 million. We expect to continue to incur losses for the foreseeable future as we continue to build our commercial and clinical infrastructure, pursue further FDA and other regulatory body clearance or certification of and commercially launch our proprietary, next generation integrated cataract treatment system, known as our ALLY System, and invest in research and development. In addition, as a public company, we will incur significant legal, accounting and other expenses. We cannot make assurances that we will ever generate sufficient revenue from our operations to achieve profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively affect the value of our securities and our ability to raise capital and continue operations.

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

We have historically derived our revenue principally 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 until we are able to fully commercialize our ALLY System. Accordingly, our ability to increase revenue is highly dependent on our ability to market and sell or lease our LENSAR Laser System and market the associated consumables. We believe 2022 is a transition year for the Company, as we have transitioned from manufacturing and selling our LENSAR Laser System and are focusing on our ALLY System. We also intend to submit additional marketing or certification applications outside the United States in an effort to commercialize the ALLY System in additional countries and operating regions. Our growth, market presence and ability to sell the ALLY System will depend on whether the ALLY System receives regulatory clearance or certifications in that region, among other factors. In addition, based on inventory of our LENSAR Laser System, our future revenue and cash flows will depend on, among other factors, our installed base of systems and the timing of and applicable clearances or certifications for our ALLY System.

Our ability to maintain our market share, execute our growth strategy, achieve commercial success and become profitable will depend upon the adoption and continued acceptance of our LENSAR Laser System and ALLY System by surgeons, hospital outpatient surgical facilities, in-office surgical suites and ambulatory surgery centers, or ASCs. Our system is currently, and upon commercial launch of our ALLY System, will be 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, like the ALLY System, and, if accepted, how frequently any such products will be used. Our current products may not maintain, and our ALLY System 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, ALLY System or other future products;
- acceptance by cataract surgeons and others in the medical community of our LENSAR Laser System and ALLY System;
- the potential and perceived advantages and disadvantages of our LENSAR Laser System and ALLY System as compared to competing products;
- the willingness of patients to pay out-of-pocket for procedures in which our LENSAR Laser System, ALLY System or other future products is used but for which limited reimbursement by third-party payors, including government authorities, is available;
- the effectiveness of our sales and marketing efforts, and of those of our international distributors;
- the prevalence and severity of any complications associated with using our LENSAR Laser System or ALLY System;
- the ease of use, reliability and convenience of our LENSAR Laser System and ALLY System relative to competing products;
- competitive response and negative selling efforts from providers of competing products;
- quality of outcomes for patients in procedures in which surgeons use our LENSAR Laser System and ALLY System;
- the results of clinical trials and post-market clinical studies relating to the use of our LENSAR Laser System and ALLY System;
- the technical leadership of our research and development teams;
- the absence of third party blocking intellectual property;
- our ability to introduce our products to the market with speed and on time with our projected timelines;
- pricing pressure, including from larger, well-capitalized and product-diverse competitors, corporate-owned ASCs, group purchasing organizations, and government payors; and
- the availability of coverage and adequate reimbursement for procedures using our LENSAR Laser System, ALLY System or other future products from third-party payors, including government authorities.

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

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

Our ALLY System has taken considerable time and resources to develop, and we may not be able to obtain FDA clearance (or regulatory bodies' certification or approval) to market and ultimately commercialize our ALLY System on a timely basis, or at all. Moreover, we are developing our ALLY System as a dual-function device that has the potential to perform both phacoemulsification and laser-assisted surgery. The ALLY System, now cleared by the FDA, enables cataract surgeons to complete the FLACS procedure seamlessly in a single, sterile environment. This clearance is the first stage of a planned, two step commercial release strategy. We expect to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. Our ability to place systems in 2022 has been limited by supply chain constraints that have delayed the delivery of certain ALLY raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. If we continue to experience supply chain constraints, we may be unable to deliver ALLY Systems as planned.

Further, we are relying on a third party to manufacture the phacoemulsification component of our ALLY System, and do not currently possess the internal resources or know-how to do so. We plan to seek an additional 510(k) clearance for the phacoemulsification features

of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as the predicate device. We were recently informed by the third party that it has withdrawn its 510(k) submission for its standalone phacoemulsification device and plans to resubmit the application at a later date. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, we are unable to submit our second 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, we will deliver the ALLY System to surgeons in the initial launch and the subsequent 2023 rollout with the phacoemulsification features remaining disabled and/or removed.

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

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

- properly identify and anticipate cataract surgeon and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- 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 our ALLY System or any other products we may develop in the future; and
- develop an effective and dedicated sales and marketing team.

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

COVID-19 and actions taken to control the spread of COVID-19 have impeded global supply chains and have had an adverse impact on our business, and we expect this situation to continue, and potentially worsen.

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 they may continue to do so. For example, "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 resulted in a significant decrease in the number of and demand for non-essential or elective medical procedures, including cataract surgeries, during 2020 and early 2021. We cannot provide assurance procedure volume levels will grow if additional business suspensions or restrictions are mandated. 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. In addition, “shelter-in-place” orders, quarantines, or similar orders or restrictions 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, federal and foreign regulators, notified bodies, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. The suspension of non-essential medical services during 2020 significantly impacted our revenues and cash flows and significantly impacted our ability to operate our commercial operations. Furthermore, these developments, including their long-term impact on our suppliers, have and may continue to adversely affect the availability of parts and components needed for our systems or, if such conditions persist, the commercial success of the ALLY System. Furthermore, we may continue to face increased costs associated with supply chain disruptions and price increases resulting from the COVID-19 pandemic. For example, we expect our contractual obligations to increase due to supply chain issues that have necessitated us to enter into longer-term and more expensive per unit contracts to build and source inventory to satisfy the expected commercial demand for the ALLY System. If these costs are passed along to customers through an increase to the overall cost of the ALLY System, customer demand may be adversely impacted. In addition, 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 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 systems is used, which would in turn adversely impact our future revenue and results of operations. Furthermore, some 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 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 products may adversely affect our business.

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

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

Payment for a standard cataract procedure is typically covered by Medicare, private insurance or other third-party payors. However, a cataract patient seeking a greater and more versatile visual outcome may desire an advanced cataract procedure involving a laser system such as ours. The patient is typically responsible for the additional costs associated with the use of these premium technologies in the physician’s practice, hospital outpatient surgical facilities, in-office surgical suites and ambulatory surgery centers. Due to this additional cost, patients may not elect to have such a procedure and our business may not grow as anticipated. Our future success depends in part upon patients achieving better visual outcomes from procedures using our LENSAR Laser System, and ALLY System upon commercial launch, 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 our ALLY System in certain aspects of the standard cataract procedure will be covered by or reimbursable through government or other third-party payors, our current LENSAR Laser System procedures are not covered by or reimbursable through government or other third-party payors. A decline in economic conditions in the United States or in international markets could result in a decline in demand for the procedures in which our systems are used and could have a material adverse effect on our business, financial condition and results of operations.

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

In order to generate future sales growth within the United States, we will need to expand the size and geographic scope of our U.S. direct sales organization. Accordingly, our future success will depend largely on our ability to train, retain and motivate skilled regional sales managers and direct sales representatives with significant technical knowledge of our systems. Because of the competition for their

services, we may not be able to retain such representatives on favorable or commercially reasonable terms, if at all. If we are unable to grow our global sales and marketing organization within the United States, we may not be able to increase our revenue, which would adversely affect our business, financial condition and results of operations.

Additionally, we rely exclusively on a network of independent distributors to generate sales and leases of our LENSAR Laser System as well as purchases of our consumables and licensed applications outside of the United States. As of June 30, 2022, two customers accounted for 17% and 11% of our accounts receivable, net. This customer concentration exposes us to a material adverse effect if any of these significant distributors were to significantly reduce purchases for any reason or favor competitors or new market participants. If a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train new personnel to market our LENSAR Laser System, and our ALLY System upon receiving regulatory clearance in the applicable region, as well as our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. In addition, our international distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing, sales, education and training efforts that we believe are necessary to enable the products to develop, achieve or sustain market acceptance. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent that distributor from helping competitors solicit business from our existing customers, which could further adversely affect us. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party distributors become unsatisfactory, we may experience delays in meeting our customers' demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose potential customers.

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

We expect our revenues and expenses to increase in connection with our on-going activities, particularly as we continue to execute on our growth strategy, including expansion of our sales and customer support teams. The primary factors determining our cash needs are the funding of operations, which we expect to continue to expand as the business grows, and enhancing our product offerings through the research and development, further regulatory clearances and launch of the ALLY System. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our commercial efforts and those of our distributors; the timing, scope and magnitude of our commercial and development activities; and the timing of further regulatory clearance or certification of our ALLY System. We 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 Quarterly 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 into 2024. 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 systems;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in procuring, manufacturing and selling our systems, including increased costs, uncertainties, and delays associated with supply chain disruptions caused by the COVID-19 pandemic;
- the costs of commercializing the ALLY System, including increased costs associated with supply chain disruptions caused by the COVID-19 pandemic, or other new products or technologies;
- the scope, rate of progress and cost of our clinical studies that we are currently conducting or may conduct in the future;
- the cost and timing of obtaining and maintaining regulatory approval, certification or clearance of our products and planned or future products;
- costs associated with any product recall that may occur;
- the costs associated with complying with state, federal and foreign laws and regulations;

- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the cost of enforcing or defending against non-competition claims;
- the number and timing of acquisitions and other strategic transactions;
- the costs associated with increased capital expenditures; 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 systems or other products associated with the systems is materially disrupted, including supply chain shortages and price increases resulting from the COVID-19 pandemic, it may adversely affect our ability to manufacture products and could negatively affect our operating results.

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

We purchase custom and off-the-shelf components from a number of suppliers and subject them to stringent quality specifications and processes. Some of the components necessary for the assembly of our systems and associated consumables are currently provided by single-sourced suppliers (the only approved supply source for us among other sources). We are also relying on a third party to manufacture the phacoemulsification component of the ALLY System. If one or more of our suppliers cease to provide us with sufficient quantities of materials in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we may experience delays in engaging additional or replacement suppliers for certain components. There may also be disruptions outside our control in the availability and pricing of various component parts needed for our ALLY System. In particular, a global semiconductor supply shortage resulting from the COVID-19 pandemic is having wide-ranging effects across multiple industries, and we are seeing more significant disruptions in the supply of, and fluctuations in pricing for, various component parts needed for our ALLY System, including the integrated circuits used in the ALLY System. Our efforts to maintain an adequate supply of inventory may not be sufficient and we may be unable to source the necessary component parts on commercially acceptable terms to reflect in the price of our system. The long-term loss of these suppliers, or their long-term inability to provide us with an adequate supply of components or products, could potentially cause delay in the manufacture of our products, thereby impairing our ability to meet the demand of our customers and causing significant harm to our business. If it becomes necessary to identify and qualify a suitable second source to replace one of our key suppliers, that replacement supplier would not have access to our previous supplier’s proprietary processes and would therefore be required to develop its own, which could also result in delay. Any disruption of this nature or increased expense could harm our commercialization efforts and could have a material adverse effect on our business, financial condition and results of operations. If these supply chain shortages and disruptions continue or worsen, there is no guarantee that the Company will be able to meet customer demand for the ALLY System following our initial launch. In addition, pricing increases in component parts our systems may necessitate an increase in the overall cost to customers, which in turn may have an adverse impact on customer demand.

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

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

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

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

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

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

We have historically sold and leased a significant portion of our LENSAR Laser Systems outside of the United States through a network of independent distributors and intend to increase our international presence in Germany, China and South Korea, as well as other international markets. 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, especially in the United States. We may experience loss from a customer's failure to make payments according to the contractual lease terms or some other material decrease in the practice revenues and surgical procedure volume. Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, economic pressures or uncertainty, or other customer-specific factors. In addition, our credit risk may be highly concentrated, as we rely exclusively on a network of independent distributors to generate sales outside of the United States. Further, ongoing consolidation among distributors, retailers and healthcare provider organizations could increase the concentration of credit risk. The factors affecting our customers' ability to make timely payments according to the contractual lease terms are out of our control, and as a result, exposes us to additional risks that may materially and adversely affect our business and results of operations. The occurrence of any such factors affecting our customers may cause delays in payments or, in some cases, defaults on payment obligations, which could result in material losses.

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

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

We generally do not maintain large volumes of finished goods and anticipating demand for our products may be challenging as cataract surgeon demand and adoption rates can be unpredictable. In addition, as use of our LENSAR Laser System 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. As we anticipate the projected commercial launch of the ALLY System, we are modifying our manufacturing operations from producing the LENSAR Laser Systems to the ALLY System. We could underestimate the worldwide demand for the LENSAR Laser System and be unable to fulfill customer requests. Conversely, if we overestimate customer demand, our excess or obsolete inventory may increase significantly, which would reduce our gross margin and adversely affect our financial results.

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

Adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs, for certain procedures (e.g., phacoemulsification) using our ALLY System or other products we may develop in the future, if approved, is central to the acceptance and adoption of these products. Hospitals, healthcare facilities, physicians and other healthcare providers that may purchase and use our ALLY System generally rely on third-party payors

to pay for a part of the costs and fees associated with certain procedures using our ALLY System. If third-party payors reduce their levels of payment, if our costs of production increase faster than increases in reimbursement levels or if third-party payors deny reimbursement for procedures using our ALLY System, our ALLY System may not be adopted or accepted by hospitals, healthcare facilities, physicians or other healthcare providers and the prices paid for a procedure using our ALLY System may decline, which could have a material adverse effect on our business, financial condition or results of operations.

Physicians are reimbursed separately for their professional time and effort to perform a cataract procedure that is covered by third-party payors. Such party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our ALLY System would be used. These updates could directly impact the demand for our future products. For example, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule, or PFS, through 2019, but no annual update from 2020 through 2025. MACRA also introduced a Quality Payment Program for Medicare physicians, nurses and other "eligible clinicians" (as defined in MACRA) that adjusts overall reimbursement under the PFS based on certain performance categories. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our ALLY System or any other products we may develop in the future. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor. Many private payors require extensive documentation of a multi-step diagnosis before authorizing procedures using our products. Some private payors may apply their own coverage policies and criteria inconsistently, and physicians and other healthcare providers may not be able to receive approval and reimbursement for certain procedures using our ALLY System consistently. Any perception by physicians and other healthcare providers that the reimbursement for procedures using our ALLY System or other future products is inadequate to compensate them for the work required, including diagnosis, documentation, obtaining third-party payor approval for the procedure and other burdens on their office staff or that they may not be reimbursed at all for the procedures using our ALLY System or other future products, may negatively affect the adoption and use of our ALLY System or other future products and technologies, and the prices paid for such products may decline.

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

We provide a limited warranty for our products.

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

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

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

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

We do not carry insurance for all categories of risk that our business may encounter. We can give no assurance that the coverage under our product liability insurance in the United States will be available or adequate to satisfy any claims. Product liability insurance is expensive, 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 and maintain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

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

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

- fluctuations in the demand for the more advanced, patient-pay procedures in which our systems are used;
- adoption of our LENSAR Laser Systems, and following the anticipated commercial launch, our ALLY Systems;
- our ability to establish and maintain an effective and dedicated sales organization in the United States and network of independent distributors outside the United States;
- pricing pressure applicable to our products competitor pricing;
- results of clinical research and trials on our products or competitive products;
- the mix of sales and leases of our systems;

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

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

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

We have experienced significant period-to-period growth in our business, 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;
- the need to hire, train and manage additional qualified personnel; and
- transitioning manufacturing from our LENSAR Laser System to our ALLY System.

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

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

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

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

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

In addition to competing for market share for our products, we also compete against our competitors for personnel, including qualified sales representatives that are necessary to grow our business. Universities and research institutions also compete with us for scientific personnel that are important to our 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.

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

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

Like most companies, despite our current security measures, our information technology systems, and those of our third-party service providers, may be vulnerable to information security breaches, acts of vandalism, computer viruses and interruption or loss of valuable business data. Stored data might be improperly accessed due to a variety of events beyond our control, including, but not limited to, natural disasters, terrorist attacks, telecommunications failures, computer viruses, hackers and other security issues. In addition, a variety of our software systems are cloud-based data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks. We have technology security initiatives in place to mitigate our risk to these vulnerabilities, but these measures may not be adequately designed or implemented to ensure that our operations are not disrupted or that data security breaches do not occur.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. Any breach of our network may result in damage to our reputation, the loss of valuable business data, the misappropriation of our valuable intellectual property or trade secret information, misappropriation of personal information, key personnel being unable to perform duties or communicate throughout the organization, significant costs for data restoration and other

adverse impacts on our business. Ransomware attacks, including those from organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational loss, diversion of funds, and may result in fines, litigation and unwanted media attention. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting payments. Despite our existing security procedures and controls, if our network were compromised, it could give rise to unwanted media attention, materially damage our customer relationships, decrease sales and leases of our products, increase overhead costs, harm our business, reputation, results of operations, cash flows and financial condition, result in fines or litigation, and may increase the costs we incur to protect against such information security breaches, such as increased investment in technology, the costs of compliance with consumer protection laws and costs resulting from consumer fraud.

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

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

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

Our business processes personal data, including some data related to health. When conducting clinical studies, 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 a reliable indicator of our future results.

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

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

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

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

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

Risks Related to Government Regulation

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

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance, certification and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval 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, foreign regulatory authorities and notified bodies enforce these regulatory requirements through, among other means, periodic unannounced inspections and audits. We do not know whether we will be found compliant in connection with any future FDA (or foreign regulatory authorities) inspections or notified bodies' audits. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, certifications or approvals; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

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.

The ALLY System, now cleared by the FDA, enables cataract surgeons to complete the FLACS procedure seamlessly in a single, sterile environment. This clearance is the first stage of a planned, two step commercial release strategy. We expect to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. The ALLY System is expected to be made widely available to U.S. cataract surgeons in 2023. Our ability to place systems in 2022 has been limited by supply chain constraints that have delayed the delivery of certain ALLY raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory. As the second stage of the commercial release strategy, we plan to seek an additional 510(k) clearance for the phacoemulsification features of the ALLY System in a subsequent 510(k) submission subject to a third party's phacoemulsification device receiving clearance and serving as the predicate device. LENSAR was recently informed by the third party that it has withdrawn its 510(k) submission for its standalone phacoemulsification device and plans to resubmit the application at a later date. As this device will be considered the predicate device for purposes of evaluating the ALLY System's phacoemulsification functionality, LENSAR is unable to submit its second 510(k) submission seeking clearance of the phacoemulsification features within the ALLY System until the predicate device receives FDA clearance. Accordingly, we will deliver the ALLY System to surgeons in the initial launch and the subsequent 2023 rollout with the phacoemulsification features remaining disabled and/or removed. If the third party is unsuccessful in obtaining clearance on its projected timelines, or at all, we could be delayed in our submission for 510(k) clearance for the phacoemulsification features of our ALLY System, and/or we may be required to find an alternative component from a different third party to replace the component the third party is developing. We may be unable to identify a replacement supplier, and even if we are, the use of a different third party component could require additional data or other activities that could increase our costs or delay our projected timing. If any of these events were to occur, we could be materially delayed in our efforts to seek 510(k) clearance of all features of our ALLY System. Even if the third party obtains clearance for the phacoemulsification device, the FDA has significant discretion in the 510(k) clearance process, and we cannot guarantee that we will obtain clearance of our ALLY System as proposed.

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

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

Subject to the transitional provisions and in order to sell our products in EU member states of the European Union, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces the Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("CE") mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU

must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

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

The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would prevent us from selling our products in the EU and these three countries. Following the end of the "Brexit" transitional period, from January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, became responsible for the UK medical device market. The new regulations require medical devices to be registered with the MHRA (but manufacturers were given a grace period of four to 12 months to comply with the new registration process) before being placed on Great Britain market. Manufacturers based outside the UK 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 UK Conformity Assessed ("UKCA") 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. On June 26, 2022, the MHRA published its long-awaited response to its consultation on the UK's post-Brexit regulatory regime for medical devices and in vitro diagnostic medical devices. The MHRA confirmed that the new regulatory landscape will mirror many of the provisions of the EU regulatory regime, as contained within the EU Medical Devices Regulation. However, the response also highlighted that in certain areas, medical devices regulation in Great Britain is likely to deviate from the EU framework. The UK government now needs to translate its proposals into legislation, via amendments to the UK Medical Devices Regulations (SI 2002 No 618, as amended). These modifications may have an effect on the way we intend to conduct our business in these countries.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

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

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;

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

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

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

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

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

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA (or other regulatory authorities) requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; 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 a foreign regulatory authority or certified by a notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

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

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA (or similar foreign authorities), and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA (or similar foreign authorities) when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA (or similar foreign authorities) could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

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

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

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA (or similar foreign authorities). We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA (or similar foreign authorities). If the FDA (or similar foreign authorities) disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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

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

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

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

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

The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators or notified bodies may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

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

- we may be required to submit an Investigational Device Exemption (“IDE”) application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials, and similar risks may apply in foreign jurisdictions;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators, Institutional Review Boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators or notified bodies may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB (or other reviewing bodies), regulatory authorities, or both, for re-examination;
- regulators, IRBs, other reviewing bodies, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for certification or approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, 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 or certification of our product candidates.

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

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs, or other reviewing bodies, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under cGMP, requirements and other regulations. Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited

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

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

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

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

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

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

In addition, the regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directive, the EU Medical Devices

Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU. The EU Medical Devices Regulation became effective on May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the Medical Devices Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

The new regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the EU Medical Devices Directive) and reinforces surveillance once they are available;

- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;

- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;

- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and

- strengthens the rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

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

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

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

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities

outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, or other regulatory authorities or notified bodies, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

In the United States, the EU and other jurisdictions, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States medical device industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA, as well as other efforts to challenge, repeal or replace the ACA that may impact our business or financial condition.

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, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments varies from 1% from April 1, 2022 through June 30, 2022, to up to 3% in the final fiscal year of this sequester. 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.

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

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

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

Although none of the procedures using our products are currently covered by any state, federal or foreign government healthcare programs or other third-party payors, applicable agencies and regulators may interpret that our commercial, research and other financial relationships with healthcare providers and institutions are nonetheless subject to various federal, state and foreign laws intended to prevent healthcare fraud and abuse, including the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration has been broadly defined to include anything of value, including

cash, improper discounts and free or reduced price items and services. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers. The federal False Claims Act has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed or for services that are not medically necessary. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The federal False Claims Act also includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, also created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

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

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

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

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

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

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and contractor research organizations, or CROs, may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, misconduct by these parties could include among other infractions or violations intentional, reckless or negligent conduct or unauthorized activity that violates: (i) FDA (and foreign regulatory authorities') regulations, including those laws that require the reporting of true, complete and accurate information to the FDA (or foreign regulatory authorities); (ii) manufacturing standards; (iii) federal, state and foreign healthcare fraud and abuse laws and regulations; (iv) laws that require the true, complete and accurate reporting of financial information or data; or (v) other commercial or regulatory laws or requirements. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Intellectual Property Matters

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

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

We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our products, brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

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

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

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or

desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. We may not be successful in protecting our proprietary rights, and unauthorized parties may be able to obtain and use information that we regard as proprietary.

We own numerous issued patents and pending patent applications. As of June 30, 2022, we owned approximately 53 U.S. patents, 35 pending U.S. patent applications, 83 issued foreign patents, and 80 pending foreign and Patent Cooperation Treaty applications. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty.

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

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

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

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

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

Even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may

introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval 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.

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

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

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

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

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks,

and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell or export our products or to use our technologies or product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

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

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

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

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

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

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

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. However, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

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

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

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

In addition to patent protection, we also rely on protection of trade secrets, know-how and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. The protections we place on our intellectual property or other proprietary rights may not be sufficient. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their

confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or products or otherwise 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 agreements with Oertli may restrict our freedom to practice and may not protect us against potential competition with respect to jointly-developed intellectual property.

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

in our industry may be adversely affected, which may have a material adverse impact on our business, financial condition and results of operation.

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

We rely on trademarks, service marks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. 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 Quarterly Report, these factors include:

- a shift in our investor base;

- actual or anticipated fluctuations in our quarterly financial condition and operating performance;

- the operating and stock price performance of similar companies;

- introduction of new products by us or our competitors;

- success or failure of our business strategy;
- our ability to obtain financing as needed;
- changes in accounting standards, policies, guidance, interpretations or principles;
- the overall performance of the equity markets;
- the number of shares of our common stock publicly owned and available for trading;
- threatened or actual litigation or governmental investigations;
- changes in laws or regulations affecting our business, including tax legislation;
- announcements by us or our competitors of significant acquisitions or dispositions;
- any major change in our board of directors or management;
- changes in earnings estimates by securities analysts or our ability to meet earnings guidance;
- publication of research reports about us or our industry or changes in recommendations or withdrawal of research coverage by securities analysts;
- large volumes of sales of our shares of common stock by existing stockholders;
- short sales of our common stock;
- investor perception of us and our industry; and
- changes in financial markets or general economic conditions, including the effects of recession or slow economic growth in the U.S. and abroad, interest rates, fuel prices, international currency fluctuations, corruption, political instability, acts of war, including the Russian Federation's invasion of Ukraine in February 2022, acts of terrorism, and the ongoing COVID-19 pandemic or other public health crises.

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

General Risk Factors

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

As a public company, we are required to file with the SEC annual, quarterly and current reports that are specified in Section 13 of the Exchange Act. We are required to prepare financial statements that are fully compliant with all SEC reporting requirements on a timely basis. In addition, we are subject to other reporting and corporate governance requirements, including the requirements of the Nasdaq Stock Market, or Nasdaq, and certain provisions of the Sarbanes-Oxley Act and the regulations promulgated thereunder, which impose significant compliance obligations upon us. 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 2.Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3.Defaults Upon Senior Securities

None.

Item 4.Mine Safety Disclosures

Not applicable.

Item 5.Other Information

None.

Item 6.Exhibits

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	Second Amended and Restated Bylaws of LENSAR, Inc.	Form 10-K	001-39473	3.2	3/12/2021	
4.1	Form of Certificate of Common Stock	Form 10/A	001-39473	4.1	09/14/2020	
31.1	Certification of Principal Executive 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 Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (as formatted as Inline XBRL and contained in Exhibit 101)					*

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

* Filed herewith.

** Furnished herewith.

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: August 8, 2022

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

Date: August 8, 2022

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

Date: August 8, 2022

/s/ KENDRA W. WONG
Kendra W. Wong
Principal Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicholas Curtis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LENSAR, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2022

By: /s/ Nicholas T. Curtis

Nicholas T. Curtis
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas R. Staab, II, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LENSAR, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles ;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2022

By: /s/ Thomas R. Staab, II

Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of LENSAR, Inc. (the "Company") for the quarterly period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2022

By: /s/ Nicholas T. Curtis

Nicholas T. Curtis
Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of LENSAR, Inc. (the "Company") for the quarterly period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2022

By: /s/ Thomas R. Staab, II

Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.