

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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 March 31, 2023

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: 001-40690

**RxSIGHT, INC.**  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

100 Columbia  
Aliso Viejo, CA  
(Address of principal executive offices)

94-3268801  
(I.R.S. Employer  
Identification No.)

92656  
(Zip Code)

Registrant's telephone number, including area code: (949) 521-7830

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	RXST	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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 April 28, 2023, the registrant had 33,981,877 shares of common stock, \$0.001 par value per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read together with our condensed consolidated financial statements and the condensed notes to those statements included elsewhere in this report. This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. In this report, "we," "us" and "our" refer to RxSight, Inc., a Delaware corporation, and its consolidated subsidiaries.

Forward-looking statements include, but are not limited to, statements concerning the following:

- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements, including our expectation that we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q as filed with the Securities and Exchange Commission ("SEC"), provided that we may opportunistically access our at-the-market ("ATM") facility under advantageous circumstances;
- our plans to conduct further clinical trials and any expectations related to the timing or outcomes of such trials;
- our plans and expected timelines related to our products, or developing new products, to address additional indications or otherwise;
- the expected acceptance and use of our products by doctors;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- the expected growth of our business and our organization;
- our intentions regarding investment in our business as we pursue growth;
- our expected uses of our existing resources;
- the expectations regarding government and third-party payer coverage and reimbursement;
- our ability to recruit and retain key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, including single- and sole-source suppliers;
- our ability to manufacture sufficient quantities of our products with appropriate quality;
- our ability to obtain, maintain and enforce intellectual property protection for our products and protect our intellectual property rights;
- our ability to expand our business into new geographic markets;
- our ability to comply with applicable SEC rules and Nasdaq continued listing requirements;
- our ability to comply with existing and future government laws, rules and regulations both in the United States and internationally;
- our expectations regarding allocation of resources toward expenses associated with being a public company;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and a smaller reporting company under the Exchange Act;

- the volatility of the trading price of our common stock;
- our ability to identify and develop new and planned products and/or acquire new products;
- development and projections relating to our competitors or our industry, including anticipated growth rates for the conventional and premium intraocular lens (“IOL”) markets;
- the impact of local, regional, national or political conditions and events;
- the impact of the COVID-19 pandemic, including currently known and unknown coronavirus variants, on our business or personnel; and
- the impact of worldwide political and economic conditions and unknown future events on our business, financial condition and results of operations.

Forward-looking statements include statements that are not historical facts and can be identified by terminology such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “intends,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” or “continue,” or the negative of such terms and other same terminology.

Forward-looking statements involve known and unknown risks, uncertainties, and other 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. We discuss these risks in greater detail in Part II, Item 1A, “Risk Factors,” elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements made in this report relate only to events as of the date on which the statements are made. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

## **DISCUSSION AND ANALYSIS OF OUR FINANCIAL CONDITION**

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to revenue recognition, the realization of income tax assets and estimates of tax liabilities, and obsolete, excess and slow-moving inventory. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ materially from these estimates. Our critical accounting policies and estimates are discussed in the Company’s Annual Report on Form 10-K filed with the SEC on March 6, 2023.

## **INDUSTRY, BUSINESS AND MARKET DATA**

This report also contains estimates, projections and other information concerning our industry, our business, and market opportunity, including data regarding the estimated size of the market. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

## **TRADEMARKS, SERVICE MARKS AND TRADE NAMES**

This report contains references to trademarks and service marks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of it by, any other companies.

**Item 1: Financial Statements (Unaudited)**

**RxSIGHT, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share amounts)

	March 31, 2023 (Unaudited)	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,012	\$ 11,834
Short-term investments	142,927	93,968
Accounts receivable	12,668	10,956
Inventories	18,067	14,835
Prepaid and other current assets	2,992	2,962
Total current assets	187,666	134,555
Property and equipment, net	9,804	10,138
Operating leases right-of-use assets	3,555	3,943
Restricted cash	761	761
Other assets	746	767
<b>Total assets</b>	<b>\$ 202,532</b>	<b>\$ 150,164</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,717	\$ 2,595
Accrued expenses and other current liabilities	9,181	12,672
Lease liabilities	1,978	1,970
Total current liabilities	14,876	17,237
Long-term lease liabilities	2,338	2,856
Term loan, net	40,309	40,169
<b>Total liabilities</b>	<b>57,523</b>	<b>60,262</b>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, \$0.001 par value, 900,000,000 shares authorized, 33,966,697 shares issued and outstanding as of March 31, 2023 and 28,268,389 shares issued and outstanding as of December 31, 2022	34	28
Preferred stock, \$0.001 par value, 100,000,000 shares authorized, no shares issued and outstanding	—	—
Additional paid-in capital	704,228	636,001
Accumulated other comprehensive loss	(9)	(95)
Accumulated deficit	(559,244)	(546,032)
Total stockholders' equity	145,009	89,903
<b>Total liabilities and stockholders' equity</b>	<b>\$ 202,532</b>	<b>\$ 150,164</b>

See accompanying notes to unaudited condensed consolidated financial statements.

**RxSIGHT, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**AND COMPREHENSIVE LOSS (UNAUDITED)**  
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Sales	\$ 17,489	\$ 8,942
Cost of sales	7,123	5,181
Gross profit	10,366	3,761
Operating expenses:		
Selling, general and administrative	16,255	13,620
Research and development	7,208	6,719
Total operating expenses	23,463	20,339
Loss from operations	(13,097)	(16,578)
Other income (expense), net:		
Interest expense	(1,507)	(1,060)
Interest and other income	1,392	46
Loss before income taxes	(13,212)	(17,592)
Income tax expense	—	4
Net loss	\$ (13,212)	\$ (17,596)
Other comprehensive income (loss)		
Unrealized gain (loss) on short-term investments	84	(74)
Foreign currency translation gain (loss)	2	(4)
Total other comprehensive income (loss)	86	(78)
Comprehensive loss	\$ (13,126)	\$ (17,674)
Net loss per share:		
Basic & diluted	\$ (0.42)	\$ (0.64)
Weighted-average shares used in computing net loss per share:		
Attributable to common stock, basic & diluted	31,637,097	27,425,610

See accompanying notes to unaudited condensed consolidated financial statements.

**RxSIGHT, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(UNAUDITED)**  
(In thousands, except number of shares)

	Three Months Ended March 31, 2023					
	Common stock		Additional paid-in	Accumulated other	Accumulated	Total
	Shares	Amount	capital	comprehensive loss	deficit	stockholders' equity
Balance at December 31, 2022	28,268,389	\$ 28	\$ 636,001	\$ (95)	\$ (546,032)	\$ 89,902
Shares issued for the exercise of stock options and vesting of restricted stock units	243,598	—	761	—	—	761
Shares redeemed for employee tax withholdings	(24,631)	—	(337)	—	—	(337)
Stock-based compensation expense	—	—	3,295	—	—	3,295
Issuance of common stock for public offering, net of underwriting discounts, commissions and offering costs	4,600,000	5	53,595	—	—	53,600
Issuance of common stock for at-the-market offerings, net of issuance costs	879,341	1	10,913	—	—	10,914
Unrealized gain on short-term investments and cash equivalents, net of tax	—	—	—	84	—	84
Foreign currency translation adjustment	—	—	—	2	—	2
Net loss	—	—	—	—	(13,212)	(13,212)
Balance at March 31, 2023	<u>33,966,697</u>	<u>\$ 34</u>	<u>\$ 704,228</u>	<u>\$ (9)</u>	<u>\$ (559,244)</u>	<u>\$ 145,009</u>

See accompanying notes to unaudited condensed consolidated financial statements



**RxSIGHT, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(UNAUDITED)**  
(In thousands, except number of shares)

Three Months Ended March 31, 2022

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2021	27,366,746	\$ 27	\$ 617,511	\$ (20)	\$ (479,276)	\$ 138,242
Shares issued for the exercise of stock options and vesting of restricted stock units	145,922	—	308	—	—	308
Shares redeemed for employee tax withholdings	(26,983)	—	(362)	—	—	(362)
Stock-based compensation expense	—	—	2,649	—	—	2,649
Unrealized loss on short-term investments and cash equivalents, net of tax	—	—	—	(74)	—	(74)
Foreign currency translation adjustment	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(17,596)	(17,596)
Balance at March 31, 2022	<u>27,485,685</u>	<u>\$ 27</u>	<u>\$ 620,106</u>	<u>\$ (98)</u>	<u>\$ (496,872)</u>	<u>\$ 123,163</u>

See accompanying notes to unaudited condensed consolidated financial statements

**RxSIGHT, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
(In thousands)

	Three Months Ended March 31,	
	2023	2022
<b>Operating Activities:</b>		
Net loss	\$ (13,212)	\$ (17,596)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	955	1,016
Amortization of right-of-use lease assets	44	19
Amortization of debt issuance costs and premium	141	130
Amortization of discount on short-term investments	(1,257)	(47)
Stock-based compensation	3,295	2,649
Provision for excess and obsolete inventory	10	73
Change in operating assets and liabilities:		
Accounts receivable	(1,712)	(764)
Inventories	(3,241)	(530)
Prepaid and other assets	(460)	814
Accounts payable	1,163	701
Accrued expenses and other liabilities	(3,490)	(1,450)
Net cash used in operating activities	(17,764)	(14,985)
<b>Investing Activities:</b>		
Purchase of property and equipment	(747)	(370)
Maturity of short-term investments	60,000	90,000
Purchases of short-term investments	(107,618)	(74,771)
Net cash (used in) provided by investing activities	(48,365)	14,859
<b>Financing Activities:</b>		
Proceeds from exercise of stock options	761	308
Proceeds from issuance of common stock from public offering	54,050	—
Proceeds from issuance of common stock for at-the-market offerings	11,102	—
Payments for employee taxes related to stock compensation	(337)	(362)
Principal payments on finance lease liabilities	(41)	(44)
Payments of deferred offering costs	(230)	—
Net cash provided by (used in) financing activities	65,305	(98)
Effect of foreign exchange rate on cash, cash equivalents and restricted cash	2	(5)
Net decrease in cash, cash equivalents and restricted cash	(822)	(229)
Cash, cash equivalents and restricted cash - beginning of period	12,595	25,172
Cash, cash equivalents and restricted cash - end of period	\$ 11,773	\$ 24,943
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	546	499
Cash paid for income taxes	—	—
Cash paid for interest on financing leases	4	3
Cash paid for interest on term loan	1,344	925
<b>Non-cash investing and financing activities:</b>		
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	—	87
Finance lease	—	192
Lease obligations recorded for right-of-use assets:		
Operating lease	—	87
Finance lease	—	166
Acquisition of property and equipment included in accounts payable and accrued expenses and other current liabilities	259	197
Deferred offering costs included in accounts payable and accrued liabilities	466	—
Reclassification of deferred financing costs	(55)	—

See accompanying notes to unaudited condensed consolidated financial statements.

**Note 1 - Organization and Basis of Presentation**

*Description of Business*

RxSight®, Inc. (the “Company”) is a Delaware corporation headquartered in Aliso Viejo, California with one wholly owned subsidiary located in Amsterdam, Netherlands. The wholly owned subsidiary has a registered branch in the United Kingdom and a wholly owned subsidiary located in Germany. The Company is engaged in the research and development, manufacture and sale of light adjustable intraocular lenses used in cataract surgery along with capital equipment used with the lenses.

The Company’s products, which include the light adjustable lens (“LAL®”) and a specially designed machine for delivering light to the eye, the Light Delivery Device (“LDD™”), are approved by the United States (“U.S.”) Food and Drug Administration (“FDA”) primarily for sale in the U.S. and have regulatory approval in the U.S., Europe, Canada and Mexico. The Company began marketing its products in 2019. The LAL is a premium intraocular lens (“IOL”) which is partially reimbursable under Medicare. The Company competes with other IOLs in the premium market.

The accompanying unaudited condensed consolidated financial statements include the accounts of RxSight, Inc. and its wholly owned subsidiaries, RxSight, B.V. and RxSight GmbH. All significant inter-company balances and transactions have been eliminated in consolidation.

*Basis of Presentation and Principles of Consolidation*

The Company’s condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and pursuant to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, the accompanying unaudited condensed consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The December 31, 2022 balance sheet data was derived from audited financial statements; however, the accompanying notes to the condensed consolidated financial statements do not include all of the annual disclosures required under GAAP and should be read in conjunction with the audited consolidated financial statements included in the Company’s 2022 Annual Report on Form 10-K filed with the SEC on March 6, 2023. The operating results presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods.

*Operating Segments*

The Company determined its operating segment on the same basis that it uses to evaluate its performance internally. The Company’s chief operating decision-maker (“CODM”), its Chief Executive Officer, reviews its consolidated operating results for the purpose of allocating resources and evaluating financial performance.

The Company determined that it operates and manages its business (including its non-U.S. subsidiaries) in one reportable segment: the research and development, manufacture and sale of light adjustable lenses and related capital equipment.

*Liquidity*

*Shelf Registration Statement*

On August 8, 2022, the Company filed a \$200.0 million shelf registration statement on Form S-3 (“shelf registration statement”) which became effective on August 12, 2022. The shelf registration statement is effective for three years and permits the Company to sell, from time to time, up to \$200.0 million in aggregate value of common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide the Company with flexibility to access additional capital. At the time of filing the shelf registration statement, the

Company also filed a prospectus supplement to sell up to an aggregate value of \$50.0 million dollars of common stock through an “at-the-market” (“ATM”) offering.

#### *ATM Offering*

As of March 31, 2023, through the ATM offering, a total of 1,355,216 shares of the Company's common stock, for total net proceeds of \$16.9 million, have been issued and sold, of which 879,341 shares of the Company's common stock, for net proceeds of \$10.9 million, were sold during the quarter ended March 31, 2023.

#### *Public Offering*

On February 7, 2023, the Company entered into an underwriting agreement with BofA Securities, Inc., in which the Company agreed to issue and sell 4,000,000 shares of the Company's common stock in a public offering (“Public Offering”), pursuant to the shelf registration statement. The shares of common stock were sold at a price to the public of \$12.50 per share. Under the terms of the underwriting agreement, the Company also granted the underwriters an option exercisable for 30 days from the date of the underwriting agreement to purchase up to an additional 600,000 shares of common stock on the same terms and conditions. The underwriters' option was exercised in full on February 10, 2023 and closed on February 14, 2023. The Company received net proceeds of approximately \$53.6 million from the Public Offering, after deducting underwriters' discounts and commissions of \$3.5 million and offering expenses of \$0.5 million.

As of March 31, 2023 and December 31, 2022 the Company had cash, cash equivalents and short-term investments of \$153.9 million and \$105.8 million, respectively.

The Company began generating revenue from its principal operations in 2019. The Company has a limited operating history, and the revenue and income potential of the Company's business and market are unproven. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. For the three months ended March 31, 2023 and 2022, the Company incurred losses from operations of \$13.1 million and \$16.6 million, respectively. Based on the Company's anticipated sales growth in relation to the anticipated costs associated with, among other things, its continuing research and development activities and the expansion of its sales and marketing activities, the Company expects to continue to incur net operating losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon gaining market acceptance of the Company's products and achieving a level of revenues adequate to support the Company's cost structure.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company believes that existing cash resources will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying condensed consolidated financial statements, though the Company expects to continue to incur operating losses and negative cash flows. The Company plans to continue to fund its losses from operations using its cash, cash equivalents and short-term investments as of March 31, 2023 and meet its future capital funding needs through equity or debt financings, other third-party funding, collaborations, strategic alliances and licensing arrangements or a combination of these. If the Company raises additional funds by issuing equity securities, its stockholders may experience dilution. Any future debt financing into which the Company enters may impose additional covenants that restrict operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity raise may contain terms that are not favorable to the Company or its stockholders. If the Company is required to enter into collaborations and other arrangements to address its liquidity needs, it may have to give up certain rights that limit its ability to develop and commercialize product candidates or may have other terms that are not favorable to the Company or its stockholders, which could materially and adversely affect its business and financial prospects. There can be no assurance that the Company will be able to obtain additional financing on acceptable terms, or at all. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

## **Note 2 - Summary of Accounting Policies**

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make informed estimates, judgments and assumptions that affect the reported amounts in the condensed consolidated financial statements and disclosures in the accompanying notes as of the date of the accompanying condensed consolidated financial statements. On an on-going basis, management evaluates the most critical estimates and assumptions for continued reasonableness. Actual results may differ materially from the estimates used in the preparation of the accompanying condensed consolidated financial statements under different assumptions or conditions.

### *Significant Accounting Policies*

There have been no significant changes to the accounting policies during the three months ended March 31, 2023, as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's audited consolidated financial statements included in its Annual Report on Form 10-K filed with the SEC on March 6, 2023.

### *Cash Equivalents*

Cash equivalents consist of investments in money market accounts. The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase that can be liquidated without prior notice or penalty to be cash equivalents.

### *Short-term Investments*

Short-term investments are classified based on the maturity date of the related securities. Based on the nature of the assets, the Company's short-term investments, which are government securities, are classified as available-for-sale and are recorded at their estimated fair value as determined by prices for identical or similar securities at the balance sheet date. The Company's short-term investments consist of Level 2 financial instruments in the fair value hierarchy. Unrealized gains and losses are recorded as a component of Other Comprehensive Loss within Stockholders' Equity on the condensed consolidated balance sheets. Realized gains and losses are included as other income (expense) in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss. The cost basis for realized gains and losses on available-for-sale securities is determined on a specific identification basis. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company periodically reviews its investments for unrealized losses other than credit losses and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In determining whether the carrying value is recoverable, management considers the following factors:

- whether the investment has been in a continuous loss position for over 12 months;
- the duration to maturity of investments;
- intention and ability to hold the investment to maturity and if it is not more likely than not that the Company will be required to sell the investment before recovery of the amortized cost basis;
- the credit rating, financial condition and near-term prospects of the issuer; and
- the type of investments made.

The Company had \$9,000 of unrealized gains and \$75,000 of unrealized losses related to short-term investments as of March 31, 2023 and December 31, 2022, respectively.

### *Concentration of Credit Risk and Other Risks and Uncertainties*

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company's policy is to invest cash in institutional money market funds and marketable securities of the U.S. government to limit the amount of credit exposure. The Company currently maintains a portfolio of cash equivalents and short-term investments in money

market funds and U.S. treasury bills. A portion of the Company's operating cash is held in accounts in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limits; however, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. The Company has not experienced material losses on cash equivalents and short-term investments.

The Company's products require approval from the FDA and foreign regulatory agencies before commercial sales can commence. There can be no assurance that the Company's products will receive any of these required approvals. The denial or delay of such approvals may have a material adverse impact on the Company's business and may impact business in the future. In addition, after approval by the FDA, there is still an ongoing risk of adverse events that did not appear during the device approval process.

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, clinical development risk, establishment of appropriate commercial partnerships, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of the Company's products, product liability and the need to obtain additional financing.

The Company is subject to the risks related to the global pandemic associated with COVID-19, including local, state, federal and other world-wide mandates imposed to reduce the spread of the virus which could interrupt or reduce the number of cataract surgeries, limit access to ambulatory surgery centers, doctors' offices and manufacturing facilities, and the expansion of global lead times, particularly in Europe and Asia, leading to a supply interruption from the Company's suppliers. In addition, the Company is currently experiencing inflation and longer lead times and limited availability in its supply chain for certain components and has continued exposure to price and supply risk related to anticipated purchases of certain commodities, materials and products used in its business.

#### *Accounts Receivable*

The Company has a diverse customer base and as of March 31, 2023 and December 31, 2022 the Company did not have any customers who individually accounted for greater than 10% of accounts receivable. The Company maintains an allowance for credit losses resulting from the inability of its customers, including ambulatory surgery centers, to make required payments. After evaluation of the collectability of accounts receivable, the Company did not record any significant allowance for credit losses as of March 31, 2023 or December 31, 2022.

#### *Fair Value of Financial Instruments*

The Company uses fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures. Fair value is measured as the price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques that are consistent with the market, income or cost approach are used to measure fair value. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three levels:

Level 1—Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical unrestricted assets or liabilities.

Level 2—Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability, for substantially the full term of the asset or liability, through correlation with market data. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and inputs to valuation models or other pricing methodologies that do not require significant judgment because the inputs used in the model, such as interest rates and volatility, can be corroborated by readily observable market data.

Level 3—One or more significant inputs that are unobservable and supported by little or no market activity and reflect the use of significant management judgment and assumptions. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation. These include the Black-Scholes option-pricing model which uses inputs such as expected volatility, risk-free interest rate and expected term to determine fair market valuation.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification at each reporting date. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented.

The Company's financial instruments consist principally of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, operating lease liabilities and a term loan. Cash, cash equivalents, accounts receivable and accounts payable are carried at their estimated fair value because of the short-term nature of these assets and liabilities. The Company's short-term investments in government securities are carried at fair value, determined based on publicly available quoted market prices for identical securities at the measurement date. The Company believes the fair values of its operating lease liabilities and amended term loan at March 31, 2023 and December 31, 2022 approximated their carrying values, based on the borrowing rates that were available for loans with similar terms as of such date.

#### *Inventories*

Inventories consist of raw materials, work-in-process and finished goods. Raw materials are comprised of chemicals and parts used in the production of the Company's lenses, cartridges, and LDDs. Finished goods are comprised of lenses, cartridges, accessories and LDDs. Inventories are valued at the lower of cost or net realizable value. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out basis. The carrying value of inventories is reviewed for potential impairment whenever indicators suggest that the cost of inventories exceeds the carrying value and management adjusts the inventories to its net realizable value. The cost of finished goods and work-in-process is comprised of raw materials, direct labor, other direct costs and related production overhead to the extent that these costs do not exceed the net realizable value of the goods produced. The Company periodically reviews inventories for potential impairment, estimated losses from obsolescence, material expirations or unmarketable inventories or excess inventories and writes down the cost of inventories to net realizable value at the time such determinations are made. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

#### *Leases*

Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property ("Commencement Date") based on the present value of lease payments over the lease term. The Company estimates the incremental borrowing rate based upon the cost of its own debt financing, current market interest rates and quoted offerings or the rate implicit in the lease. Operating lease right-of-use assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The lease terms used to calculate the right-of-use asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the accompanying condensed consolidated balance sheets. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as reduction of the right-of-use leased assets and are amortized on a straight-line basis as a reduction to operating lease costs. Leases with an initial term of 12 months or less are expensed as incurred and are not recorded as right-of-use assets on the condensed consolidated balance sheets.

#### *Net Loss per Share*

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock and potential dilutive securities outstanding during the period.

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders because their impact under the treasury stock method was anti-dilutive for the periods presented:

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Stock options issued and outstanding under the Calhoun Vision, Inc. 2006 Stock Plan, Calhoun Vision, Inc. 2015 Equity Incentive Plan and the 2021 Equity Incentive Plan	1,814,375	1,986,088
Restricted stock units issued under the 2021 Equity Incentive Plan	478,610	53,545
Stock issuable in offering period under the 2021 Employee Stock Purchase Plan	51,180	46,733

#### *Revenue Recognition*

The Company's revenue is generated from the sale of LALs used in cataract surgery along with a specifically designed machine for delivering light to the eye, the LDD, to adjust the lens post-surgery, as needed. Revenue is recognized from sales of products in the U.S. and Europe. Customers are primarily comprised of ambulatory surgery centers, hospitals, and physician private practices.

The Company recognizes revenues when promised goods or services are transferred to customers at a transaction price that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services. Specifically, the Company applies the following five steps to recognize revenue: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies a performance obligation. The Company applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods promised within each customer contract to determine the individual deliverables in its product offerings as separate performance obligations and assesses whether each promised good or service is distinct. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company recognizes revenue as the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. The Company elected to account for shipping costs as fulfillment costs rather than a promised service and excludes from revenue any taxes collected from customers that are remitted to government authorities.

The Company's LDD contracts contain multiple performance obligations bundled for one transaction price, with all obligations generally satisfied within one year. For these bundled arrangements, the Company accounts for individual products and services as separate performance obligations if they are distinct, that is, if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. The Company's LDD contracts include a combination of the following performance obligations: (i) LDD capital asset and related components, (ii) training and (iii) device service (initial year). Each of these three performance obligations are considered distinct. The LDD capital asset is distinct because the customer can benefit from it together with other resources that are readily available to the customer. Training on the use of the machine is offered as a distinct activity after installation of the LDD to enhance the customer's ability to utilize the machine by having an industry professional provide best practices and customize training to the specific needs of the customer. Each LDD comes with a twelve-month manufacturer's warranty (service-type) that includes preventative maintenance, unscheduled service (labor and parts) and software updates. After the first year, service contracts can be purchased separately on a standalone basis. The Company recognizes revenue as performance obligations are satisfied by transferring control of the product or service to a customer. Specifically, revenue for the LDD capital asset is recognized at a point in time at installation. Revenue for training is also recorded at a point in time, generally 60 days after installation. Revenue for the device service is recognized ratably over time after installation, generally 12 months. The Company has determined that the transaction price is the invoice price, net of adjustments, if any. The allocation to the separate performance



obligations is based upon the relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. The Company estimates the standalone selling price using the market assessment approach considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer and market conditions. The Company regularly reviews and updates standalone selling prices as necessary.

LALs are generally held at customer sites on consignment. The single performance obligation is satisfied, and revenue from sales is recognized for LALs upon customer notification that the LALs have been implanted in a patient. For the three months ended March 31, 2023 and 2022, credits related to returns and rebates on list prices were not significant.

The Company has adopted the practical expedient permitting the direct expensing of costs incurred to obtain contracts where the amortization of such costs would occur over one year or less, and it applied to substantially all the Company's contracts. Revenue for service agreements is recognized ratably over the term of each contract.

For the three months ended March 31, 2023 and 2022, contract liabilities from sales activity recorded as liabilities on the Company's condensed consolidated balance sheets consisted of the following (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
LDD (including training)	\$ 6,475	\$ 4,569
LAL	10,395	4,105
Service warranty, service contracts, and accessories	619	268
	<u>\$ 17,489</u>	<u>\$ 8,942</u>

As of March 31, 2023 and December 31, 2022, the Company recognized contract liabilities on its condensed consolidated balance sheets of \$1,388,000 and \$1,187,000 respectively, related to the service agreement performance obligation. Revenue for service agreements is recognized ratably over the term of each contract.

The following table represents the contract liabilities from sales activity for the three months ended March 31, 2023 and 2022, respectively (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Balance at beginning of period	\$ 1,191	\$ 540
Additions during the period	795	326
Revenue recognized during the period	(598)	(244)
Balance at end of period	<u>\$ 1,388</u>	<u>\$ 622</u>

For the three months ended March 31, 2023 and 2022, the Company did not have any customers who individually accounted for greater than 10% of revenue.

#### *Stock-Based Compensation Expense*

The Company has three equity incentive compensation plans, the Calhoun Vision, Inc. 2006 Stock Plan ("2006 Plan"), the Calhoun Vision, Inc. 2015 Equity Incentive Plan ("2015 Plan"), and the 2021 Equity Incentive Plan ("2021 Plan"), which are collectively referred to as the ("Equity Plans"). The Company also has an employee stock purchase plan, the 2021 Employee Stock Purchase Plan ("2021 ESPP").

The purpose of the 2021 Plan and 2021 ESPP is to provide a means by which eligible participants may be given an opportunity to benefit from increases in the value of the common stock in order to retain or procure the services of the employees, members of the board of directors of the Company (the "Board") and consultants and provide them with an incentive to promote the Company's success and accomplish corporate goals.

Stock option awards are granted with an exercise price of no less than 100% of estimated fair market value on the date of grant. Time based awards generally vest over four years as follows, subject to the optionee's continuing

service, (i) one fourth of the total number of shares vest and become exercisable on the one-year anniversary; 1/48th of the total number of shares subject to the option vest and become exercisable on each monthly anniversary thereafter for the remaining three years, or (ii) 1/48th of the total number of shares subject to the option vest and become exercisable each month over four years.

Prior to the Company's shares being traded on the Nasdaq Global Market, the fair value of the Company's common stock was determined by the Board at the time of each option grant by considering a number of objective and subjective factors. These factors included the valuation of a select group of public peer group companies within the medical device industry that focus on technological advances and development that the Board believed were comparable to the Company's operations. Operating and financial performance, the lack of liquidity of the common stock and trends in the broader economy and medical device industry also impacted the determination of the fair value of the common stock. In addition, the Company regularly engaged a third-party valuation specialist to assist with estimates related to the valuation of the Company's common stock. For all grants subsequent to the Company's shares being traded on the Nasdaq Global Market in July 2021, the fair value of common stock was determined by using the closing price per share of common stock as reported on the Nasdaq Global Market.

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, such as the fair market value of the Company's common stock, expected term, expected volatility, the risk-free interest rate, and dividend yield as discussed below. Each of these inputs is subjective and generally requires significant judgment.

*Expected term*—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company used the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

*Expected volatility*—Prior to the completion of the Company's initial public offering ("IPO"), when the Company was privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded medical device companies over a period equal to the expected term of the stock option grants. Comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-free interest rate*—The risk-free interest rate used is based on the published U.S. Department of Treasury interest rates in effect at the time of stock option grant for zero coupon U.S. Treasury notes with maturities approximating each grant's expected term.

*Dividend yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

#### *Recent Accounting Pronouncements*

Changes to GAAP are established by the Financial Accounting Standards Board ("FASB") in the form of accounting standards updates ("ASU"). There have been no recent accounting pronouncements, changes in accounting pronouncements or recently adopted accounting guidance during the three months ended March 31, 2023 that are of significance or potential significance to the Company.

#### *Emerging Growth Company Status*

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not take this exemption and, as a result, will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

**Note 3 – Short-Term Investments**

Short-term investments, principally U.S. Treasury bills, are available-for-sale and consisted of the following (in thousands):

	<b>As of March 31, 2023</b>		
	<b>Amortized Cost</b>	<b>Unrealized Gain, Net</b>	<b>Estimated Fair Value</b>
U.S. Treasury securities	\$ 142,918	\$ 9	\$ 142,927
	<b>As of December 31, 2022</b>		
	<b>Amortized Cost</b>	<b>Unrealized Loss, Net</b>	<b>Estimated Fair Value</b>
U.S. Treasury securities	\$ 94,043	\$ (75)	\$ 93,968

All available-for-sale securities held as of March 31, 2023 and December 31, 2022 had a maturity of less than one year. The Company has classified all marketable securities, regardless of maturity, as short-term investments based upon the Company's ability and intent to use any and all of those marketable securities to satisfy the Company's liquidity requirements.

**Note 4 – Inventories**

Inventories consisted of the following (in thousands):

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
Finished goods	\$ 8,087	\$ 6,408
Raw materials	7,294	6,494
Work-in-process	3,085	2,567
	18,466	15,469
Less: reserve for excess and obsolete inventory	(399)	(634)
	\$ 18,067	\$ 14,835

At March 31, 2023 and December 31, 2022, finished goods included \$3.3 million and \$2.8 million of inventory held on consignment at customer sites, respectively.

**Note 5 – Fair Value Measurements**

The table and disclosures for the periods presented below (in thousands) present the Company's assets and liabilities measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. The Company did not have any assets or liabilities measured at fair value on a recurring basis within Level 3 fair value measurements.

	<b>As of March 31, 2023</b>		
	<b>Level I</b>	<b>Level II</b>	<b>Total</b>
<b>Assets:</b>			
Money market securities	\$ 5,386	\$ —	\$ 5,386
U.S. Treasury securities	—	142,927	142,927
Total assets at fair value	\$ 5,386	\$ 142,927	\$ 148,313
	<b>As of December 31, 2022</b>		
	<b>Level I</b>	<b>Level II</b>	<b>Total</b>
<b>Assets:</b>			
Money market securities	\$ 8,909	\$ —	\$ 8,909
U.S. Treasury securities	—	93,968	93,968
Total assets at fair value	\$ 8,909	\$ 93,968	\$ 102,877

## Note 6 – Term Loan

In October 2020, the Company entered into a loan facility (“Term Loan”) with an initial draw of \$25.0 million. Proceeds were used to help fund the Company’s ongoing operations. As part of the Term Loan, Oxford Finance LLC (“Oxford Finance”) committed to providing further loans of up to \$35.0 million to the Company at its election (or for one specific draw, upon the occurrence of a revenue milestone) during various draw periods in the future, provided the Company is not in default at the time of the additional loan draws. In March 2021, the Company drew an additional \$5.0 million from the facility for the purpose of funding ongoing operations. In June 2021, the Company drew an additional \$10.0 million from the facility for the purpose of funding ongoing operations.

On May 3, 2022, the Company entered into a Second Amendment (“Second Amendment”) to the Term Loan (as amended through the Second Amendment, the “Amended Term Loan”). The Amended Term Loan increased the loan and security agreement to \$60.0 million, of which \$40.0 million was fully funded as of May 3, 2022 from the original term loan. Under the Amended Term Loan, the Company may borrow an additional amount of up to \$10.0 million through June 30, 2023, upon satisfaction of the applicable drawdown conditions and achieves sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending March 31, 2023. Subject to the terms and conditions of the Amended Term Loan, the Company may also borrow an additional amount of up to \$10.0 million through September 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending June 30, 2023. The Amended Term Loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 1-Month Term Secured Overnight Financing Rate (“SOFR”) (or, if greater, 0.16%) plus an applicable margin of 9.09%. If there is an event of default under the Amended Term Loan additional interest of 5% applies. The Amended Term Loan extends the maturity date of the loan and security agreement, which was due to expire on October 1, 2025, to February 1, 2027. The Company refers to its \$60.0 million Amended Term Loan as its credit facility. The Amended Term Loan was recorded as a debt modification.

The Amended Term Loan is secured by substantially all of the Company’s personal property other than its intellectual property, but includes any accounts receivable, other amounts owed and any proceeds of intellectual property. The Company also entered into a negative pledge arrangement with the collateral agent and lenders where the Company agreed not to encumber any of its intellectual property. The Amended Term Loan also includes certain customary representations and warranties, affirmative and negative covenants, and events of default, including a financial performance-to-plan covenant that requires the Company to achieve certain minimum net sales, measured on a trailing twelve-month basis.

The Amended Term Loan requires 35 months of interest-only payments, followed by 22-months of principal and accrued interest payments. If the Company is in compliance with its performance-to-plan covenant through April 1, 2025 and has not provided an IP lien election notice before May 1, 2025, the interest-only period is extended by 12 months, and the amortization period is reduced to ten months. Payments are due on the first day of each month in arrears. All unpaid amounts under the Amended Term Loan mature on February 1, 2027. The Company may elect to prepay the loans under the credit facility at any time in full or in part; however, the Company may only elect to prepay the loans in part once, in an amount not less than \$5.0 million. Any amounts prepaid may not be subsequently reborrowed. Under the Amended Term Loan, a final payment (“Final Payment”) will be due at the earlier of the maturity date, acceleration of the loans, or a voluntary or mandatory prepayment of the loans, in an amount equal to (a) if the Final Payment is due on or after January 1, 2022 through and including October 31, 2022, three percent (3.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid), (b) if the Final Payment is due on or after November 1, 2022 through and including October 31, 2023, four percent (4.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid) and (c) if the Final Payment is due on or after November 1, 2023, five percent (5.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid). The Final Payment is being accreted to the carrying value of the debt as a debt premium and interest expense over the life of the loan using the effective interest method.

The Company paid \$0.1 million in loan amendment fees and other closing costs that are directly attributable to execution of the Amended Term Loan transaction. These issuance costs are recorded as a discount to the carrying amount of the debt and are being amortized, along with the unaccreted portion of the Final Payment and unamortized debt issuance costs from the original Term Loan, to interest expense over the expected term of the debt using the effective interest method. The loans may be accelerated by Oxford Finance in the event of default.

As of March 31, 2023 and December 31, 2022, the Company was in compliance with all Amended Term Loan covenants, respectively.

For the three months ended March 31, 2023 and 2022 the cash interest paid and effective interest rate on the Amended Term Loan were as follows:

	<b>For the Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Cash interest paid	13.62 %	9.25 %
Effective interest rate	15.13 %	10.72 %

As of March 31, 2023 future principal payments due under the Amended Term Loan were as follows (in thousands):

<b>Year Ended December 31,</b>	
2023 (remainder)	\$ —
2024	—
2025	16,364
2026	21,818
2027	1,818
Total	40,000
Plus: exit fee and unamortized issuance costs	309
Term loan, net	\$ 40,309

#### **Note 7 – Stock-Based Compensation Expense**

The Company has three equity incentive compensation plans: the 2006 Plan, the 2015 Plan and the 2021 Plan.

##### **2006 Plan**

The 2006 Plan was originally adopted by the Board and approved by the Company's stockholders in 2006. The 2006 Plan was terminated in 2015 in connection with the adoption of the 2015 Plan and as a result no new awards may be issued under the 2006 Plan. However, the 2006 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2006 Plan.

##### **2015 Plan**

The 2015 Plan was originally adopted by the Board and approved by the Company's stockholders in 2015. The 2015 Plan was most recently amended in March 2021. In July 2021, upon completion of the IPO, the 2015 Plan terminated immediately prior to effectiveness of the 2021 Plan with respect to the grant of future awards. However, the 2015 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2015 Plan.

##### **2021 Plan**

On July 28, 2021, the 2021 Plan was adopted and approved by the Board and stockholders prior to the IPO and became effective on the business day immediately prior to the effective date of the Company's IPO registration statement. The 2021 Plan provides for the grant of incentive stock options to employees and any subsidiary corporations' employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units ("RSUs"), and performance awards to employees, directors, and consultants and subsidiary corporations' employees and consultants. The number of shares of the Company's common stock originally available for issuance under the 2021 Plan was equal to 2,420,135 shares of common stock plus any shares subject to awards granted under the 2015 Plan and the 2006 Plan that, after the effectiveness of the 2021 Plan, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by the Company for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest, with the maximum number of shares to be added to the 2021 Plan from the 2015 Plan and 2006 Plan equal to 4,569,530 shares of common stock.

***Evergreen provision***

The number of common shares reserved for issuance under the 2021 Plan will be increased automatically on the first day of each fiscal year beginning with the 2022 fiscal year and ending on the ten year anniversary of the date the Board approved the 2021 Plan, by a number equal to the least of: (i) 7,260,406 shares of our common stock; (ii) 4% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year; or (iii) such lesser number of shares of our common stock as the administrator may determine. The 2021 Plan is administered by the Board. On January 1, 2022, the number of shares available under the 2021 Plan increased by 1,094,670 shares of common stock pursuant to this feature. On January 1, 2023, the number of shares available under the 2021 Plan further increased by 1,130,735 shares of common stock pursuant to this feature. As of March 31, 2023, the number of shares of the Company's common stock available for future issuance under the 2021 Plan was equal to 461,796 shares of common stock.

***2021 ESPP***

On July 28, 2021, the Board and stockholders adopted and approved the 2021 ESPP. As of March 31, 2023, the number of shares of the Company's common stock available for future issuance under the 2021 ESPP was equal to 664,976 shares of common stock.

The 2021 ESPP provides eligible employees of the Company and its subsidiaries with the opportunity to purchase shares of the Company's common stock at a purchase price equal to 85% of the common stock's fair market value on the first trading day or last trading day of each purchase period, whichever is lower. The 2021 ESPP provides for two six-month purchase periods every twelve months: May 1 through October 31 and November 1 through April 30. The initial purchase period began on November 1, 2021.

***Evergreen provision***

The number of common shares reserved for issuance under the 2021 ESPP plan will be increased automatically on the first day of each fiscal year beginning with the 2022 fiscal year, by a number equal to the least of: (i) 1,452,081 shares; (ii) 1% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year; or (iii) such other amount as the administrator may determine. The 2021 ESPP is administered by the Board. On January 1, 2022, the number of shares available under the 2021 ESPP increased by 273,667 shares of common stock pursuant to this feature. No additional shares were reserved for issuance on January 1, 2023 pursuant to this feature.

***Stock-Based Compensation Expense***

The purpose of the 2021 Plan and 2021 ESPP is to provide a means by which eligible recipients of stock awards may be given an opportunity to benefit from increases in the value of the common stock in order to retain or procure the services of the employees, members of the Board and consultants and provide them with an incentive to promote the Company's success and accomplish corporate goals.

Stock option awards are granted with an exercise price of no less than 100% of estimated fair market value on the date of grant. Time based awards generally vest over four years as follows, subject to the optionee's continuing service, (i) one fourth of the total number of shares vest and become exercisable on the one-year anniversary; 1/48th of the total number of shares subject to the option vest and become exercisable on each monthly anniversary thereafter for the remaining three years, or (ii) 1/48th of the total number of shares subject to the option vest and

become exercisable each month over four years.

A summary of the stock option activities related to the Equity Plans for the three months ended March 31, 2023 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Avg Remaining Contractual Life (Years)
Options outstanding as of December 31, 2022	6,339,558	\$ 11.88	6.48
Granted	1,266,307	14.85	
Exercised	(164,907)	4.62	
Forfeited	(32,585)	13.00	
Expired	(58,653)	18.71	
Options outstanding as of March 31, 2023	7,349,720	12.50	7.03
Exercisable as of March 31, 2023	3,948,677	\$ 10.94	5.28

As of March 31, 2023 and December 31, 2022 the intrinsic value of options vested was \$24.5 million and \$15.9 million, respectively, and of all options outstanding was \$32.6 million and \$16.4 million, respectively. During the three months ended March 31, 2023 and 2022, the total cash received from the exercise of stock options was \$0.8 million and \$0.3 million, respectively. The total fair value less strike price of these options was \$1.7 million and \$1.8 million, respectively.

A summary of non-vested restricted stock unit activities for the three months ended March 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	492,862	\$ 15.08
Granted	385,078	14.79
Vested	(78,691)	14.84
Forfeited	(1,455)	15.38
Unvested at March 31, 2023	797,794	\$ 14.97

Stock-based compensation expense was classified in the accompanying condensed consolidated statements of operations and comprehensive income (loss) as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 802	\$ 774
Selling, general and administrative	2,272	1,655
Cost of goods sold	221	220
	\$ 3,295	\$ 2,649

As of March 31, 2023 and December 31, 2022, there were 3,401,043 and 2,447,687 unvested options, respectively. As of March 31, 2023 and December 31, 2022, total unrecognized expense related to unvested stock options was approximately \$28.5 million and \$19.1 million, respectively. Amounts are expected to be recognized over a weighted average period of approximately 2.9 and 2.6 years, respectively.

As of March 31, 2023, and December 31, 2022, total unrecognized expense related to non-vested restricted stock units was approximately \$10.9 million and \$6.1 million, respectively. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.9 years and 2.3 years, respectively.

The following table presents the range and weighted-average assumptions, used in the Black-Scholes option pricing model to determine the fair value of stock options:

	Three Months Ended March 31,			
	2023		2022	
	Range	Weighted Average	Range	Weighted Average
Expected volatility	64.9% to 65.2%	65.1%	62.5%	62.5%
Risk-free interest rate	3.4% to 4.2%	4.1%	2.0%	2.0%
Expected life (in years)	6.0 to 10.0 years	6.0 years	6.0 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Grant date fair value	\$12.91 to \$16.68	\$14.86	\$12.85	\$12.85

### Common Stock

Each share of common stock is entitled to one vote. Common stock reserved for future issuance under the Equity Plans, 2021 ESPP and the at-the-market offering consisted of the following:

	March 31, 2023	December 31, 2022
Stock options issued and outstanding under the Equity Plans	7,349,720	6,339,558
Shares available for future issuance under the Equity Plans	461,796	865,122
Restricted stock units issued under the 2021 Plan	797,794	492,862
Shares available for future issuance under 2021 ESPP	664,976	664,976
Shares available for future sale under the at-the-market offering <sup>(1)</sup>	1,937,385	3,454,064
Total shares of common stock reserved	11,211,671	11,816,582

<sup>(1)</sup> Based on the closing stock price of \$16.68 as reported on the Nasdaq Global Market on March 31, 2023.

### Note 8 – Leases

The Company has operating and finance leases for facilities and certain equipment. Leases with an initial term of 12 months or less are not recorded on the condensed consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company does not combine lease and non-lease components in the recognition of lease expense.

As of March 31, 2023 the Company held four leases for office, manufacturing and warehouse facilities in Aliso Viejo, California. The four leases are for approximately 121,000 square feet in the aggregate and expire between August 31, 2024 and January 31, 2026. For one of the facilities operating leases, the lessor provided \$900,000 in tenant allowances.

On April 4, 2022, the Company entered into a thirty-four-month sublease agreement for a portion of the 5 Columbia Building, in Aliso Viejo, CA. The sublease commencement date was June 13, 2022 and will expire on March 31, 2025. The base rent receivable is \$11,410 per month. On January 4, 2023 the Company entered into a second amendment to the sublease agreement adjusting the base rent receivable to \$5,319 per month.



The following table presents the lease balances within the Condensed Consolidated Balance Sheets as of March 31, 2023 and December 31, 2022 (in thousands):

Leases	Classification	March 31, 2023	December 31, 2022
<b>Assets</b>			
Operating	Operating leases right-of-use assets	\$ 3,555	\$ 3,943
Finance	Property and equipment, net	122	206
<b>Total lease assets</b>		<u>3,677</u>	<u>4,149</u>
<b>Liabilities</b>			
<b>Current</b>			
Operating	Lease liabilities	1,864	1,818
Finance	Lease liabilities	114	152
<b>Noncurrent</b>			
Operating	Long-term lease liabilities	2,338	2,813
Finance	Long-term lease liabilities	—	43
<b>Total lease liabilities</b>		<u>\$ 4,316</u>	<u>\$ 4,826</u>

For the three months ended March 31, 2023 and 2022, the components of operating and finance lease expenses were as follows (in thousands):

Lease Cost	Classification	Three Months Ended March 31,	
		2023	2022
Operating lease cost	Cost of sales	\$ 3	\$ 3
	Research and development	37	74
	Selling, general and administrative	449	403
Finance lease cost	Research and development	34	14
	Selling, general and administrative	9	5
Finance lease cost	Interest expense	4	3

Maturities of the Company's operating and finance lease liabilities as of March 31, 2023 were as follows (in thousands):

Year Ended December 31,	Operating Leases	Finance Leases
2023 (remainder)	\$ 1,666	\$ 103
2024	1,954	16
2025	1,043	—
2026	79	—
2027	—	—
2028	—	—
<b>Total lease payments</b>	<u>4,742</u>	<u>119</u>
Less: imputed interest	(540)	(5)
<b>Total lease liabilities</b>	<u>\$ 4,202</u>	<u>\$ 114</u>

The weighted average remaining lease term and weighted average discount rate used to determine lease liabilities related to the Company's operating and finance leases as of March 31, 2023 and December 31, 2022 were:

<b>Lease Term and Discount Rate</b>	<b>March 31, 2023</b>	<b>December 31, 2022</b>
<b>Weighted average remaining lease term (years)</b>		
Operating leases	2.28	2.42
Finance leases	0.83	1.29
<b>Weighted average discount rate</b>		
Operating leases	10.3 %	10.3 %
Finance leases	9.5 %	9.5 %

#### **Note 9 – Commitments and Contingencies**

##### *Letter of credit*

The Company has a standby letter of credit, expiring September 30, 2024, issued by a financial institution as required security for one operating lease. The aggregate amount of the letter of credit was \$260,000 as of March 31, 2023 and December 31, 2022.

##### *Legal Matters*

From time-to-time, the Company may be involved in certain legal proceedings or regulatory matters arising in the ordinary course of business, including without limitation, actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. In connection with these proceedings or matters, the Company regularly assesses the probability and amount (or range) of possible issues based on the developments in these proceedings or matters. A liability is recorded in the consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated. Because of the uncertainties related to any pending proceedings or matters, the Company is currently unable to predict their ultimate outcome and, with respect to any legal proceeding or regulatory matter where no liability has been accrued, to make a reasonable estimate of the possible loss (or range of loss) that could result from an adverse outcome. At March 31, 2023 and December 31, 2022, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the outcome, legal proceedings, regulatory matters, and other disputes and claims can have an adverse impact on the Company because of legal costs, diversion of management time and resources, and other factors.

## 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 unaudited condensed consolidated financial statements and the related notes to those statements included elsewhere in this report and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 6, 2023. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part II, Item 1A (“Risk Factors”) of, and elsewhere in, this report. See “Special Note Regarding Forward-Looking Statements.”*

We are a commercial-stage medical technology company dedicated to providing high quality customized vision to patients following cataract surgery. Our proprietary RxSight® Light Adjustable Lens system (“RxSight system”) is the first and only commercially available premium cataract technology that enables doctors to customize and optimize visual acuity for patients after surgery. The RxSight system is comprised of our RxSight Light Adjustable Lens® (“LAL”®), RxSight Light Delivery Device (“LDD”™) and accessories. Our LAL is a premium intraocular lens (“IOL”) made of proprietary photosensitive material that changes shape in response to specific patterns of ultraviolet (“UV”) light generated by our LDD.

We designed our RxSight system to address the shortcomings of competitive premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. Competitive premium IOLs require patients to specify their visual priorities before surgery and be willing to accept various optical trade-offs associated with those choices. Once a patient has selected a competitive premium IOL, the surgeon must rely on a series of preoperative diagnostic tests and predictive formulae to choose the appropriate lens power. If the doctor’s prediction isn’t exact, the patient may experience suboptimal results that could necessitate a subsequent corneal refractive procedure or certain other compromises in order to reach vision targets.

In contrast, with the RxSight system, the surgeon implants the LAL during a standard cataract procedure, determines refractive error with patient input several weeks following surgery and then uses the LDD to modify the LAL with the precise visual correction needed to achieve the patient’s desired vision outcomes. We believe our RxSight system provides doctors and patients increased confidence and peace of mind by eliminating the high-stakes preoperative guesswork common to competitive premium IOLs and allowing patients to iterate their final vision characteristics with customized post-surgical adjustments.

We compete in the IOL market in the U.S. The LAL is a premium IOL which is partially reimbursable under Medicare, and in some cases by private payors. Premium IOLs are sold at a higher price point than conventional IOLs, as they provide refractive correction of vision unlike a conventional IOL that only replaces the natural lens with a clear lens (which is the standard for Medicare reimbursement). Our RxSight system is approved in Mexico and Canada for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error. We may selectively pursue commercial expansion in these or other geographies that accept these approvals in the future, with a priority on markets where we see significant potential opportunity. New approvals may also be sought in large cataract markets with more complex regulatory processes such as Asia.

We are a Delaware corporation headquartered in Aliso Viejo, California with one wholly owned subsidiary located in Amsterdam, Netherlands. The wholly owned subsidiary has a registered branch in the United Kingdom and a wholly owned subsidiary located in Germany.

Our commercial efforts began in 2019 and have been primarily focused in the United States, where we are building a “razor and razor blade” business model to drive new customer adoption and ongoing LAL volume growth. Our United States commercial organization includes a direct sales team of LDD sales personnel and LAL account managers, as well as clinical specialists, field service engineers and marketing personnel. Our sales efforts are concentrated on the roughly 3,000 U.S. cataract surgeons that perform 70%-80% of all premium IOL procedures. As of March 31, 2023, we had established an installed base of 456 LDDs in ophthalmology practices and, since our inception through March 31, 2023, surgeons have implanted over 52,000 LALs.

We believe this business model provides an attractive and concentrated market opportunity addressable with a focused sales force. We intend to continue to make significant investments in our sales and marketing organization. We believe selectively increasing the number of sales representatives, practice development personnel and clinical

trainers will help facilitate further adoption of our products among existing customer accounts as well as broaden awareness of our products to new accounts. We plan to grow our business primarily by expanding the size of our LDD installed base and driving increased utilization of our LAL through heightened awareness of the superior clinical outcomes that our RxSight system provides patients. To continue to strengthen our competitive position in the premium IOL market, our research and development activities are focused primarily on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management.

Our near-term research and development activities are focused on enhancements to the RxSight system to improve the patient and doctor experience, expand the range of patients that can be treated, as well as expand the RxSight system indications and drive adoption. We believe that over time, our adjustable lens solution can be used to address a broad range of cataract surgery patients, including those that would otherwise elect for a conventional cataract procedure today. Additional development and clinical studies that are designed to provide clinical evidence of the safety and effectiveness of our existing and future generations of products are also anticipated. Finally, we may in the future seek to acquire or invest in additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities.

We intend to continue to make investments in our sales and marketing organization, primarily sales representatives, clinical applications specialists and technical service personnel to support new customers and upgrades and LAL account managers to facilitate adoption of use of our LALs among existing accounts. We will expand our marketing efforts with additional print and digital, social media and other customer tools to expand their local advertising. We will also continue to make significant investments in research and development and clinical expenses to make enhancements in our current products. As a public company, we will incur costs that we have not previously incurred or have previously incurred at lower rates, including increased costs for employee-related expenses, director and officer insurance premiums, audit and legal fees, investor relations fees, fees to members of our Board and expenses for compliance with public-company reporting requirements. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations in the future.

We believe that our existing cash and cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure and meet our term loan covenant requirements for at least the next 12 months from the date of filing of this report. Although we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC, we may be required to raise additional capital through public or private equity offerings or debt financings, credit or loan facilities or by entering into partnerships or a combination of one or more of these funding sources in order to meet our liquidity requirements. We may also opportunistically access our at-the-market ("ATM") facility under advantageous circumstances. If we raise additional funds by issuing equity securities, our stockholders may experience dilution.

### Key business metrics

We regularly review several operating and financial metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. We believe the number of LDDs installed and LALs implanted are indicators of our ability to drive adoption and generate revenue. We believe these are important metrics for our business. We may not yet be able to accurately assess seasonality and other trends, and we will continue to evaluate our business in the future using these and other financial metrics as we observe trends in our business.

We believe the number of LDDs sold in each quarter and our LDD installed base at the end of each period are important metrics as they represent an installed base into which we can sell our LALs.

	2023	2022			
	Q1	Q1	Q2	Q3	Q4
LDDs Sold	56	40	49	49	57
Installed Base at End of Period	456	246	294 *	343	400

\* Reduced by one LDD taken out of installed base in Q2 2022.

We believe the number of LALs sold (reported as implanted in a patient) in each quarter is an important metric indicative of adoption and utilization of our RxSight system. During the quarter ended March 31, 2023, we had

increased LDD sales of 16 and increased LAL sales of 6,357 when compared to the quarter ended March 31, 2022 from strong adoption of our RxSight technology by practices and doctors combined with an increased LDD installed base.

	2023	2022			
	Q1	Q1	Q2	Q3	Q4
LALs Sold	10,523	4,166	5,400	6,595	9,123

## Components of results of operations

### Sales

Our sales consist of the sale of LALs used in cataract surgeries, the LDDs for delivering light to the LALs to adjust the lens post-surgery, as needed, and service and accessories. Revenue is derived from sales of products primarily in the United States. Customers are primarily comprised of ophthalmic practices (LDD sales) and ambulatory surgery centers (LAL sales). We expect revenue to increase in absolute dollars as we expand our sales organization and sales territories, add customers, expand the base of doctors that are trained to use our products, and expand awareness of our products with new and existing customers and as doctors perform more procedures using our products.

LALs are held at customer sites on consignment. The single performance obligation is satisfied, and revenue is recognized for LALs upon customer notification that the LALs have been implanted in a patient.

Our LDD contracts contain multiple performance obligations bundled into one transaction price, with all obligations generally satisfied within one year. The LDD capital asset and related components revenue is recognized upon installation and customer acceptance, training revenue is recognized upon completion of training by at least one doctor and the initial warranty and service agreement are recognized ratably over the service period. After the first year, service contracts can be purchased separately on a standalone basis. Revenue for such service agreements will be recognized over the term of each contract. We recorded contract liabilities of \$1,388,000 and \$1,187,000 related to such service agreements as of March 31, 2023 and December 31, 2022, respectively.

For the three months ended March 31, 2023 and 2022, sales from contracts with customers consisted of the following (in thousands):

	Three Months Ended March 31,	
	2023	2022
LDD (including training)	\$ 6,475	\$ 4,569
LAL	10,395	4,105
Service warranty, service contracts, and accessories	619	268
	\$ 17,489	\$ 8,942

For the three months ended March 31, 2023 and 2022 we did not have any one customer who individually accounted for more than 10% of revenue.

### Cost of sales

Cost of sales consist of materials, labor and manufacturing overhead internally to produce the Company's products as well as the cost of shipping and handling. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management and stock-based compensation. Cost of sales also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalty and license fee expense. Shipping costs billed to customers are included in sales. We expect cost of sales to increase in absolute dollars as our revenue grows and more of our products are sold.

We calculate gross margin as gross profit/(loss) divided by sales. Our gross margin has been and will continue to be affected by a variety of factors, including average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. Our gross margin could

fluctuate from quarter to quarter as we introduce new products, and as we adopt new manufacturing processes and technologies.

Our LDD, as is typical of many medical device capital equipment products, has a low gross margin, as the material cost of the LDD is significant, representing greater than 50% of the total cost to manufacture. In addition, we do not mark up our LDD substantially, as LDDs, as sold, generate LAL procedures. Our LAL gross margin is higher, with low material cost but high fixed overhead costs. As our manufacturing volume of the LAL increases, we expect the gross margin may improve significantly.

### **Operating expenses**

#### ***Selling, general and administrative expenses***

Selling, general and administrative (“SG&A”) expenses consist primarily of personnel-related expenses, including wages, incentive bonuses, stock-based compensation and benefits related to administrative, selling and marketing functions, education programs for doctors, commercial operations and analytics, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, training for doctors, professional services fees such as legal, patent registration costs, accounting, audit and tax fees, board of directors’ expenses, insurance costs, general corporate expenses and facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our sales and marketing organization and infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting audit and tax fees, insurance and other expenses associated with being a public company.

#### ***Research and development expenses***

Research and development expenses consist of expenses incurred in performing research and development and engineering activities for new products and technology, clinical studies and regulatory submissions and compliance. The expenses include personnel-related expenses, including wages, incentive bonuses, stock-based compensation and benefits, costs incurred at clinical trial sites, regulatory and manufacturing engineering costs, including those related to various laboratory and research equipment and supplies, expense of pre-approved inventory utilized for clinical trial and research purposes, costs incurred in the development of manufacturing processes in excess of capitalizable value, fees paid to consultants and contract clinical organizations and direct FDA related costs and costs related to FDA premarket approval submission preparation. Research and development expenses are expensed as incurred. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trials and registries and other related activities.

#### ***Interest expense***

Interest expense consist primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our indebtedness.

#### ***Interest and other income***

Interest and other income consist primarily of interest income earned on our short-term investments and cash and cash equivalents.

#### ***Comprehensive loss***

All components of comprehensive loss, including net loss, are reported in the condensed consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments and foreign currency translation adjustments.

## Results of operations

### Comparison of the three months ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022 together with the dollar increase or decrease and percentage change in those items.

(in thousands, except percentages)	Three Months Ended March 31,		Change	
	2023	2022	(\$)	(%)
Sales	\$ 17,489	\$ 8,942	\$ 8,547	95.6%
Cost of sales	7,123	5,181	1,942	37.5
Gross profit	\$ 10,366	\$ 3,761	\$ 6,605	175.6%
Operating expenses:				
Selling, general and administrative	16,255	13,620	2,635	19.3
Research and development	7,208	6,719	489	7.3
Total operating expenses	23,463	20,339	3,124	15.4
Loss from operations	\$ (13,097)	\$ (16,578)	\$ 3,481	(21.0)%
Other income (expense), net:				
Interest expense	(1,507)	(1,060)	(447)	42.1
Interest and other income	1,392	46	1,346	2,910.1
Total other (expense) income, net:	(115)	(1,014)	899	(88.6)%
Loss before income taxes	(13,212)	(17,592)	4,380	(24.9)
Income tax expense	—	4	(4)	(100.0)
Net loss	\$ (13,212)	\$ (17,596)	\$ 4,384	(24.9)%
Other comprehensive loss				
Unrealized gain (loss) on short-term investments	84	(74)	158	(213.5)
Foreign currency translation gain (loss)	2	(4)	6	(152.6)
Total other comprehensive loss	86	(78)	164	(210.6)
Comprehensive loss	\$ (13,126)	\$ (17,674)	\$ 4,548	(25.7)%

### Sales

Sales increased by \$8.6 million, or 95.6%, to \$17.5 million for the three months ended March 31, 2023, from \$8.9 million for the three months ended March 31, 2022. The increase in total sales was primarily due to incremental sales of 6,357 LALs and 16 LDDs from strong adoption of our RxSight technology by practices and doctors.

### Cost of sales

Cost of sales increased by \$1.9 million, or 37.5%, to \$7.1 million for the three months ended March 31, 2023, from \$5.2 million for the three months ended March 31, 2022, primarily due to the increase in the number of LALs and LDDs sold during the period. Gross margin increased to 59.3% in the three months ended March 31, 2023, from 42.6% for the three months ended March 31, 2022 primarily due to improved operating leverage from increased sales volumes and favorable product mix.

### SG&A expenses

SG&A expenses increased by \$2.7 million, or 19.3%, to \$16.3 million for the three months ended March 31, 2023, from \$13.6 million for the three months ended March 31, 2022. This increase was primarily attributable to an increase in selling and marketing costs of \$2.0 million mainly due to increased salaries from increased headcount of 36, \$0.3 million of increased stock-based compensation expense due to increased headcount, and increased travel costs of \$0.2 million from increased LDD sales when compared to the three months ended March 31, 2022. General and administrative expenses increased \$0.1 million due to increased personnel expenses of \$0.3 million primarily due to increased headcount, and increased stock-based compensation of \$0.2 million which were partially offset by lower insurance costs of \$0.3 million when compared to the three months ended March 31, 2022.

### **Research and development expenses**

Research and development expenses increased by \$0.5 million, or 7.3%, to \$7.2 million for the three months ended March 31, 2023, from \$6.7 million for the three months ended March 31, 2022. This increase was primarily attributable to increased salaries of \$0.5 million from increased headcount and \$0.3 million from increased clinical study costs which were partially offset by reduced material costs of \$0.2 million.

### **Other income (expense), net**

Other income (expense), net, decreased by \$0.9 million to expense of \$0.1 million for the three months ended March 31, 2023 from expense of \$1.0 million for the three months ended March 31, 2022 due to an increase in interest expense of \$0.5 million on our amended term loan due to increased interest paid from higher interest rates which were offset by increased interest income of \$1.3 million from higher interest rates earned on our short-term investments.

### **Liquidity and capital resources**

#### **Sources of liquidity**

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses in the future.

As of March 31, 2023, we had cash, cash equivalents and short-term investments of \$153.9 million. For the three months ended March 31, 2023, and 2022, our loss from operations were \$13.1 million and \$16.6 million, respectively. We had an accumulated deficit of \$559.2 million as of March 31, 2023.

### **Recent Developments**

#### **Shelf Registration Statement**

On August 8, 2022, we filed a \$200.0 million shelf registration statement which became effective on August 12, 2022. The shelf registration is effective for three years and permits us to sell, from time to time, up to \$200.0 million in aggregate value of our common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement was intended to provide us with flexibility to access additional capital when market conditions are appropriate. At the time of filing the shelf registration statement, we also filed a prospectus supplement to sell up to an aggregate value of \$50.0 million dollars of our common stock through an ATM offering. The ATM shares are offered through BofA Securities, Inc. as sales agent. As of March 31, 2023, a total of 1,355,216 shares of common stock, for total net proceeds of \$16.9 million, have been issued and sold through the ATM offering, of which 879,341 shares of common stock, for net proceeds of \$10.9 million, were sold during the quarter ended March 31, 2023.

On February 7, 2023, we entered into an underwriting agreement with BofA Securities, Inc., pursuant to which we agreed to issue and sell 4,000,000 shares of our common stock in a public offering, pursuant to the shelf registration statement. The shares of common stock were sold at a price to the public of \$12.50 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option exercisable for 30 days from the date of the underwriting agreement to purchase up to an additional 600,000 shares of common stock on the same terms and conditions. The public offering closed on February 10, 2023. The underwriters' option was exercised in full on February 10, 2023 and closed on February 14, 2023. We received net proceeds of approximately \$53.6 million from the public offering, after deducting underwriters' discounts and commissions of \$3.5 million and offering expenses of \$0.5 million.

#### **Term Loan**

On May 3, 2022, we entered into a Second Amendment ("Second Amendment") to the Term Loan (as amended through the Second Amendment, ("Amended Term Loan"). The Amended Term Loan increased the loan and security agreement to \$60.0 million, of which \$40.0 million was fully funded as of May 3, 2022 from the original term loan. Under the Amended Term Loan, we may borrow an additional amount of up to \$10.0 million through June 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending March 31, 2023. Subject to the terms and conditions of the Amended Term Loan, we may also borrow an additional amount of up to \$10.0 million through September 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending June 30, 2023. The



Amended Term Loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 1-Month Term Secured Overnight Financing Rate (“SOFR”) (or, if greater, 0.16%) plus an applicable margin of 9.09%. If there is an event of default under the Amended Term Loan additional interest of 5% applies. The Amended Term Loan extends the maturity date of the loan and security agreement from October 1, 2025 to February 1, 2027. The Company refers to its \$60.0 million Amended Term Loan as its credit facility. See Note 6 - Term Loan in the Notes to the unaudited condensed consolidated financial statements included in this report.

### ***Standby letter of credit***

We also have a standby letter of credit, expiring September 30, 2024, issued by a financial institution as a required security for one operating lease. The aggregate amount of the letter of credit was \$0.3 million as of March 31, 2023 and December 31, 2022, respectively.

### ***Funding requirements***

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our sales growth;
- our research and development efforts;
- our sales and marketing activities;
- working capital investments, primarily in inventories and accounts receivable;
- debt service and debt covenant requirements;
- our ability to raise additional funds or borrow on our credit facility to finance our operations;
- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand, enforce and defend our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management, sales, research and development, scientific and customer support personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- operating and finance lease payments for our facilities;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

During the quarter ended March 31, 2023, we sold 879,341 common shares through the ATM offering for \$10.9 million in net proceeds after deducting underwriting discounts and commissions. In addition, in February 2023, we sold 4,600,000 common shares in a public offering and received net proceeds of approximately \$53.6 million, after deducting underwriters' discounts and commissions of \$3.5 million and offering expenses of \$0.5 million.

We expect that our current cash, cash equivalents and short-term investments through the date of filing of this report will be sufficient to fund our operations for at least the next 12 months. Although, based on our current planned operations, we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC, we may be required to raise additional capital through public or private equity offerings or debt financings, credit or loan facilities or by entering into partnerships or a combination of one or more of these funding sources in order to meet our liquidity requirements. We may also opportunistically access our ATM facility under advantageous circumstances.

See Part II, Item 1A (“Risk Factors”) of this report for additional risks associated with our substantial capital requirements.

## Summary statement of cash flows

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for each of the periods presented below:

	For the Three Months Ended March 31, (unaudited)	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (17,764)	\$ (14,985)
Investing activities	(48,365)	14,859
Financing activities	65,305	(98)
Effect of foreign exchange rate on cash, cash equivalents and restricted cash	2	(5)
Net decrease in cash, cash equivalents and restricted cash	\$ (822)	\$ (229)

### Cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2023, was \$17.8 million, consisting primarily of a net loss of \$13.2 million and a change in operating assets and liabilities of \$7.7 million, partially offset by non-cash stock-based compensation of \$3.3 million.

Net cash used in operating activities for the three months ended March 31, 2022, was \$15.0 million, consisting primarily of a net loss of \$17.6 million and a net increase in operating assets and a net decrease in operating liabilities of \$1.2 million, which was partially offset by non-cash stock-based compensation of \$2.6 million and depreciation and amortization of \$1.0 million.

### Cash (used in) provided by investing activities

Net cash used in investing activities for the three months ended March 31, 2023, was \$48.4 million, consisting primarily of net purchases of short-term investments of \$47.6 million and purchases of property and equipment of \$0.7 million.

Net cash provided by investing activities for the three months ended March 31, 2022, was \$14.9 million, consisting primarily of net maturities of short-term investments of \$15.2 million.

### Cash provided by (used in) financing activities

Net cash provided by financing activities for the three months ended March 31, 2023, was \$65.3 million consisting primarily of proceeds from issuances of common stock from our public offering of \$54.1 million, proceeds from issuance of common stock for at-the-market offerings of \$11.1 million and proceeds from stock options exercised of \$0.8 million.

Net cash used in financing activities for the three months ended March 31, 2022, was \$0.1 million, primarily consisting of payments for employee taxes related to stock compensation of \$0.4 million offset by proceeds from stock options exercised of \$0.3 million.

### Contractual obligations and commitments

We have a standby letter of credit, expiring September 30, 2024, issued by a financial institution as a required security for one operating lease. The aggregate amount of the letter of credit was \$0.3 million as of March 31, 2023 and December 31, 2022.

### Critical accounting policies, significant judgments and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under

the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, which may affect our future financial statement presentation, financial condition, results of operations and cash flows. Our significant accounting policies are more fully described in the notes to our financial statements included in our Annual Report on Form 10-K filed with the SEC on March 6, 2023. We believe that the accounting policies we use are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

We believe that accounting policies we have identified as critical involve a greater degree of judgment and complexity than our other accounting policies. Accordingly, those are the policies we believe are the most critical to understanding and evaluating our consolidated financial condition and results of operations.

For a summary of our critical accounting policies and estimates, refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K filed with the SEC on March 6, 2023. There have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2023.

#### **Indemnification agreements**

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement, misappropriation or other violation claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

#### **Recent accounting pronouncements**

See the section titled “Summary of Significant Accounting Policies—Recent Accounting Pronouncements” in Note 2 to our financial statements included elsewhere in this report for additional information.

#### **Emerging growth company and smaller reporting company status**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements. We have elected to take advantage of certain of the reduced disclosure obligations in this report and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. However, we have chosen to irrevocably “opt out” of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering (i.e. December 31, 2026); (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior 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.

### **Supply chain constraints, inflation and COVID-19 pandemic**

We rely on third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of our products. We do not have long-term supply agreements with, or guaranteed commitments from our suppliers, including single and sole source suppliers. We utilize purchase orders or blanket orders covering the medium term of 18–24 months for the majority of our supplier base. While we depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements, since the start of the COVID-19 pandemic and resultant supply chain constraints, vendors will miss delivery dates, extend delivery dates or in some circumstances cancel purchase orders because these suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. The expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, and COVID related shutdowns in China and the military conflict in Ukraine, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply and pushed out delivery dates. Additionally, due to these supply chain constraints we will identify and qualify new vendors or substitute components which requires testing, validations and documentation adding to internal costs and diverting engineering resources from other projects. On January 31, 2023, the FDA approved our premarket approval supplement to our lower cost LDD for various modifications that are intended to reduce the cost to manufacture the device. However, we have deferred the introduction of our lower cost-to-manufacture LDD to the market until the second half of 2023, as it is less difficult to procure components and subcomponents for our existing LDD than the lower cost-to-manufacture LDD. Currently, we are procuring materials for both LDD's, which have the same functionality. Management's expectation is that our gross margin will be impacted by the decision to continue to produce both LDD's, which is necessary to mitigate potential supply chain issues. While we have taken measures to mitigate business continuity risk, including increasing standard lead times, payment of expedite fees, issuance of a limited number of non-cancelable purchase orders, advance delivery of critical components ahead of normal delivery dates and second sourcing, our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could have a material adverse effect on our business, financial condition and results of operations.

Uncertain macroeconomic conditions including recent inflationary pressures and the rise in interest rates have created significant uncertainty in the U.S. economy and capital markets, which is expected to continue in 2023 and beyond and could negatively impact our financial results and liquidity.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company, we are not required to provide disclosure under this item.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

As of March 31, 2023, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the

Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

#### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ***Limitations on the Effectiveness of Controls***

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

## **Part II. OTHER INFORMATION**

### **Item 1: Legal Proceedings**

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are currently not a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, financial condition, and results of operations. Accordingly, the Company cannot determine the final amount, if any, of its liability beyond the amount accrued in the condensed consolidated financial statements as of March 31, 2023, nor is it possible to estimate what litigation-related costs will be in the future; however, the Company believes that the likelihood that claims related to litigation would result in a material loss to the Company, either individually or in the aggregate, is remote.

### **Item 1A: Risk Factors**

*We operate in a rapidly changing environment that involves numerous uncertainties and risks. In addition to the other information included in this report, the following risks and uncertainties may have a material and adverse effect on our business, financial condition, results of operations, or stock price. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this report. The risks and uncertainties described below may not be the only ones we face. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this report. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.*

### **Summary Risk Factors**

Our following risks and uncertainties are among the most significant we face, however, the risks and uncertainties identified in this subsection are not the only ones we face and are qualified in their entirety by reference to all of the risk factors described herein:

**Risks related to our business and products:**

- We have a limited operating history, and if we fail to effectively train our sales force, increase our sales and marketing capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business will suffer.
- We have a history of net operating losses, and we expect to continue to incur losses in the future. If we ever achieve profitability, we may not be able to sustain it.
- Our success depends in large part on our RxSight system. If we are unable to successfully market and sell our RxSight system, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.
- We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.
- Global economic, political and market conditions, including downgrades of the U.S. credit rating, may adversely affect our business, results of operations and financial condition, including our revenue growth and profitability.
- We currently maintain all of our cash, cash equivalents and short-term investments in a limited number of financial institutions and, therefore, our cash, cash equivalents and short-term investments could be adversely affected if any of the financial institutions in which we hold our cash, cash equivalents and short-term investments fails.

**Risks related to intellectual property:**

- If we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.
- We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

**Risks related to government regulation:**

- If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations may be harmed.

**Risks related to reliance on third parties:**

- We depend upon third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of the RxSight system, making us vulnerable to supply disruptions and price fluctuations.

**Risks related to our common stock:**

- The price of our stock may be volatile, and you could lose all or part of your investment.
- We do not know whether an active, liquid and orderly trading market will exist for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

**General risk factors:**

- We must recruit, retain, manage and motivate qualified executives as we build out the management team, and we are highly dependent on our management team.
- Future litigation proceedings could adversely affect our business.

## Risks related to COVID-19:

- Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID-19 pandemic and may continue to be harmed.

## Risks related to our business and products

***We have a limited operating history and if we fail to effectively train our sales force, increase our sales and marketing capabilities or develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business will suffer.***

We were incorporated in March 1997 and began commercializing our products in the second half of 2019, when we initiated a full launch of our LAL and LDD. Accordingly, our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and assess our prospects. We also currently have limited sales and marketing experience. If we are unable to establish or scale effective sales and marketing capabilities, or if we are unable to commercialize any of our products, we may not be able to generate sufficient product revenue, sustain revenue growth and compete effectively. In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our customer base and grow our business.

Identifying and recruiting qualified sales and marketing personnel and training them on our products, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, or in the event we are unable to reduce costs in the face of an unexpected decline in demand for our products. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or timely leverage our fixed costs could have a material adverse effect on our business, financial condition and results of operations. Moreover, the members of our direct sales force are at-will employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

Our ability to increase our customer base and achieve broader market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate patient or doctor awareness or increased revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the doctor acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

These factors also make it difficult for us to forecast our financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully develop additional products that add functionality, reduce the cost of products sold, and broaden our commercial portfolio offerings and our ability to obtain the required regulatory approvals and clearances under applicable law both domestically and internationally, including FDA 510(k) clearance or pre-market approval, or PMA, for, and successfully commercialize, market and sell, our planned or future products in the United States or in international markets. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

***We have a history of net losses, and we expect to continue to incur losses in the future. If we ever achieve profitability, we may not be able to sustain it.***

We have incurred losses from operations since our inception and expect to continue to incur losses from operations in the future. We reported losses from operations of \$63.3 million and \$52.8 million for the years ended December 31, 2022 and 2021, respectively and \$13.1 million for the three months ended March 31, 2023. As a result of these losses, as of March 31, 2023, we had an accumulated deficit of \$559.2 million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, we expect our general and administrative expenses to increase due to the costs associated with being a public company.

The net losses that we incur may fluctuate from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

***In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.***

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations and research and development activities. Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we may in the future seek to acquire or invest in additional businesses, products, services or technologies that we believe could complement or expand our product portfolio, enhance our technical capabilities or otherwise offer growth opportunities.

Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations in the future. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our sales growth;
- our research and development efforts;
- our sales and marketing activities;
- our success in leveraging future strategic partnerships;
- working capital investments, primarily in inventories and accounts receivable;
- debt service and debt covenant requirements;
- our ability to borrow on our credit facility or raise additional funds through our at-the-market offering to finance our operations;
- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand, enforce and defend our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management, sales, research and development, scientific and customer support personnel;



- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- operating and finance lease payments for our facilities;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

If we determine that we need to raise additional funds, we may do so through equity or debt financings, which may not be available to us when needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce or terminate certain of our product discovery and development activities or future commercialization efforts.

Moreover, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to products or technologies we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise.

As of March 31, 2023 and December 31, 2022, we had \$153.9 million and \$105.8 million, respectively, in cash, cash equivalents and short-term investments. While we believe that our existing cash, cash equivalents and short-term investments and anticipated cash generated from sales of our products will be sufficient to meet our anticipated cash needs for at least 12 months following the date of this report, we cannot assure you that we will be able to generate sufficient liquidity as and when needed. Further, although we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC (though we may opportunistically access our ATM facility under advantageous circumstances), we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We cannot assure you that we will be able to generate sufficient liquidity as and when needed.

***Global economic, political and market conditions, including downgrades of the U.S. credit rating, may adversely affect our business, results of operations and financial condition, including our revenue growth and profitability.***

The current worldwide economic and financial environment, as well as various social and political tensions in the U.S. and around the world, may contribute to increased market volatility, may have long-term effects on the U.S. and worldwide financial markets and may cause economic uncertainties or deterioration in the U.S. and worldwide. The impact of downgrades by rating agencies to the U.S. government's sovereign credit rating or its perceived creditworthiness as well as potential government shutdowns could adversely affect the U.S. and global financial markets and economic conditions. U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the U.S. In addition, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Continued adverse

political and economic conditions could have a material adverse effect on our business, financial condition, results of operations and prospects.

Deterioration in the economic conditions globally resulting in instability in global financial markets, including the following, may pose a risk to our business: inflation and rising interest rates, large sovereign debts and fiscal deficits of several countries in Europe and in emerging markets' jurisdictions, levels of non-performing loans on the balance sheets of European banks, the effect of the United Kingdom leaving the European Union, instability in the capital markets and the COVID-19 pandemic.

Various social and political circumstances in the U.S. and around the world (including wars and other forms of conflict, terrorist acts, security operations and catastrophic events such as fires, floods, earthquakes, tornadoes, hurricanes and global health epidemics) may also contribute to increased market volatility and economic uncertainties or deterioration in the U.S. and worldwide and have a material adverse effect on our business, financial conditions, results of operations and prospects.

***The terms of our amended term loan place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the term loan may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our securities to decline.***

Our amended term loan (the "Amended Term Loan"), also referred to as our credit facility, with Oxford Finance, provides for a \$60.0 million term-loan facility scheduled to mature on February 1, 2027, of which \$40.0 million was fully funded as of May 3, 2022, from the original term loan. Subject to the terms and conditions of the Amended Term Loan, we may borrow up to \$10.0 million during the second quarter of 2023 and up to another \$10.0 million in the third quarter of 2023.

Our payment obligations under the Amended Term Loan reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the Amended Term Loan bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

Our obligations under the Amended Term Loan are secured by substantially all of our assets, excluding intellectual property. The security interest granted over our assets could limit our ability to obtain additional debt financing. The Amended Term Loan also requires us to comply with a number of other covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; dispose of a portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions.

In addition to other specified events of default, the lenders could declare an event of default upon the occurrence of any event that they interpret as having a material impairment on their lien on the collateral under the agreement, a material adverse change in our business, operations or condition (financial or otherwise) or a material impairment in the prospect of repayment of our obligations under the agreement. If we default under the credit facility, the lenders may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, the lenders could take control of our pledged assets and we would have to immediately cease operations. During the continuance of an event of default, the then-applicable interest rate on the then-outstanding principal balance will increase by 5.0%. Upon an event of default, the lenders could also require us to repay the loan immediately, together with a final payment charge of 5.0% of the total term loan advances we borrowed, together with other fees. If we were to renegotiate the agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, the lenders' right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by the lenders

of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

***We currently maintain all of our cash, cash equivalents and short-term investments in a limited number of financial institutions and, therefore, our cash, cash equivalents and short-term investments could be adversely affected if any of the financial institutions in which we hold our cash, cash equivalents and short-term investments fails.***

We currently maintain all of our cash, cash equivalents and short-term investments with a limited number of financial institutions. At the current time, our cash, cash equivalents and short-term investment balances with such financial institutions are held primarily in U.S. treasury bills with a duration of less than 12 months. A portion of our operating cash is held in accounts in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. The failure of one or more of the financial institutions in which our cash, cash equivalents and short-term-investments are held, the resulting inability for us to obtain the return of our funds from any of those financial institutions, or any other adverse condition suffered by any of those financial institutions, could impact access to our operating cash and a temporary inability to access our short-term investments in U.S. treasury bills which could have an adverse effect on our business, financial condition and results of operations.

***Our success depends in large part on our RxSight system. If we are unable to successfully market and sell our RxSight system, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.***

Our future financial success will depend substantially on our ability to effectively and profitably market and sell our RxSight system to ophthalmic practices. The commercial success of our RxSight system and any of our planned or future products will depend on a number of factors, including the following:

- the actual and perceived effectiveness and reliability of our RxSight system, especially relative to alternative products;
- the prevalence and severity of any adverse patient events involving our RxSight system;
- the results of clinical studies and trials relating to our RxSight system;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to obtain regulatory approval to market our planned or future products for use in the United States or internationally;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;
- the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, including governmental and private insurers, as well as patient willingness to pay for the additional costs associated with our premium intraocular lens out of pocket;
- the degree to which doctors adopt our RxSight system;
- the fact that governmental and private health care providers and payors around the world are increasingly utilizing managed care for the delivery of health care services, centralizing purchasing, limiting the number of vendors that may participate in purchasing programs, forming group purchasing organizations and integrated health delivery networks and pursuing consolidation to improve their purchasing leverage and using competitive bid processes to procure health care products and services;

- our ability to obtain, maintain, protect and enforce our intellectual property rights in and to our RxSight system;
- the degree to which patients value the customized vision delivered by the RxSight system and are satisfied with their results;
- achieving and maintaining compliance with regulatory requirements applicable to our products;
- the extent to which we are successful in educating doctors about IOLs in general, and the benefits of our RxSight system;
- our reputation among doctors;
- the strength of our marketing and commercial organization;
- the effectiveness of our marketing and sales efforts in the United States, including our efforts to build out our sales team;
- our ability to expand the commercialization of our products into international markets;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with the Quality Systems Regulations (“QSR”), and other applicable foreign, federal and state regulatory requirements;
- the success of our ongoing or future clinical trials; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for current or future indications.

If we fail to successfully market and sell our products, we will not be able to grow our revenue or achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations. Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our RxSight system and any new product or product indications that we introduce, which will, in turn, depend in part on our success in growing our user base and driving increased use of our products. New products or product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies in any international markets we target in order to commercialize them. If we cannot achieve revenue growth or achieve or sustain profitability, it could have a material adverse effect on our business, financial condition and results of operations.

***Adoption of our products depends upon appropriate training for doctors, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business.***

The success of our products depends in part on our customers’ adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our RxSight system. However, doctors rely on their previous medical training and experience, and we cannot guarantee that all such doctors will have the necessary skills or training to effectively utilize our products. We do not control which doctors use our products or how much training they receive, and doctors who have not completed our training sessions may nonetheless attempt to use our products. In addition, doctors may use our products in a manner that is not consistent with their labeled indications for which no training is available. If doctors use our products in a manner that is inconsistent with their labeled indications, with components that are not compatible with our products or otherwise without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved by other doctors or in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products, which would have a material adverse effect on our business, financial condition and results of operations.

We currently require limited training in the use of our products because we market primarily to doctors who are experienced in the specific techniques required to use our devices. If demand for our products continues to grow, less experienced doctors will likely use our products, potentially leading to more injury and an increased risk of

product liability claims. The use or misuse of our products may in the future result in complications and potentially lead to product liability claims.

The commercial success of our RxSight system will depend upon attaining significant market acceptance of these products among patients and doctors.

Our success will depend, in part, on the acceptance of our RxSight system as safe, effective and, with respect to doctors, cost-effective. We cannot predict how quickly, if at all, patients, doctors, or payors will accept our RxSight system or, if accepted, how frequently it will be used. Our RxSight system and planned or future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. Patients and doctors must believe that our products offer benefits over alternative treatment methods. To date, a substantial majority of our product sales and revenue have been derived from a limited number of customers who have adopted our RxSight system. Our future growth and profitability largely depend on our ability to increase doctors' awareness of our RxSight system and our products and on the willingness of patients and doctors to adopt them. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products are safe, effective and, with respect to providers, cost-effective, on a stand-alone basis and relative to competitors' products. Patients and doctors must believe that our products offer benefits over alternative treatment methods. Even if we are able to raise awareness, doctors tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- competitive response and negative selling efforts from providers of alternative products;
- lack of experience with our products and concerns that we are relatively new to market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits;
- time commitment and skill development that may be required to gain familiarity and proficiency with our products;
- patient confusion regarding the wide range of commercially available premium IOL offerings and their ability to deliver promised results at near, middle and far distances without reliance on glasses;
- patient reticence to select a premium IOL due to nonperformance and adverse side effects associated with competing products in the market;
- patient non-compliance with the RxSight system requirement to wear protective glasses following surgery until the LAL is locked to avoid UV exposure and an unintended change to the LAL, resulting in patient dissatisfaction with the results and possible need to remove the LAL; and
- an inability to generate patient referral due to dissatisfaction with results obtained through treatment with our products, the out-of-pocket cost of treatments using our products or otherwise.

In order for doctors to use our RxSight system, they must make a significant up-front investment to purchase the LDD. This can result in a lengthy sales cycle and require extensive negotiations and management time. If we are unsuccessful in placing LDDs with providers, our sales may decrease, and our operating results may be harmed.

Doctors play a significant role in determining the course of a patient's treatment, and, as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing and education efforts primarily on doctors, and aim to educate referring doctors on the patient population that would benefit from our products. However, we cannot assure you that we will achieve broad market acceptance among doctors.

For example, some doctors may choose to utilize our RxSight system on only a subset of their total patient population or may not adopt our RxSight system at all. If we are not able to effectively demonstrate that the use of our RxSight system is beneficial in a broad range of patients, adoption of our product will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial

condition and results of operations. We cannot assure you that our products will achieve broad market acceptance among doctors. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Our reputation among our current or potential customers, as well as among doctors, could also be negatively affected by safety or customer satisfaction issues involving us or our products, including product recalls. Future product recalls or other safety or customer satisfaction issues relating to our reputation could negatively affect our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Our RxSight system involves surgical risks and is contraindicated in certain patients, which may limit adoption.

Risks of using our products include those associated with cataract surgery and IOL implantation. There are also possible, but rare, complications due to the use of UV light from the LDD, including a temporary or long-lasting change to vision. We are aware of certain characteristics and features of our RxSight system that may prevent widespread market adoption, including the fact that doctors would need to adopt a new procedure, and training for doctors will be required to enable them to effectively operate our products.

***We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.***

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with manufacturers and distributors of premium and conventional IOLs. Our most significant competitors in the IOL field include Alcon, Johnson & Johnson Vision and Bausch + Lomb. Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. Therefore, they can spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have a single product or a limited range of products. In addition, patients who receive an LAL will be required to wear UV protective glasses until final lock-in which is approximately four to five weeks after surgery. They will also be required to return for an additional two to three clinic visits compared to traditional monofocal cataract surgery. The additional clinic visits are non-surgical but do require the patient's eyes to be dilated. Due to these additional requirements, market acceptance of the LAL may be impacted. We believe the principal competitive factors in our markets include:

- The quality of patient outcomes, oftentimes measured by visual acuity, and adverse event rates;
- Patient experience, including patient recovery time and level of discomfort;
- Acceptance by treating doctors and referral sources;
- Doctor learning curves and willingness to adopt new technologies;
- Ease-of-use and reliability;
- Economic benefits and cost savings;
- Strength of clinical evidence;
- Effective distribution and marketing to surgeons and potential patients; and
- Product price and qualification for coverage and reimbursement.

We compete primarily on the basis that our products are designed to enable more doctors to treat more patients more efficiently and effectively. Our continued success depends on our ability to:

- continue to develop innovative, proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for doctors;

- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- expand our sales force across key markets to increase doctors' awareness;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products;
- provide doctors with a sufficient return on investment as compared to alternative premium IOL procedures that justifies the upfront cost of our LDD; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

We can provide no assurance that we will be successful in developing new products or commercializing them in ways that achieve market acceptance. If we develop new products, sales of those products may reduce revenue generated from our existing products. Moreover, any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

In addition, many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue may decrease, which could have a material adverse effect on our business, financial condition and results of operations.

***If our facilities become damaged or inoperable, or if we are required to vacate a facility, we may be unable to manufacture our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.***

We currently maintain our research and development, manufacturing and administrative operations in Aliso Viejo, California, and we do not have redundant facilities. We operate in four separate facilities, designated as a single manufacturing facility, and should any one of these facilities be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. A major interruption in the manufacturing operations at this facility would materially impact our ability to operate. Because of the time required to authorize manufacturing in a new facility under federal, state and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities if our facilities become inoperable, combined with our limited inventory of materials and components and manufactured products, may cause doctors to discontinue using our products or harm our reputation, and we may be unable to re-establish relationships with such doctors in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current leases on our four facilities expire, respectively, on (i) September 30, 2024, with one option to extend for five years; (ii) January 31, 2026, with three options to extend for five years each; (iii) March 31, 2023 with two options to extend for five years each, and (iv) August 31, 2024, with one option to extend for five years. We may be unable to renew our leases or find a new facility on commercially reasonable terms, or at all. If we

were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by any such move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

***Technological change may adversely affect sales of our products and may cause our products to become obsolete.***

The medical device market is characterized by extensive research and development and rapid technological change. There can be no assurance that other companies, including current competitors or new entrants, will not succeed in developing or marketing products that are more effective than our products or that would render our products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Our failure to develop new products, applications or features could result from insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, a lack of other research and development resources or other constraints. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our current or future competitors could have a material adverse effect on our business, financial condition and results of operations.

***We have limited data and experience regarding the safety and efficacy of our RxSight system. Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for our RxSight system and other planned or future products, which would affect market acceptance of our RxSight system.***

Because our RxSight system technology is a relatively new treatment to optimize vision after cataract surgery, we have performed clinical trials only with limited patient populations. The long-term effects of using our products in a large number of patients have not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. 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 other patient populations. 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 and subsequently failed to obtain marketing approval. 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.

***If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.***

Clinical development is a long, expensive and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. We are currently engaged in post-market clinical trials of our RxSight system. Completion of clinical trials may take several years or more. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products, modifications of existing products, or new indications for existing products, including:



- successful and timely completion of nonclinical studies or clinical development of our products, as well as the associated costs, including any unforeseen costs we may incur as a result of clinical trial delays due to the COVID-19 pandemic or other causes;
- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find that one or more of our products is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or governmental approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites;
- we may have trouble finding patients to enroll in our trials;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

***Unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users.***

Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and patients to manage their conditions. While currently bidirectional connectivity and interoperability of our RxSight system with other devices, local networks and the internet is not enabled, this may change in the future. Enablement of such features may increase cybersecurity risks and the risks of unauthorized access and use by third parties. For example, unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users and potential exposure to the company.

***We may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on specific products and indications. As a result, we may forgo or delay pursuit of other opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications or enhancements may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular potential product, we may relinquish valuable rights to that potential product through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such potential product.

***We may not be able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business, financial condition and results of operations.***

Our success depends on our ability to develop, license or acquire and commercialize additional products and to develop new applications for our technologies in existing and new markets, while improving the performance and cost-effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We intend to develop and commercialize additional products through our research and development program and by licensing or acquiring additional products and technologies from third parties. Our success is dependent upon several factors, including functionality, competitive pricing, ease of use, the safety and efficacy of our products and our ability to identify, select and acquire the rights to products and technologies on terms that are acceptable to us.

The medical device industry is characterized by rapid technological change and innovation. New technologies, techniques or products could emerge that might offer better combinations of price and performance or better address customer requirements as compared to our current or future products. Competitors, who may have greater financial, marketing and sales resources than we do, may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. Any new product we identify for internal development, licensing or acquisition may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. Due to the significant lead time and complexity involved in bringing a new product to market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of a new product. These assumptions and estimates may prove incorrect, resulting in our introduction of a product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Our ability to mitigate downward pressure on our selling prices will be dependent upon our ability to maintain or increase the value we offer to doctors as well as payors. All new products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition and results of operations.

Our ability to attract new customer accounts depends in large part on our ability to enhance and improve our existing products and to introduce compelling new products. The success of any enhancement to our products depends on several factors, including adoption and continued use by doctors, competitive pricing and overall market acceptance. Any new product that we develop may not be introduced in a timely or cost-effective manner, may contain defects or may not achieve the market acceptance necessary to generate significant revenue. If we are unable to successfully develop, license or acquire new products, enhance our existing products to meet customer requirements or otherwise gain market acceptance, our business, financial condition and results of operations would be harmed.

The typical development cycle of new medical device products can be lengthy and complicated and may require complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted, and our business and operating results may be harmed.

***If we fail to identify, acquire and develop other products, we may be unable to grow our business.***

As a significant part of our growth strategy, we intend to develop and commercialize additional products through our research and development program or by licensing or acquiring additional products and technologies from third parties. The success of this strategy depends upon our ability to identify, select and acquire the right to products and technologies on terms that are acceptable to us.

Any product we identify, license or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. All products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable product or technology acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of approved or cleared products. We may not be able to acquire or license the rights to additional approved or cleared products on terms that we find acceptable, or at all.

If we are unable to develop suitable potential products through internal research programs or by obtaining rights from third parties, it could have a material adverse effect on our business, financial condition and results of operations.

***We may acquire other companies or technologies, which could fail to result in a commercial product or increased revenue, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.***

Although we currently have no agreements or commitments to complete any such transactions, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

***Coverage and adequate reimbursement and/or the ability of patients to pay for the difference between the price charged by practices and the reimbursement amount may not be available for our products in sufficient markets, which could diminish our sales or affect our ability to sell our products.***

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial remuneration to doctor practices

and surgical centers. This remuneration can come from a combination of sources, including third-party payors, such as Medicare and Medicaid programs in the United States, managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. They also can preclude patients from paying extra to receive additional services, such as those associated with placement of premium IOLs. Our products are purchased by doctors who will then seek reimbursement from third-party payors and patients for the procedures performed using our products. Reimbursement systems and patient billing rules in international markets vary significantly by country and by region within some countries, and reimbursement and/or non-reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures, as well as the ability to charge patients directly for non-reimbursed devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

While third-party payors currently cover and provide reimbursement for a portion of the cost of the procedures performed using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement or permit patient payment for the non-reimbursed portion sufficient to permit doctors to offer procedures using our products to patients requiring treatment. If sufficient coverage and reimbursement or flexibility to enable patient payment is not available for the procedures performed using our products, in either the United States or any international markets we enter, the demand for our products and our revenue will be adversely affected.

Furthermore the overall amount of reimbursement available for products and procedures intended to treat cataract and refractive conditions of the eye could remain at current levels or decrease in the future. Failure by doctors to obtain and maintain coverage and adequate reimbursement as well as patient charges for the procedures performed using our products would materially adversely affect our business, financial condition and results of operations.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed (or continue to be viewed) as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.***

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on doctors in connection with the use of our products on patients. If these doctors are not properly trained or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

***We intend to expand sales of our products internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our products internationally even if approved. A variety of risks associated with marketing our products internationally could materially adversely affect our business.***

Sales of our products outside of the United States would be subject to foreign regulatory requirements governing clinical trials and marketing approval. We will incur substantial expenses in connection with our international expansion. Additional risks related to operating in foreign countries include:

- differing regulatory requirements and reimbursement regimes in foreign countries, including changes to regulatory requirements and implementation of new regulations in foreign countries;
- difficulties in compliance with non-U.S. laws and regulations;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- trade protection measures, import or export licensing requirements, or other restrictive actions by U.S. or non-U.S. governments;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations in international markets, which would have a material adverse effect on our business, financial condition and results of operations.

Further, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, where applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

In addition, there can be no guarantee that we will receive approval to sell our products in the international markets we target, nor can there be any guarantee that any sales would result even if such approval is received. Even if the FDA grants marketing approval for a product, comparable regulatory authorities of foreign countries must also approve the manufacturing or marketing of the product in those countries. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional trials and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could negatively affect our business, financial results and results of operations.

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

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse doctors performing cataract procedures, or any reduction in the flexibility to charge patients for non-reimbursed procedures could make it difficult for us to convince our customers to make the up-front investment in our LDD and could create additional pricing pressure with respect to the patient's decision to pay the additional cost associated with our LALs and potentially a reduction in the number of procedures performed using the RxSight system and corresponding sales of LDDs, LALs, accessories and services. If we are forced to lower the price we charge for our products, our revenue and gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business, financial condition and results of operations.

***The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate.***

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients who have undergone cataract surgery, and the assumed prices at which we can sell our RxSight system. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. In addition, our estimates of the sizes of the cataract surgery patient population include patients who might never be likely candidates for treatment with our products. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

***Changes to state regulations and interpretation of the practice of optometry, for public health insurance coverage and government reimbursement rates for our products and related procedures and/or medical or professional malpractice insurance coverage for doctors who perform procedures using our products could affect the adoption of our products and our future revenue.***

States regulate the practice of optometry, including the types of procedures optometrists are authorized to perform in each state. To the extent states change or narrow the scope of the practice of optometry or their interpretation of the scope of optometry with respect to those who are qualified to perform LDD procedures involving our RxSight system, such state regulation or policy can have a material impact on which doctors may use our RxSight system, our customer base and market share, and the adoption of our RxSight system. Additionally, payor restrictions on the coverage and/or reimbursement levels for procedures using our RxSight system can negatively impact the adoption of our products and the pricing of our products, which can have a material impact on our profitability. Changes to medical or professional malpractice insurance coverage policies for doctors who perform procedures using our products, including refusal to cover malpractice liability insurance related to the use of our products can have a material impact on the adoption of our products and our business operations. We can provide no assurance on the impact of current and future federal and state legislative, executive, and administrative actions, including measures implemented by state boards of examiners in optometry, as well as policies of malpractice insurance carriers and payors on us, our business operations, and the business of our customers. The implementation of cost containment measures or other policy and regulatory changes may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to doctors. In addition, CMS establishes Medicare payment levels for doctors on an annual basis, which can increase or decrease payment to such entities. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. In addition, the ability to charge patients directly for premium IOLs and associated services

also varies widely across different countries and could become more restricted. Even if we succeed in bringing our products to market internationally, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

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

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual 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. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

***We expect to significantly expand our organization, including expanding our sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We have and expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Certain of our operating results and financial metrics may be difficult to predict as a result of seasonality.***

While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end-of-year holiday season. We may be affected by other seasonal trends in the future, including severe weather (which can impact the number of elective procedures performed), particularly as our business matures. Additionally, this seasonality may be reflected to a much lesser extent, and sometimes may not be immediately apparent, in our revenue. To the extent we experience this seasonality, it may cause fluctuations in our operating results and financial metrics and make forecasting our future operating results and financial metrics more difficult.

***Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.***

As of March 31, 2023, we had federal net operating loss carryforwards (“NOLs”) of approximately \$300.4 million, which will begin to expire in various years ranging from 2023 to 2037. Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Under the Tax Cuts and Jobs Act (“Tax Act”), as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act, as modified by the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change” (generally defined as a cumulative change in our ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may



be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience an ownership change in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in our stock ownership. Our ability to utilize those NOLs could be limited by an “ownership change” as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

### **Risks related to intellectual property**

***If we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

Our success depends in large part on our ability to obtain, maintain, protect and enforce patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop. If we fail to obtain, maintain, protect and enforce our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We seek to protect our position by in-licensing intellectual property relating to our products and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret and other intellectual property rights to protect the proprietary aspects of our brands, products, 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 obtaining and maintaining patents, copyrights, trademarks, trade secrets, data and know-how and other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, contractors, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our owned and in-licensed issued patents may be challenged in courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO, challenging the validity of one or more claims of our owned or in-licensed issued patents. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of our owned or in-licensed pending patent applications.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, contractors, collaborators, vendors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We may not be able to obtain or maintain patent applications and issued patents due to the subject matter claimed in such patent applications and issued patents being in disclosures in the public domain, and we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with

our technologies. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or in-licensed issued patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or in-licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and in-licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also 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 compete with our products. In these circumstances, we may need to defend and/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, in which case, our competitors and other third parties 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.

Given that 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. Competitors may also contest our patents, if issued, by showing the USPTO, or the applicable other foreign patent agency that the invention was not original, was not novel or was obvious. In litigation, 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.

In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our other intellectual property, including our trademarks, could also 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, in which case 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.

We may in the future also be subject to claims by our former employees, consultants or contractors asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, 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, or that they will not be breached, for which we may not have an adequate remedy.

Failure to obtain and maintain patents, trademarks and other intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the United States government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Moreover, a portion of our intellectual property has been acquired from one or more third parties. While we have conducted diligence with respect to such acquisitions, because we did not participate in the development or prosecution of much of the acquired intellectual property, we cannot guarantee that our diligence efforts identified and/or remedied all issues related to such intellectual property, including potential ownership errors, potential errors during prosecution of such intellectual property, and potential encumbrances that could limit our ability to enforce such intellectual property rights.

***Patent terms may be inadequate to protect our competitive position on technology for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U.S. non-provisional or Patent Cooperation Treaty application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired for a product, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for a meaningful amount of time, or at all.

***Obtaining and maintaining our 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 noncompliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and patent applications are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of such issued patents and patent applications. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. We are dependent on our licensors to take the necessary action to comply with these requirements with respect to certain of our in-licensed intellectual property, and if we or any of our current or future licensors fail to maintain the patents and patent applications covering our RxSight system or any future products, our competitors may be able to enter the market, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

***Our future reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we expect to rely on a third party to manufacture our RxSight system, and any future products, and we expect to collaborate with third parties on the continuing development of our RxSight system, and any future products, we must, at times, share trade secrets with them. We also expect to conduct R&D programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations with our advisors, employees, contractors, CMOs, CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, CMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets,

although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.***

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors. Litigation may be necessary to defend against these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. In addition, we may lose personnel as a result of such claims. Any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or in-licensed issued patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology. Such challenges may also result in our inability to develop, manufacture or commercialize our technology without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or in-licensed issued patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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.

***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, copyrights, 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, copyrights, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents, copyrights, or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. 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. We may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our owned or in-licensed patent portfolio may therefore have no deterrent effect. We may in the future become party to adversarial proceedings or litigation where our competitors or other third parties may assert claims against us, alleging that our products or services infringe, misappropriate or otherwise violate their intellectual property rights, including patents and trade secrets. 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, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

Further, if patents, trademarks, copyrights, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, marketing or selling our products, or result in obligations to pay license fees, damages, attorney fees and court costs, which could be significant. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties.

Although patent, copyright, trademark, trade secret and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary

licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition and results of operations.

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 partes 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, which we may not always be able to detect. 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 or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure

in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition and results of operations.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing, misappropriating or otherwise violating our owned or in-licensed patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

***Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.***

We rely, in part, upon licenses to certain patent rights, proprietary technology and other intellectual property from third parties that are important or necessary to the development of our products and technology. Further development and commercialization of our current products, and development of any future products, may require us to enter into additional license or collaboration agreements. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. Additionally, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could materially and adversely affect our business, financial condition and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to



successfully develop and commercialize the affected products. Any of these events could materially and adversely affect our business, financial condition and results of operations.

***In the future, we may enter agreements involving licenses or collaborations that provide for access or sharing of intellectual property. If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future products.***

We currently, and in the future may continue to, license from third parties certain intellectual property relating to our current and future products. In the event we do so, we may have certain obligations to such licensors. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our future licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Further, we or our future licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under future license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed in the future from various third parties may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or future licensed technologies, or if we lose our rights to critical future in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and possibly in the future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our products.

***We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.***

We may need to obtain additional licenses from our existing licensors or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially and adversely affect our business, financial condition and results of operations.

***Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.***

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future products;

- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We or our licensors may be subject to claims that former consultants, contractors or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Furthermore, individuals executing invention assignment agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Any such events could have a material adverse effect on our business, financial condition and results of operations.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, 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 inside and outside the United States 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 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. Despite the protections we do place on our intellectual property or other proprietary rights, 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 otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties or those to whom they communicate such trade secrets. 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 similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

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.

***Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The America Invents Act

and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. We cannot predict how decisions or actions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not be able to protect our intellectual property rights throughout the world, which could impair our business.***

Filing, prosecuting, and defending patents covering our RxSight system, and any of our future products throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or in-licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in enforcing and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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 develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business, financial condition, results of operations and prospects could be materially and adversely affected.

No earlier than June 1, 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (“UPC”). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. RxSight will consider its options on a case-by-case basis regarding UPC and will coordinate with foreign counsel in a timely manner.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make a product that is similar to our current products and future products we intend to commercialize and that is not covered by the patents that we own or exclusively in-license and have the right to enforce;
- we and any of our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or may own or license in the future;
- we or any of our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our current or future owned or in-licensed patent applications will not lead to issued patents;
- issued patents that we own or in-license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

***Our future use of “open source” software could subject our proprietary software to general release, adversely affect our ability to sell our products and subject us to possible litigation.***

We intend to incorporate open source software in future products or technologies licensed, developed and/or distributed by us. Open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary source code in that software, as well as distribute our products that use particular open source software at no cost to the user. We intend to monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations

regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations.

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

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. We cannot assure you that our trademark and service mark applications will be approved. During trademark and service mark 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 and service mark applications and to seek to cancel registered trademarks and service marks. Opposition or cancellation proceedings may be filed against our trademarks and service marks, and our trademarks and service marks may not survive such proceedings. In the event that our trademarks and service marks 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, trademarks or service marks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our trademark and service mark rights and prevent infringement and other violations, we may be required to file claims against third parties or initiate opposition proceedings. This can be expensive and time-consuming. In addition, there could be potential trademark or service mark infringement claims brought by owners of other registered trademarks, service marks, or trademarks or service marks that incorporate variations of our registered or unregistered trademarks or service marks. Certain of our current or future trademarks or service marks may become so well known by the public that their use becomes generic and they lose trademark or service mark protection. Over the long term, if we are unable to establish name recognition based on our trademarks, service marks 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 government regulation**

***If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.***

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we may choose to do business. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product safety and effective;
- product changes;
- product marketing, promotion and advertising, sales and distribution; and

- post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, in order to clear the proposed device for marketing. 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 is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA’s 510(k) clearance process usually takes from three to 12 months but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- the applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- the FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data



generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA and European Union regulatory authorities strictly regulate the labeling, promotion and advertising of medical devices, including comparative and superiority claims vis a vis competitors' products, that may be made about products.

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to timely file various reports with the FDA, including MDR, that requires that we report to the regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause doctors to delay or cancel procedures, which could harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity and warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products;
- withdrawal of 510(k) clearance or PMAs that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

***Our products and operations are subject to extensive government regulation and oversight in the United States.***

Medical devices regulated by the FDA are subject to “general controls” which include: registration with the FDA; listing commercially distributed products with the FDA; complying with all applicable requirements under the QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as “510(k)-exempt” devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the “general controls,” some Class II medical devices are also subject to “special controls,” including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA.

Although our products have received regulatory approval or clearance from FDA in the United States for a particular patient population, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, effectiveness and other post-market information, including both federal and state requirements in the United States and requirements of comparable non-U.S. regulatory authorities in any international markets we choose to enter.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted, will be subject to the conditions of approval, or will contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the products’ cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. We received a PMA for the LAL and LDD, which is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag, in adult patients with pre-existing corneal astigmatism of  $> 0.75$  diopters and without pre-existing macular disease. We also received a 510(k) clearance for our contact lens, which is indicated for visualization and treatment in the anterior segment of the eye. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use, known as “off-label uses.” However, doctors may use our products for off-label purposes and are allowed to do so when in the doctor’s independent professional medical judgment he or she deems it appropriate. If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, or that our internal policies and procedures are inadequate to prevent such off-label uses, it could subject us to regulatory or enforcement actions as discussed below.

In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time-consuming. If the FDA determines that our promotional, reimbursement or training materials for sales representatives or doctors constitute promotion of an off-label use, the FDA could request that we modify our training, promotional or reimbursement materials and/or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting

false claims for reimbursement. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the federal civil False Claims Act for which it might impose significant civil fines and even pursue criminal action. In those possible events, our reputation could be damaged, and adoption of the products would be impaired.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the FDCA relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

***Material modifications to our products may require new 510(k) clearances or pre-market approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.***

Modifications that could significantly affect the safety and effectiveness of our approved or cleared products, such as changes to the intended use or technological characteristics of our products, will require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain the required 510(k) clearances or PMAs, or PMA supplements, or similar marketing authorization in applicable foreign

jurisdictions, for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA or a comparable foreign regulatory authority disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions.

***Obtaining and maintaining regulatory approval of our current and future products in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our current and future products in other jurisdictions. The FDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.***

Obtaining and maintaining regulatory approvals or clearances of our current and future products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval or clearance of a current or future product, comparable regulatory authorities in foreign jurisdictions must also approve or clear the manufacturing, marketing and promotion and reimbursement of a current or future product in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

The RxSight system is approved for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error, including for -2.0 to + 2.0 diopters of sphere and -3.0 to -0.50 diopters of cylinder and by changing lens curvature to introduce controlled amounts of spherical aberration (+/- 1 micron) and center near add (up to 2.0 diopters) which is also registered with the MHRA in the United Kingdom, in Canada and in Mexico. Obtaining additional foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements in jurisdictions where we conduct business currently or in the future, such as requirements under the EU MDR, could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals or clearances, our target market will be reduced and our ability to realize the full market potential of our current and future products will be harmed.

In addition, we have conducted clinical trials in Mexico and may choose to conduct further international clinical trials. The acceptance of study data by the FDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices regulations; and (3) audits by regulatory authorities of the clinical data do not identify significant data integrity issues. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our products not receiving approval or clearance for commercialization in the applicable jurisdiction.

***Our products may be subject to recalls after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation and adversely affect our business.***

The FDA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls.

Doctors may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

***If we, or our suppliers, fail to comply with the FDA's QSR or applicable foreign regulations, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.***

Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the FDA's Quality System Regulation ("QSR"), which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products in the United States. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service, to maintain our CE Mark in Europe. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies, and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health ("CDPH"), and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers.

We can provide no assurance that we will continue to remain in material compliance with the QSR. If the FDA, CDPH, or any applicable notified body in the European Union or United Kingdom inspects any of our facilities and

discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business.

***Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.***

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act (“ACA”), was enacted. The ACA is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. The ACA has impacted existing government healthcare programs and has resulted in the development of new programs.

Certain provisions of the ACA have been subject to judicial and Congressional challenges. For example, various portions of the ACA have been the subject of legal and constitutional challenges, including legal proceedings in the Fifth Circuit Court of Appeals. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is unclear how this Supreme Court decision, future litigation, and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, our financial operations. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;

- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several United States Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, Congress and the federal administration have each indicated that it will continue to seek new legislative and/or administrative measures to control healthcare costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations.

***If we fail to comply with United States federal and state fraud and abuse and other healthcare laws and regulations, we could face substantial penalties and our business operations and financial condition could be adversely affected.***

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals, third-party payors and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, a Code of Conduct and associated policies and procedures, but 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 noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act. There are similar laws in other countries. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, or order of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Federal False Claims Act, including its civil provisions that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibiting individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid,

decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;

- the Federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, also referred to as the CMS Open Payments, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require medical device manufacturers to report information related to payments and other transfers of value to doctors or marketing expenditures and require the registration of their sales representatives; state laws that require medical device companies to report information on the pricing of certain medical device products; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 (“BBA”), increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies recently have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and HIPAA’s healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to doctors that have entered into consulting agreements with us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. We may be subject to private “qui tam” actions brought by individual whistleblowers on behalf of the federal or state governments.

The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our



business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment of individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling federal civil False Claims Act, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition and results of operations.

***Changes in the CMS fee schedules may harm our revenue and operating results.***

Government payers, such as CMS as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the United States Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

***Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, 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 regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

***Compliance with the EU Medical Device Regulation, applicable regulations in the United Kingdom, and other applicable foreign regulations, as well as any changes to existing regulations, may be costly and disruptive to our business, and expose us to increased liability.***

In 2017, the European Union (“EU”) published the new EU Medical Device Regulation (“MDR”) (2017/745), the application of which was postponed until May 26, 2021 for class I devices (lowest risk) and May 26, 2024 for all other class devices (higher risk devices). In February 2023, EU Parliament voted to extend the MDR transition timelines, which postpones application until December 2027 for higher-risk Class III and implantable IIB devices and until December 2028 for lower-risk Class I and IIa devices. The new regulations replace predecessor directives and emphasize a global convergence of regulations. With the transition from the Medical Devices Directive (“MDD”), to the MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law. While we are currently in compliance with the MDR and in process of transferring certification from MDD to MDR, compliance with any new or changing regulations in the EU or other jurisdictions where we currently commercialize our products or intend to commercialize in the future is a time consuming process that may require comprehensive quality system audits and new conformity assessment certifications for our products. Major changes include:

- reclassification of some products;
- greater emphasis on clinical data;
- data transparency, including publication of clinical trial data and safety summaries;
- defined content and structure for technical files to support registration;
- unique device identification system;
- greater burden on post-market surveillance and clinical follow-up;
- reduction of adverse event reporting time from 30 to 15 days after the event; and
- more power to notified bodies.

Implementation of the Medical Device Regulations introduces substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. For any products that we may develop in the future, complying with these new regulations may result in Europe being less attractive as a “first market” destination. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated.

***Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.***

We may be required to conduct clinical studies that demonstrate competent and reliable evidence that our products are safe and effective before we can commercialize our products. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our products for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our products. Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

***Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.***

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component

failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications and offer to repair the LDD in the event of a defect and replace or refund the purchase price of a defective LAL. 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 such recovery, or any recovery from such vendor or supplier may be inadequate or unavailable.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to doctor error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, doctors or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid a determination of fault, even if we believe fault was not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for such products or any or all of our other products and could harm our brand and reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage 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 are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA that are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

***Our employees, independent contractors, consultants, commercial partners, distributors and vendors 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, consultants, commercial partners, distributors and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include

intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but 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 these activities 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 result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

***Environmental health and safety laws may result in liabilities, expenses and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability.***

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal and remediation of, as well as human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties,

personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition and results of operation.

***We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.***

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as the Common Rule ("GCP") guidelines, or FDA human subject protection 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 United States 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 and/or criminal liability. 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.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business. In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security and have prioritized privacy and information security violations for enforcement actions. Additionally, in the United States, California adopted CCPA in January 2020, which requires certain companies that process information of California consumers to, among other things, provide new disclosures to California consumers and afford such consumers new abilities to exercise certain rights with respect to their personal information and opt out of certain sales of personal information, in addition to severely limiting our ability to use their information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. It remains unclear how various provisions of the CCPA will be interpreted and enforced. Furthermore, in November 2020, California voters passed the CPRA, which became effective January 1, 2023. The CPRA imposes additional obligations on covered companies and significantly modifies the CCPA, including by expanding California residents' rights with respect to certain sensitive personal information. Other states have passed, or plan to pass, data privacy laws that are similar to the CCPA and CPRA, further complicating the legal landscape. In addition, laws in all 50 states require businesses to provide notice to consumers whose personal information has been accessed or acquired as a result of a data breach (and, in some cases, to regulators). The effects of the CCPA, CPRA and other such privacy laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

In addition, we are subject to international laws, regulations and standards in many jurisdictions, which apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the GDPR, which was adopted by the EU and became effective in May 2018, applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data.

The GDPR provides that EU member states may make their own laws and regulations limiting the (i) processing of personal data, including special categories of data (e.g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and (ii) profiling and automated individual decision-making of individuals, which could limit our ability to use and share personal data or other data and could cause our costs to increase, harming our business and financial condition. Non-compliance with GDPR is subject to significant penalties, including fines of up to €20 million or 4% of total worldwide revenue, whichever is greater. Interpretations of the GDPR by local data protection authorities in EU member states, along with the complexity of the regime itself, create uncertainty regarding the interpretation and enforcement of the law, with potential inconsistencies across EU member states. Other jurisdictions outside the EU are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws. Further, the United Kingdom's decision to leave the European Union has created uncertainty with regard to data protection regulation in the United Kingdom. We are subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GDPR in the United Kingdom's national law and provides for a penalty structure similar to the GDPR. These recent developments have required us to review and modify the legal means by which we process personal data and may require us to make other modifications. The implementation and enforcement of the GDPR and other evolving legislation may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected.

Additionally, we are subject to laws and regulations regarding cross-border transfers of personal data, including laws relating to transfer of personal data outside of the European Economic Area ("EEA"), Switzerland, and the United Kingdom. We rely on transfer mechanisms permitted under these laws, including EU Standard Contractual Clauses ("SCCs"). Such mechanisms have received heightened regulatory and judicial scrutiny in recent years. The Court of Justice of the European Union ("CJEU") issued a decision in 2020 invalidating a transfer of personal data from the EEA and Switzerland to the U.S. and imposing additional obligations on companies using the SCCs. The European Commission has adopted new SCCs that are required to be implemented over time, and the United Kingdom has adopted new standard contractual clauses that also are required to be implemented over time. In June 2021, the European Commission issued an adequacy decision in respect of the United Kingdom's data protection framework, enabling data transfers from EU member states to the United Kingdom to continue without requiring contractual or other additional measures. While it is intended to last for at least four years, the European Commission may revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. These developments and other regulatory guidance or developments may impose additional obligations with respect to the transfer of personal data from the EEA, Switzerland, and the United Kingdom, all of which could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices, and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the EEA, Switzerland, and the United Kingdom to the U.S. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies. If our practices are not consistent, or are viewed as not consistent, with changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to fines, audits, inquiries, whistleblower complaints, adverse media coverage, investigations, lawsuits, loss of export privileges, severe criminal or civil sanction or other penalties. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our businesses and discourage potential users from our products and services. Any of the foregoing could have an adverse effect on our business, financial condition, results of operations and prospects.

***Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a***

***timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies, including delays or disruptions due to the COVID-19 pandemic, travel restrictions, and staffing shortages, may also slow the time necessary for new medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies such as the FDA had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current inspection pace or may be unable to complete required inspections during the review period, which can delay clinical development and result in a complete response letter. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Recently, President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on the FDA and other regulatory policies and operations is unclear. Disruptions to the FDA could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns, if any, could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Our global operations can expose us to numerous and sometimes conflicting legal and regulatory requirements, including to anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act, and violation of these requirements could result in substantial penalties and prosecution and harm our business.***

We have commercialized the RxSight system outside of the United States, and each component is registered with the MHRA in the United Kingdom. We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our operations outside of the United States are subject to various heavily enforced anti-bribery and anti-corruption laws, such as the FCPA, U.K. Bribery Act and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws could result in whistleblower complaints, adverse media coverage,

investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our business, financial condition and results of operations.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition and results of operations.

#### **Risks related to reliance on third parties**

***From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products.***

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as GCP guidelines, the Common Rule, and FDA human subject protection regulations. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products.

***We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition and results of operations.***

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies in jurisdictions where we commercialize our products, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our manufacturer, component, and sub-component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. The failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

For products that we currently distribute or market in the EU and the United Kingdom, as well as future products for which we obtain the applicable marketing authorization, we must maintain certain International Organization for Standardization ("ISO"), certifications to sell our products and must undergo periodic inspections by notified bodies, such as BSI, to obtain and maintain these certifications. If we fail these inspections or fail to meet



these regulatory standards, it could have a material adverse effect on our business, financial condition and results of operations.

***We depend upon third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of the RxSight system making us vulnerable to supply disruptions and price fluctuations.***

We rely on third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of our products. We do not have long-term supply agreements with, or guaranteed commitments from our suppliers, including single and sole source suppliers. We utilize purchase orders or blanket orders covering the medium term of 18–24 months for the majority of our supplier base. While we depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements, since the start of the COVID-19 pandemic and resultant supply chain constraints, vendors will miss delivery dates, extend delivery dates or in some circumstances cancel purchase orders because these suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. The expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, and COVID related shutdowns in China and the military conflict in Ukraine, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply and pushed out delivery dates. Additionally, due to these supply chain constraints we will identify and qualify new vendors or substitute components which requires testing, validations and documentation adding to internal costs and diverting engineering resources from other projects. On January 31, 2023, the FDA approved our premarket approval supplement to our lower cost LDD for various modifications that are intended to reduce the cost to manufacture the device. However, we have deferred the introduction of our lower cost-to-manufacture LDD to the market until the second half of 2023, as it is less difficult to procure components and subcomponents for our existing LDD than the lower cost-to-manufacture LDD. Currently, we are procuring materials for both LDD's, which have the same functionality. Management's expectation is that our gross margin will be impacted by the decision to continue to produce both LDD's, which is necessary to mitigate potential supply chain issues. While we have taken measures to mitigate business continuity risk, including increasing standard lead times, payment of expedite fees, issuance of a limited number of non-cancelable purchase orders, advance delivery of critical components ahead of normal delivery dates and second sourcing, our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could have a material 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, and other third parties to research, develop, manufacture and commercialize our products. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) 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 have a material adverse effect on our business, financial condition and results of operations.

**Risks related to our common stock**

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which we cannot control. From the date of our initial public offering through May 1, 2023, our common stock has traded at a low of \$8.80 and a high of \$19.67 on the Nasdaq Global Market. The stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry

factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in Part II, Item 1A, “Risk Factors,” and elsewhere in this report, these factors include:

- the timing and results of preclinical studies and clinical trials of our current and future products or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the medical device sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- general economic, industry and market conditions, including global and national events, such as the conflicts in Eastern Europe, and general economic downturns; and
- the impact of the COVID-19 pandemic.

The realization of any of the above risks or any of a broad range of other risks, including those described in this Part II, Item 1A, “Risk Factors,” could have a dramatic and adverse impact on the market price of our common stock.

In addition, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We will not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of

our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

***We do not know whether an active, liquid and orderly trading market will exist for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.***

Our common stock is currently traded on Nasdaq Global Market, but we can provide no assurance that we will be able to maintain an active trading market on Nasdaq Global Market or any other exchange in the future. If an active trading market does not develop, or is not maintained, or if we fail to satisfy the continued listing standards of the Nasdaq Global Market or applicable SEC rules for any reason and our securities are delisted, you may have difficulty selling any of our shares of common stock that you buy. The lack of an active trading market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active trading market may also reduce the fair market value of your shares. Furthermore, an inactive trading market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of March 31, 2023, we had 33,966,697 shares of common stock issued and outstanding. All of these shares are available for sale in the public market, subject to limitations under Rule 144 with respect to affiliates of our company.

We have filed registration statements on Form S-8 under the Securities Act registering the offer and sale of up to an aggregate of 9,216,217 shares of common stock pursuant to our Equity Incentive Plans and an aggregate of 757,694 shares of common stock pursuant to our 2021 ESPP. Our 2021 Plan and 2021 ESPP each contain an evergreen provision that may increase the number of shares available for issuance pursuant to such plans on the first day of each fiscal year. See Note 7 – Stock-Based Compensation Expense in the Notes to the unaudited condensed consolidated financial statements included in this report.

On August 8, 2022, we filed a \$200.0 million shelf registration statement which became effective on August 12, 2022. The shelf registration statement is effective for three years and permits us to sell, from time to time, up to \$200.0 million in aggregate value of our common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide us with flexibility to access additional capital when market conditions are appropriate. At the time of filing of the shelf registration statement, we also filed a prospectus supplement to sell up to an aggregate value of \$50.0 million dollars of our common stock through an “at-the-market” (the “ATM”) offering. The shares are being offered through BofA Securities, Inc. as sales agent. As of March 31, 2023, a total of 1,355,216 shares of common stock, for total net proceeds of \$16.9 million, have been issued and sold through the ATM offering, of which 879,341 shares of common stock, for net proceeds of \$10.9 million, were sold during the quarter ended March 31, 2023.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, and employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of March 31, 2023, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned approximately 40% of our voting common stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control

elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***We are an “emerging growth company” and a “smaller reporting company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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 be more volatile.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering (i.e. December 31, 2026); (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion; (iii) the date on which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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.

***We have incurred increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to***

***maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

As a public company we incur significant legal, accounting and other expenses and these expenses may increase even more after we are no longer an “emerging growth company.” We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm if we are an accelerated filer or large accelerated filer. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

***Provisions in our certificate of incorporation, bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.***

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified Board of Directors so that not all members of our board are elected at one time;
- permit only the Board of Directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan (also known as a poison pill);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our Board of Directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, (“DGCL”), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

***Our bylaws provide that, unless the company consents in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This Delaware forum provision may limit a stockholder's ability to bring a claim in a judicial forum that the stockholder finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find this Delaware forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with litigating such disputes in multiple and/or other jurisdictions, which could seriously harm our business.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended against any person in connection with any offering of the Company's securities, including but not limited to any auditor, underwriter, expert, control person, or other defendant. This federal forum provision may limit a stockholder's ability to bring a Securities Act claim in a judicial forum that the stockholder finds favorable, which may discourage lawsuits against us and our directors, officers and other employees. Any person purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. While the Delaware Supreme Court has held such provisions to be facially valid as a matter of Delaware law and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions. If a court were to find this federal forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business.

This Delaware forum provision does not apply to actions arising under the Securities Exchange Act of 1934 because the federal courts have exclusive jurisdiction over such claims.

***Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and we could be subject to liability with respect to past or future sales, which could adversely affect our results of operations.***

We rely on third party software for state and local tax rates, updated whenever tax rates change. We also rely on state exemptions, when applicable, for medical devices and services, which are determined by management's review of each state's sales tax laws and regulations concerning prescribed medical treatments. However, as laws and regulations change from time to time, these exemptions may or may not continue to apply to our products in the various taxing jurisdictions. Certain jurisdictions in which we do not collect such taxes on sales of our products may later assert that such taxes are applicable, which could result in tax assessments, penalties and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may adversely affect the results of our operations.

***Our Board of Directors are authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.***

Our certificate of incorporation authorizes our Board of Directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

***Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.***

The Tax Act enacted many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings and the deductibility of expenses contained in the Tax Act or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years and could increase our future U.S. tax expense. As an example, beginning in 2022, the Tax Act eliminates the option to immediately deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to

Section 174 of the Code, which may impact our effective tax rate and our cash tax liability in 2022 or in future years. Regulatory or legislative developments may arise from the proposed U.S. tax reform under the Biden Administration, which has proposed several changes to the corporate income tax regime, which, if adopted, could result in increased taxation of our business operations. There is uncertainty regarding what changes, if any, will be enacted and the effect on our business and financial results. The foregoing items, as well as any future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition or results of operations. We will also continue to monitor and assess the impact of international tax reform, including but not limited to the 15% global minimal tax proposed by the Organisation for Economic Co-operation and Development. Finally, the Inflation Reduction Act of 2022 (the “IRA”), will become effective beginning in fiscal year 2024. We do not currently expect that the IRA will have a material impact on our income tax liability.

### **General risk factors**

#### ***Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.***

To succeed, we must recruit, retain, manage and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and need to add executives with operational and commercialization experience as we plan for commercialization of our current and future products and build out a leadership team that can manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the medical device and ophthalmology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other medical device and biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our current and future products will be limited and the potential for successfully growing our business will be harmed.

#### ***Our business and operations would suffer in the event of system failures or security breaches or incidents.***

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, ransomware and other malicious code, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of the commercialization of our RxSight system and our future products. For example, the loss, corruption, or unavailability of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any disruption or security breach or incident resulting in, or believed or perceived to have reported in, the loss or unavailability of or damage to our data or applications, or inappropriate disclosure or other processing of personal, confidential or proprietary information, could cause us to incur liability and cause the commercialization of our RxSight system and the further development of our current and future products to be delayed.

The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to technical vulnerabilities, employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced such material security breach to date, any security breach or security incident could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, stolen, or otherwise processed without authorization. Any such actual or perceived access, disclosure or other security breach or incident, loss, or unauthorized processing of information (whether affecting us or one of



our third-party service providers) could result in legal claims and proceedings, regulatory investigations, and other proceedings and liability under laws that protect the privacy of personal information, significant regulatory penalties or other fines or remedies, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to commercialize our products and conduct clinical trials, which could adversely affect our reputation and delay the commercialization of our RxSight system and clinical development of our current and future products.

The techniques and sophistication used to conduct cyber-attacks and breaches of information technology systems, as well as the sources and targets of these attacks, may take many forms (including phishing, social engineering, denial or degradation of service attacks, ransomware, malware or other malicious code), change frequently and are often not recognized until such attacks are launched or have been in place for a period of time. In addition, our employees, contractors, or third parties with whom we do business or to whom we outsource business operations may attempt to circumvent our security measures in order to misappropriate regulated, protected, or personally identifiable information, and may purposefully or inadvertently cause a breach or incident involving or compromise of such information. Third parties may have the technology or know-how to breach the security of the information collected, stored, or transmitted by us, and our respective security measures, as well as those of our third-party service providers, may not effectively prohibit others from obtaining improper access to this information. Advances in computer and software capabilities and encryption technology, new tools, and other developments may increase the risk of such a breach, incident, or compromise. There is no assurance that any security procedures or controls that we or our third-party providers have implemented will be sufficient to prevent data-security related incidents from occurring.

We may be required to expend significant capital and other resources to protect against, respond to, and recover from any potential, attempted or existing security breaches, incidents, or failures and their consequences. As data security-related threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. We could be forced to expend significant financial and operational resources in responding to a security breach or incident, including investigating and remediating any information security vulnerabilities, defending against and resolving legal and regulatory claims and complying with notification obligations, all of which could divert resources and the attention of our management and key personnel away from our business operations and adversely affect our business, financial condition and results of operations. In addition, our remediation efforts may not be successful, and we could be unable to implement, maintain and upgrade adequate safeguards.

***Economic conditions may adversely affect our business.***

Global economic, political and market conditions, including those related to the COVID-19 pandemic, conflicts in Eastern Europe, and general economic downturns, may negatively impact our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition and results of operations.

***Litigation and other legal proceedings may adversely affect our business.***

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, severe weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our products. Our ability to obtain clinical supplies of our products could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Aliso Viejo, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

***Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.***

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but due to the expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components, limiting our ability to maintain as much inventory of components, sub-assemblies, materials and finished products on hand as would be ideal under normal circumstances. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, the expansion of global lead times, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand, including as a result of our introduction of product enhancements, may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which could have a material adverse effect on our business, financial condition and results of operations. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our business, financial condition and results of operations.

**Risks related to COVID-19**

***Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID-19 pandemic and may continue to be harmed.***

We are subject to risks related to public health crises such as the global pandemic associated with COVID-19. The COVID-19 outbreak has negatively impacted and may continue to negatively impact our operations and revenues and overall financial condition by decreasing the number of our RxSight systems sold.

The expansion of global lead times related to the COVID-19 pandemic, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply. Our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business

with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could have a material adverse effect on our business, financial condition and results of operations.

While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. We expect any new shelter-in-place policies and restrictions on elective surgical procedures worldwide to have a substantial near-term impact on our revenue. During the COVID-19 pandemic, our customers, including doctors, have experienced financial hardship and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and/or additional pricing pressure on our products. The COVID-19 pandemic has also resulted in a significant increase in unemployment in the United States which may continue even after the pandemic. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of RxSight systems sold after the pandemic has ended.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

***(a) Recent Sales of Unregistered Securities***

None

***(b) Use of Proceeds from Registered Securities***

None

***(c) Issuer Purchases of Equity Securities***

None

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The following exhibits are filed as part of, or incorporated by reference into, this report unless otherwise stated.

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>Incorporated by Reference</b>		<b>Filing Date</b>
			<b>File No.</b>	<b>Exhibit</b>	
10.1	<a href="#">Amendment #2 to Sublease, dated as of January 16, 2023, by and between the Registrant and Compass Bible Church for premises located at 5 Columbia, Aliso Viejo, California 92656.</a>	10-K	001-40690	10.18	March 6, 2023
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1†	<a href="#">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.</a>				
32.2†	<a href="#">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.</a>				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover page Interactive Data File (embedded with the Inline XBRL document).				

\* Filed herewith

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this report are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of RxSight Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this report, irrespective of any general incorporation language contained in such filing.

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**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.

RxSight, Inc.

Date: May 9, 2023

By:

\_\_\_\_\_  
/s/ Ron Kurtz, M.D.

Ron Kurtz, M.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 9, 2023

By:

\_\_\_\_\_  
/s/ Shelley Thunen

Shelley Thunen  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**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, Ron Kurtz, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of RxSight, 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 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 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: May 9, 2023

By: \_\_\_\_\_ /s/ Ron Kurtz, M.D.

**Ron Kurtz, M.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**





**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, Shelley Thunen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of RxSight, 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 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 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: May 9, 2023

By: \_\_\_\_\_ /s/ Shelley Thunen  
**Shelley Thunen**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

**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 of RxSight, Inc. (the “Company”) on Form 10-Q for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Ron Kurtz, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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: May 9, 2023

By: \_\_\_\_\_ /s/ Ron Kurtz, M.D.

**Ron Kurtz, M.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

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**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 of RxSight, Inc. (the “Company”) on Form 10-Q for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Shelley Thunen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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: May 9, 2023

By: \_\_\_\_\_ /s/ Shelley Thunen  
**Shelley Thunen**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

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