

**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 June 30, 2021

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 August 31, 2021, the registrant had 27,313,004 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 consolidated financial statements and the condensed notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q 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. The forward-looking statements are contained principally in the section entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements concerning the following:

- our plans to conduct further clinical trials and any expectations related to such trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected 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 retain and recruit 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 sufficient 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;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the time during which we will be an emerging growth company under 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 IOL markets;

- the impact of local, regional, national and international economic conditions and events; and
- the impact of the COVID-19 pandemic, including currently known and unknown coronavirus variants, as applied to our business.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “seeks,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” or similar expressions and the negatives of those terms.

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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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.

Our discussion and analysis of our financial condition and results of operations is based upon our Unaudited Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or 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; valuation of the Company’s common stock, warrants and other equity awards; estimated probability and timing of redemption of equity instruments, 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 in the Company’s final prospectus for its Initial Public Offering (the “IPO”), filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the SEC on July 29, 2021 (the “Prospectus”) and there have been no material changes during the six months ended June 30, 2021.

This Quarterly Report on Form 10-Q 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.

This Quarterly Report on Form 10-Q contains references to trademarks and service marks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q 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 number of shares and per share amounts)

	June 30, 2021 (Unaudited)	December 31, 2020 ⁽¹⁾
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,731	\$ 13,994
Short-term investments	19,998	54,981
Accounts receivable	3,936	2,865
Inventories	8,543	8,288
Prepaid and other current assets	1,338	1,372
Total current assets	75,546	81,500
Property and equipment, net	12,686	13,287
Operating leases right-of-use assets	4,749	5,319
Restricted cash	561	461
Other assets	1,344	110
Total assets	\$ 94,886	\$ 100,677
Liabilities, redeemable common stock, stock options, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 2,342	\$ 1,134
Accrued expenses and other current liabilities	4,781	4,174
Warrant liability	2,614	5,018
Lease liabilities	1,365	1,274
Total current liabilities	11,102	11,600
Long-term warrant liability	—	3,828
Long-term lease liabilities	4,374	5,079
Term loan, net	39,506	24,399
Total liabilities	54,982	44,906
Commitments and contingencies (Note 12)		
Redeemable common stock:		
Common stock, \$0.001 par value, 24,545,966 shares authorized, 3,813,450 shares issued and outstanding as of December 31, 2020	—	80,780
Notes receivable for common stock issued	—	(803)
Redeemable stock options	—	53,085
Convertible preferred stock:		
Preferred stock, \$0.001 par value, 16,572,792 shares authorized, 14,376,272 shares issued and outstanding as of June 30, 2021 and December 31, 2020 (redeemable), respectively	353,300	353,300
Stockholders' deficit:		
Common stock, \$0.001 par value, 24,545,966 shares authorized, 4,124,211 shares issued and outstanding as of June 30, 2021	4	—
Additional paid-in capital	137,838	—
Notes receivable for common stock issued	(365)	—
Series G common stock, \$0.001 par value, 1 share authorized and outstanding as of June 30, 2021 and December 31, 2020	—	—
Series W common stock, \$0.001 par value, 1 share authorized and no shares outstanding as of June 30, 2021 and December 31, 2020	—	—
Accumulated other comprehensive loss	(3)	(3)
Accumulated deficit	(450,870)	(430,588)
Total stockholders' deficit	(313,396)	(430,591)
Total liabilities, redeemable common stock, stock options, convertible preferred stock and stockholders' deficit	\$ 94,886	\$ 100,677

⁽¹⁾ The balance sheet at December 31, 2020 has been derived from the audited consolidated financial statements included in RxSight, Inc.'s final prospectus for its public offering filed on July 29, 2021.

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Sales	\$ 4,897	\$ 2,706	\$ 8,381	\$ 5,594
Cost of sales	5,709	3,180	8,074	5,989
Gross profit (loss)	(812)	(474)	307	(395)
Operating expenses:				
Selling, general and administrative	6,502	3,249	12,113	6,948
Research and development	6,563	5,084	13,206	10,861
Total operating expenses	13,065	8,333	25,319	17,809
Loss from operations	(13,877)	(8,807)	(25,012)	(18,204)
Other income (expense), net:				
Change in fair value of warrants	1,214	(4,178)	1,214	(11,585)
Expiration of warrant	—	—	5,018	—
Interest expense	(826)	(4)	(1,524)	(9)
Interest and other income	15	147	32	459
Loss before income taxes	(13,474)	(12,842)	(20,272)	(29,339)
Income tax expense	3	40	10	45
Net loss	(13,477)	(12,882)	(20,282)	(29,384)
Accretion to redemption value of redeemable preferred stock and redeemable stock options	—	(4,097)	—	(8,343)
Net loss attributable to common stockholders	(13,477)	(16,979)	(20,282)	(37,727)
Other comprehensive loss				
Unrealized gain (loss) on short-term investments	(4)	(112)	3	(35)
Foreign currency translation gain (loss)	1	3	(3)	2
Total other comprehensive loss	(3)	(109)	—	(33)
Comprehensive loss	\$ (13,480)	\$ (12,991)	\$ (20,282)	\$ (29,417)
Net loss per share:				
Attributable to redeemable common stock, basic and diluted	\$ —	\$ (4.66)	\$ —	\$ (10.46)
Attributable to Series G common stock, basic and diluted	\$ (0.32)	\$ (0.58)	\$ (0.48)	\$ (1.24)
Attributable to common stock, basic	\$ (3.28)	\$ —	\$ (5.00)	\$ —
Attributable to common stock, diluted	\$ (3.53)	\$ —	\$ (5.23)	\$ —
Weighted-average shares used in computing net loss per share:				
Attributable to redeemable common stock, basic and diluted	—	3,645,699	—	3,608,190
Attributable to Series G common stock, basic and diluted	1	1	1	1
Attributable to common stock, basic	4,106,403	—	4,052,920	—
Attributable to common stock, diluted	4,166,439	—	4,113,249	—

See accompanying notes to unaudited condensed consolidated financial statements.

RXSIGHT, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK, STOCK OPTIONS, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
DEFICIT (UNAUDITED)
(In thousands, except number of shares)

Three and Six Months Ended June 30, 2020

	Redeemable common stock		Notes receivable for redeemable common stock		Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)		Accumulated deficit	Total stockholders' deficit
	Shares	Amount	common stock issued	Redeemable stock options	Shares	Amount	Shares	Amount		income (loss)	deficit		
Balance at December 31, 2019	3,563,884	\$ 56,422	\$ (855)	\$ 59,631	14,374,455	\$ 327,581	1	\$ -	\$ -	\$ 46	\$ (419,855)	\$ (419,809)	
Exercise of stock options	11,351	303	-	(257)	-	-	-	-	-	-	-	-	
Stock-based compensation expense	-	-	-	-	-	-	-	-	623	-	-	623	
Accretion to redemption value of redeemable stock options	-	-	-	(2,924)	-	-	-	-	-	-	2,924	2,924	
Accretion to redemption value of redeemable stock	-	3,493	-	-	-	7,170	-	-	(623)	-	(10,040)	(10,663)	
Unrealized gain on short-term investments and cash equivalents, net of tax	-	-	-	-	-	-	-	-	-	77	-	77	
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	(1)	-	(1)	
Change in notes receivable for common stock issued	-	-	84	-	-	-	-	-	-	-	-	-	
Net loss	-	-	-	-	-	-	-	-	-	-	(16,502)	(16,502)	
Balance at March 31, 2020	3,575,235	\$ 60,218	\$ (771)	\$ 56,450	14,374,455	\$ 334,751	1	\$ -	\$ -	\$ 122	\$ (443,473)	\$ (443,351)	
Exercise of stock options	211,590	5,128	-	(4,293)	-	-	-	-	-	-	-	-	
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,083	-	-	1,083	
Accretion to redemption value of redeemable stock options	-	-	-	(2,259)	-	-	-	-	-	-	2,259	2,259	
Accretion to redemption value of redeemable stock	-	4,975	-	-	-	6,355	-	-	(1,083)	-	(10,247)	(11,330)	
Unrealized gain on short-term investments and cash equivalents, net of tax	-	-	-	-	-	-	-	-	-	(112)	-	(112)	
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	3	-	3	
Change in notes receivable for common stock issued	-	-	(6)	-	-	-	-	-	-	-	-	-	
Net loss	-	-	-	-	-	-	-	-	-	-	(12,882)	(12,882)	
Balance at June 30, 2020	3,786,825	\$ 70,321	\$ (777)	\$ 49,899	14,374,455	\$ 341,106	1	\$ -	\$ -	\$ 13	\$ (464,343)	\$ (464,330)	

See accompanying notes to unaudited condensed consolidated financial statements

RXSIGHT, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK, STOCK OPTIONS, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
DEFICIT (UNAUDITED)
(In thousands, except number of shares)

Three and Six Months Ended June 30, 2021

	Redeemable common stock		Notes receivable for redeemable common stock		Convertible preferred stock		Common stock			Notes receivable for common stock		Accumulated other comprehensive income (loss)		Total stockholders' deficit	
	Shares	Amount	issued	Redeemable stock options	Shares	Amount	Shares	Amount	Additional paid-in capital	issued	comprehensive income (loss)	Accumulated deficit	Total stockholders' deficit		
														Shares	Amount
Balance at December 31, 2020	3,813,450	\$ 80,780	\$ (803)	\$ 53,085	14,376,272	\$ 353,300	1	\$ -	\$ -	\$ -	\$ (3)	\$ (430,588)	\$ (430,591)		
Exercise of stock options	280,545	6,922	-	(5,715)	-	-	-	-	-	-	-	-	-		
Stock-based compensation expense	-	-	-	-	-	-	-	1,239	-	-	-	-	1,239		
Unrealized gain on short-term investments and cash equivalents, net of tax	-	-	-	-	-	-	-	-	-	7	-	-	7		
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	(4)	-	-	(4)		
Change in notes receivable for common stock issued	-	-	(14)	-	-	-	-	-	-	-	-	-	-		
Reclassification of 4,093,995 shares of redeemable common stock to 4,093,995 shares of common stock	(4,093,995)	(87,702)	817	-	-	-	4,093,995	4	87,698	(817)	-	-	86,885		
Reclassification of redeemable common stock options to common stock options	-	-	-	(47,370)	-	-	-	-	47,370	-	-	-	47,370		
Net loss	-	-	-	-	-	-	-	-	-	-	-	(6,805)	(6,805)		
Balance at March 31, 2021	-	\$ -	\$ -	\$ -	14,376,272	\$ 353,300	4,093,996	\$ 4	\$ 136,307	\$ (817)	\$ -	\$ (437,393)	\$ (301,899)		
Exercise of stock options	-	-	-	-	-	-	30,215	-	125	-	-	-	125		
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,406	-	-	-	1,406		
Unrealized gain on short-term investments and cash equivalents, net of tax	-	-	-	-	-	-	-	-	-	(4)	-	-	(4)		
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	1	-	-	1		
Change in notes receivable for common stock issued	-	-	-	-	-	-	-	-	452	-	-	-	452		
Net loss	-	-	-	-	-	-	-	-	-	-	-	(13,477)	(13,477)		
Balance at June 30, 2021	-	\$ -	\$ -	\$ -	14,376,272	\$ 353,300	4,124,211	\$ 4	\$ 137,838	\$ (365)	\$ (3)	\$ (450,870)	\$ (313,396)		

See accompanying notes to unaudited condensed consolidated financial statements

RXSIGHT, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Six Months Ended June 30,	
	2021	2020
Operating Activities:		
Net loss	\$ (20,282)	\$ (29,384)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,944	1,832
Amortization of right-of-use lease assets	15	106
Amortization of debt issuance costs and premium	229	—
Change in fair value of warrants	(1,214)	11,585
Gain on expiration of warrant	(5,018)	—
Amortization of discount on short-term investments	(15)	(401)
Stock-based compensation	2,645	1,706
Provision for excess and obsolete inventory	1,749	47
Change in operating assets and liabilities:		
Accounts receivable	(1,071)	(175)
Inventories	(2,004)	(1,912)
Prepaid and other assets	(1,250)	443
Accounts payable	1,195	(197)
Accrued expenses and other liabilities	846	(3,678)
Net cash used in operating activities	(22,231)	(20,028)
Investing Activities:		
Purchases of property and equipment	(1,321)	(1,398)
Maturity of short-term investments	40,000	73,000
Purchase of short-term investments	(4,999)	(47,900)
Net cash provided by investing activities	33,680	23,702
Financing Activities:		
Proceeds from term loan	15,000	—
Payments of debt issuance costs	(122)	—
Principal payments on finance lease liabilities	(16)	(103)
Payments of deferred offering costs	(242)	—
Change in notes receivable for redeemable common stock issued	439	78
Proceeds from exercise of stock options	1,332	882
Net cash provided by financing activities	16,391	857
Effect of foreign exchange rate on cash, cash equivalents and restricted cash		
Net increase in cash, cash equivalents and restricted cash	27,837	4,533
Cash, cash equivalents and restricted cash - beginning of period	14,455	8,830
Cash, cash equivalents and restricted cash - end of period	\$ 42,292	\$ 13,363
Supplemental disclosure of cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 598	\$ 374
Cash paid for income taxes	\$ 14	\$ 46
Cash paid for interest on financing leases	\$ 3	\$ 9
Cash paid for interest on term loan	\$ 1,291	—
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	\$ —	\$ 1,893
Lease obligations recorded for right-of-use assets:		
Operating lease	\$ —	\$ 1,893
Acquisition of property and equipment included in accounts payable and accrued expenses and other current liabilities	\$ 76	\$ 142
Accretion to redemption value of redeemable stock and stock options	\$ —	\$ 26,543
Deferred offering costs included in accrued expenses	\$ (1,233)	\$ —
Payment-in-kind interest income added to principal of notes receivable	\$ 26	\$ 27
Reclassification of 4,093,995 shares of redeemable common stock to 4,093,995 shares of common stock	\$ 87,702	\$ —
Reclassification of redeemable common stock options to common stock options	\$ 47,370	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Organization and Basis of Presentation

RxSight®, Inc. (the “Company”) is a Delaware corporation headquartered in Aliso Viejo, California with two wholly owned subsidiaries. One subsidiary is located in Amsterdam, Netherlands, with registered branches in the United Kingdom and Ireland (closed in 2020). The Netherlands entity also has a wholly owned subsidiary in Germany. A second subsidiary, closed in 2020, was located in Tijuana, Mexico. 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”® or “RxLAL”®) 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”) for sale in the U.S. and have regulatory approval in the U.S and Europe. The Company began marketing its products in the U.S. during the second quarter of 2019 and in Europe during the third quarter of 2019. The RxLAL is a premium intraocular lens (“IOL”) which is partially reimbursable under Medicare. The Company competes with other IOLs in the premium market in the U.S. and Europe.

The accompanying consolidated financial statements include the accounts of RxSight, Inc. and its wholly owned subsidiaries, RxSight, B.V., located in the Netherlands, RxSight GmbH, located in Germany, and RxSight S de R.L. de C.V., located in Mexico. All significant inter-company balances and transactions have been eliminated in consolidation.

Basis of Presentation

The Company’s 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 10 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 consolidated balance sheet as of December 31, 2020 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for complete financial statements. 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. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company’s final prospectus for its IPO, filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the SEC on July 29, 2021 (the “Prospectus”).

Initial Public Offering and Reverse Stock Split

On July 22, 2021, the Company’s Board of Directors approved an amendment to the Company’s Articles of Incorporation to effect a reverse split of shares of the Company’s common stock, excluding Series G and Series W common stock, and convertible preferred stock on a 1-for-10.33 basis (the “Reverse Stock Split”). The par values of the common stock and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split was effected on July 23, 2021. Accordingly, all common stock, excluding Series G and Series W common stock, options to purchase common stock, convertible preferred stock, share data, per share data and related information contained in the accompanying condensed consolidated financial statements and notes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The Reverse Stock Split resulted in an adjustment to the convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

On July 29, 2021, the Company completed its initial public offering (“IPO”) through an underwritten sale of 7,350,000 shares of its common stock at a price of \$16.00 per share. The aggregate net proceeds from the offering, inclusive of an additional 898,549 common shares sold upon the partial exercise of the underwriters’ purchase

option, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$120.0 million. On July 29, 2021, the Company restated its articles of incorporation and bylaws which provide for, among other things, the Company's authorized capital stock to consist of 900,000,000 shares of common stock, par value \$0.001 per share, and 100,000,000 shares of convertible preferred stock, par value \$0.001 per share. The restated articles define the voting rights, dividends, liquidation, rights and preferences of each class of stock.

Immediately prior to the completion of the offering, 14,376,272 outstanding shares of the Company's convertible preferred stock were converted into an aggregate of 14,850,993 shares of common stock and 225,945 warrants to purchase Series H convertible preferred stock were exercised and converted into 225,945 shares of common stock.

Liquidity and Financial Position

As of June 30, 2021, the Company had cash, cash equivalents and short-term investments of \$61.7 million.

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 June 30, 2021 and 2020, the Company incurred losses from operations of \$13.9 million and \$8.8 million, respectively. For the six months ended June 30, 2021 and 2020, the Company incurred losses from operations of \$25.0 million and \$18.2 million, respectively. Due to the Company's continuing research and development activities and expansion of its sales and marketing efforts, 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 financial statements have been prepared assuming the Company will continue as a going concern. The Company believes that existing capital resources, including the net proceeds from the IPO in July 2021, 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.

COVID-19

The Company has been actively monitoring the novel coronavirus, or COVID-19, situation and its impact. In response to the pandemic, numerous state and local jurisdictions imposed "shelter-in-place" orders, quarantines and other restrictions. Starting in March 2020 in the United States, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled. Similarly, in March 2020, the governor of California, where the Company's headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions resulted in reduced operations at the Company's headquarters, slowdowns and delays, travel restrictions and cancellation of events. These orders and restrictions significantly decreased the number of procedures performed using the Company's products during March and April 2020.

In response to the impact of COVID-19, the Company implemented a variety of measures to help manage through the impact and position it to resume operations quickly and efficiently once these restrictions were lifted. These measures included: remote work as needed, suspension of non-essential travel, restrictions on in-person work-related meetings, the wearing of personal protective equipment, social distancing, increased facility cleaning and air purification in all of the Company's buildings and daily health monitoring of all Company employees to prevent or contain COVID-19 exposure. In addition, the Company took steps to preserve liquidity, reduce expenses and monitor operations to mitigate the impact on its current and future financial condition. The impact of COVID-19 continues to change and cannot be predicted. As a result, the Company expects the pandemic could continue to negatively impact its business, financial condition and results of operations.

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. In particular, management makes estimates with respect to revenue recognition; valuation of the Company's common stock, warrants and other equity awards; estimated probability and timing of redemption of equity instruments, the realization of income tax assets and estimates of tax liabilities, and excess, obsolete and slow-moving inventory. 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 six months ended June 30, 2021 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 the Prospectus.

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' deficit 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 income. 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 realized 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 we 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 recorded \$1,000 of unrealized gains and \$2,000 of unrealized losses related to short-term investments as of June 30, 2021 and December 31, 2020, respectively. To date, the Company has not identified any unrealized losses other than credit losses for its short-term investments 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.

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 short-term

money market funds and U.S. treasury bills. Additionally, 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.

Accounts Receivable

As of June 30, 2021, the Company had one customer who individually accounted for approximately 10% of accounts receivable, and as of December 31, 2020, the Company had one customer who individually accounted for approximately 35% of accounts receivable. After evaluation of the collectability of accounts receivable, the Company did not record an allowance for doubtful accounts as of June 30, 2021 and December 31, 2020.

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 lenses, injectors, and LDDs. Finished goods are comprised of lenses, injectors, 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 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.

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. The Company's financial instruments consist principally of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, operating lease liabilities, warrant liabilities and a term loan. 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.

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 term loan at June 30, 2021 and December 31, 2020 approximated their carrying values, based on the borrowing rates that were available for loans with similar terms as of that date.

Warrants to Purchase Stock

The Company recognizes the freestanding warrants to purchase shares of convertible preferred stock as liabilities at fair value as these warrant instruments are embedded in contracts that may be cash settled. The convertible preferred stock warrants were issued for no cash consideration as detachable freestanding instruments but can be converted to convertible preferred stock at the holder's option based on the exercise price of the warrant. However, the deemed liquidation provisions of the convertible preferred stock are considered contingent redemption provisions that are not solely within the control of the Company. Therefore, the convertible preferred stock is classified in temporary equity on the accompanying condensed consolidated balance sheets, and the warrants to purchase the convertible preferred stock are classified as liabilities. The Company recognized a freestanding warrant to purchase a share of Series W common stock as a liability at fair value because this instrument was not indexed to the Company's own stock as the settlement calculation incorporated variables other than those used to determine the fair value of a fixed-for-fixed forward or option on equity shares. The common stock warrant was issued for cash consideration as a freestanding instrument and could be converted to one share of common stock, Series W, at the holder's option based on the exercise price of the warrant and prior to the expiration date of March 31, 2021.

The warrants were recorded on the accompanying condensed consolidated balance sheets at their fair value on the date of issuance and were subject to re-measurement to fair value at each balance sheet date. Changes in fair value were recognized as a component of other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss. Upon issuance of the Series W common stock warrant, the Company engaged valuation specialists to assist with determining its fair value using a Monte Carlo simulation approach. In addition, the Company engaged the valuation specialists to derive an estimated fair value of the preferred stock warrants using a probability weighted expected return model/option pricing model ("PWERM/OPM") hybrid valuation model. Pursuant to the terms of the preferred stock warrants, upon the conversion of the class of preferred stock underlying the warrant, the warrants automatically become exercisable for shares of the Company's common stock based upon the conversion ratio of the underlying class of preferred stock. The exercise of the common stock warrant or consummation of a qualified initial public offering would result in the automatic conversion of all classes of the Company's preferred stock into common stock. Upon such conversion of the underlying classes of preferred stock, the warrants would be classified as a component of equity and will no longer be subject to remeasurement. Accordingly, the Company continued to adjust the warrant liabilities for changes in fair value through the date of the conversion of the underlying convertible preferred stock into common stock which occurred upon the completion of the Company's IPO in July 2021.

Deferred Offering Costs

The Company capitalized deferred offering costs consisting of all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's IPO. As of June 30, 2021, the total deferred offering costs of \$1.2 million were included in other assets on the accompanying condensed consolidated balance sheet. Upon the completion of the IPO in July 2021, the total deferred offering costs of \$1.2 million were reclassified to additional paid-in capital.

Net Loss per Share

The Company computes basic net (loss) per share for common stock using the two-class method required for companies with participating securities based upon the weighted-average number of common shares outstanding during the period. Diluted net (loss) per share assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's stock options, warrants and the shares issuable upon the conversion of the

preferred stock. For stock options and preferred stock, the calculation of diluted (loss) per share requires an adjustment for the additional share of undistributed earnings and accretion to redemption value for the period that the common stockholders are entitled to if exercise is assumed. For warrants that are recorded as a liability in the accompanying condensed consolidated balance sheets, the calculation of diluted (loss) per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to the loss per share for the period, an adjustment is made to net (loss) used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

The following tables show the computation of basic and diluted net (loss) per share for the three and six months ended June 30, 2021 and 2020 (common stock in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Common Stock				
Numerator:				
Net (loss) available to stockholders, basic	\$ (13,477)	\$ (16,979)	\$ (20,282)	\$ (37,727)
Effect of dilutive securities:				
Preferred stock warrants	1,214	—	1,214	—
Net (loss) available to stockholders, diluted	\$ (14,691)	\$ (16,979)	\$ (21,496)	\$ (37,727)
Denominator:				
Weighted-average shares outstanding, basic	4,106,403	3,645,699	4,052,920	3,608,190
Effect of dilutive securities:				
Preferred stock warrants	60,036	—	60,329	—
Weighted-average shares, diluted	4,166,439	3,645,699	4,113,249	3,608,190
Basic net (loss) per share	\$ (3.28)	\$ (4.66)	\$ (5.00)	\$ (10.46)
Diluted net (loss) per share	\$ (3.53)	\$ (4.66)	\$ (5.23)	\$ (10.46)
Series G Common Stock				
Numerator:				
Net (loss) available to stockholder, basic	\$ (0.32)	\$ (0.58)	\$ (0.48)	\$ (1.24)
Effect of dilutive securities:				
Preferred stock warrants	—	—	—	—
Net (loss) available to stockholder, diluted	\$ (0.32)	\$ (0.58)	\$ (0.48)	\$ (1.24)
Denominator:				
Weighted-average shares outstanding, basic and diluted	1	1	1	1
Basic net (loss) per share	\$ (0.32)	\$ (0.58)	\$ (0.48)	\$ (1.24)
Diluted net (loss) per share	\$ (0.32)	\$ (0.58)	\$ (0.48)	\$ (1.24)

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” and “if-converted method” was anti-dilutive for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Redeemable convertible preferred stock	-	14,849,188	-	14,849,188
Convertible preferred stock	14,850,993	-	14,850,993	-
Preferred stock warrants	-	227,762	-	227,762
Redeemable stock options	4,610,950	3,272,454	4,368,665	3,338,396

Revenue Recognition

The Company’s revenue is generated from the sale of light adjustable intraocular lenses (“RxLAL”) used in cataract surgery along with a specifically designed machine for delivering light to the eye, the Light Delivery Device (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 revenue 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: (1) LDD capital asset and related components, (2) training and (3) 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 30 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.

RxLALs are held at customer sites on consignment. The single performance obligation is satisfied, and revenue is recognized for RxLALs upon customer notification that the RxLALs have been implanted in a patient. For the three and six months ended June 30, 2021 and 2020, credits related to returns and rebates on list prices were not significant.

The Company 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.

For the three and six months ended June 30, 2021 and 2020, revenue from contracts with customers consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
LDD (including training)	\$ 2,965	\$ 2,050	\$ 4,802	\$ 4,209
LAL	1,792	619	3,321	1,290
Service warranty, service contracts, and accessories	140	37	258	95
	<u>\$ 4,897</u>	<u>\$ 2,706</u>	<u>\$ 8,381</u>	<u>\$ 5,594</u>

As of June 30, 2021 and December 31, 2020, the Company recognized deferred revenue on its condensed consolidated balance sheets of \$380,000 and \$345,000, 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 deferred revenue activity for the six months ended June 30, 2021 and 2020, respectively (in thousands):

	2021	2020
Balance at beginning of period	\$ (345)	\$ (41)
Consideration earned during the period	(272)	(194)
Recognized during the period	237	74
Balance at end of period	<u>\$ (380)</u>	<u>\$ (161)</u>

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, Intangibles – Goodwill and Other – Internal Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, which changes the accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. The update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The implementation costs should be presented as a prepaid expense in the balance sheet and expensed over the term of the hosting arrangement. The Company adopted the standard on January 1, 2021, and adoption did not have a material impact on its condensed consolidated financial statements.

In June 2020, the FASB issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which is intended to simplify the accounting for convertible instruments. This new guidance eliminates certain models that require separate accounting for embedded conversion features and eliminates certain of the conditions for equity classification for contracts in an entity's own equity. Accordingly, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance can be adopted through either a modified retrospective method of transition or a fully retrospective method of transition. ASU 2020-06 is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020, including interim periods

within those fiscal years. The Company is in the process of determining the impact of the adoption of the standard on its condensed consolidated financial statements.

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):

	As of June 30, 2021		
	Amortized Cost	Unrealized Gain, Net	Estimated Fair Value
Government securities	\$ 19,997	\$ 1	\$ 19,998

	As of December 31, 2020		
	Amortized Cost	Unrealized Loss, Net	Estimated Fair Value
Government securities	\$ 54,983	\$ (2)	\$ 54,981

All available-for-sale securities held as of June 30, 2021 and December 31, 2020 had a maturity of less than one year.

Note 4 – Inventories

Inventories consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Finished goods	\$ 4,288	\$ 5,092
Raw materials	3,380	1,827
Work-in-process	2,716	1,685
	10,384	8,604
Less: reserve for excess and obsolete inventory	(1,841)	(316)
	<u>\$ 8,543</u>	<u>\$ 8,288</u>

At June 30, 2021 and December 31, 2020, finished goods included \$3.0 million and \$2.7 million of inventory held on consignment at customer sites, respectively.

Note 5 – Fair Value Measurements

The table and disclosures 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.

	As of June 30, 2021			
	Level I	Level II	Level III	Total
Assets:				
Money market securities	\$ 40,693	\$ —	\$ —	\$ 40,693
Government securities	—	19,998	—	19,998
Total assets at fair value	<u>\$ 40,693</u>	<u>\$ 19,998</u>	<u>\$ —</u>	<u>\$ 60,691</u>
Liability:				
Convertible preferred stock warrant liability	\$ —	\$ —	\$ (2,614)	\$ (2,614)
Total liabilities at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (2,614)</u>	<u>\$ (2,614)</u>
	As of December 31, 2020			
	Level I	Level II	Level III	Total
Assets:				
Money market securities	\$ 11,822	\$ —	\$ —	\$ 11,822
Government securities	—	54,981	—	54,981
Total assets at fair value	<u>\$ 11,822</u>	<u>\$ 54,981</u>	<u>\$ —</u>	<u>\$ 66,803</u>
Liabilities:				
Common stock warrant liability	\$ —	\$ —	\$ (5,018)	\$ (5,018)
Redeemable convertible preferred stock warrant liability	—	—	(3,828)	(3,828)
Total liabilities at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (8,846)</u>	<u>\$ (8,846)</u>

The Series W warrant fair value was determined by management, with input and assistance from a third-party valuation specialist, upon issuance and was revalued as of each reporting date until expiration. The valuation specialist utilized a Monte Carlo Simulation ("MCS") under the income method utilizing assumptions and financial data prepared by the Company. This valuation approach uses a discounted cash flow ("DCF") method to calculate the starting equity value of the Company based upon future cash flow generation. The starting equity value of the Company was determined utilizing significant unobservable inputs, including (1) forecasted financial projections for the next five years developed by management, (2) a terminal value assigned using an exit multiple method, and (3) a discount rate based on the weighted average cost of capital. Then a simulated equity value of the Company as of the expected exercise date was determined using the MCS method. The MCS inputs included: (1) the assumed amount of time until the exercise of the warrant, (2) the risk-free interest rate over the period until the assumed warrant exercise, (3) the assumed volatility in the value of the equity of the company, and (4) the starting equity value of the Company as determined from the discounted cash flow method. In order to determine the overall value of the warrant, the valuation specialists also simulated the payments for sales-based, operating and regulatory milestones based upon similar inputs to determine the expected overall purchase price of the Company. The net difference between the expected purchase price and the average simulated equity value determines the "option payoff". Finally, management assigned a probability that the warrant will be exercised, which was applied to the present value of the "option payoff" to arrive at the recorded value reflected in the accompanying condensed consolidated financial statements. The Series W warrant expired unexercised on March 31, 2021 and the remaining value was recorded in the Statement of Operations and Comprehensive Loss in the three and six months ended June 30, 2021.

The fair value of the preferred stock warrants was determined by management, with input and assistance from a third-party valuation specialist using a probability weighted expected return model/option pricing model ("PWERM/OPM") hybrid valuation model. This method essentially utilizes a combination of market and income method approaches for each part of the calculation of enterprise value using assumptions and financial data prepared by the Company and combines them in a probabilistic manner. The valuation considered several future scenarios for the Company, each of which assumed a shareholder exit either through initial public offering ("IPO"), sale ("M&A") or dissolution. Based upon the current IPO market, M&A values for private companies and the historical likelihood of dissolution or no exit, the Company concluded that the probabilities and time frames were reasonable. Implicit in the timing used in the application of the PWERM/OPM Hybrid Method is also the possibility of no exit. The option pricing model's significant unobservable inputs included: (1) the assumed time until a liquidity event, (2) the risk-free interest rate over the period until the assumed liquidity event, (3) the assumed volatility in the value of the equity of the company (which corresponds to the model's underlying asset volatility), (4) the enterprise value and

preferred investment amount and (5) the key price points in the Company's capital structure in terms of exit levels on the assumed liquidation date. A significant increase (decrease) in any of these inputs in isolation, particularly the estimated price of the Company's preferred stock, would have resulted in a significantly higher (lower) fair value measurement.

The following table sets forth changes in the estimated fair values for the Company's warrant liabilities measured using significant unobservable inputs (in thousands):

	Six Months Ended	Year Ended
	June 30,	December 31,
	2021	2020
Beginning of period	\$ 8,846	\$ 71,881
Exercise of preferred stock warrants	—	(24)
Expiration of common stock warrant	(5,018)	—
Change in fair value of common stock warrant	—	(64,628)
Change in fair value of preferred stock warrants	(1,214)	1,617
End of period	<u>\$ 2,614</u>	<u>\$ 8,846</u>

Note 6 – Term Loan

In October 2020, the Company entered into a loan facility (“Term Loan”) with an initial draw of \$25 million. Proceeds were used to help fund the Company's ongoing operations. As part of the Term Loan, the lender committed to providing further loans of up to \$35 million to the Company at its election (or for one specific draw, upon 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 million from the facility for the purpose of funding ongoing operations. In June 2021, the Company drew an additional \$10 million from the facility for the purpose of funding ongoing operations.

As of June 30, 2021 and December 31, 2020, the Company was in compliance with all covenants.

For the three and six months ended June 30, 2021, cash interest paid for all borrowings under the Term Loan was 9.25%. The effective interest rate during the three and six months ended June 30, 2021 was 10.90% and 11.09%, respectively.

As of June 30, 2021 future principal payments due under the Term Loan were as follows (in thousands):

Year Ended December 31,	
2021 (remainder)	\$ —
2022	—
2023	1,739
2024	20,870
2025	17,391
Total	<u>40,000</u>
Less: unamortized issuance costs and exit fee	(494)
Term loan, net	<u>\$ 39,506</u>

Note 7 – Common Stock Warrant Liability

Warrant Agreement and Share Purchase Agreement

On October 12, 2017, the Company issued to a “Strategic Partner” a warrant to purchase Series W common stock (the “Warrant Agreement”) for a non-refundable payment of \$60 million. This Series W common stock warrant (the “Series W Warrant”) had an initial expiration date of December 31, 2018 unless extended as provided for in the Warrant Agreement. On December 27, 2018, the Strategic Partner chose to extend the expiration date of the Series W Warrant, by making an additional non-refundable payment of \$40 million, until the sooner of the achievement of performance milestones (as defined in the Warrant Agreement) or November 22, 2021. On March

18, 2020, the Company and the Strategic Partner signed an amendment to the Warrant Agreement that removed the milestone triggers for early exercise and changed the expiration date to March 31, 2021.

Concurrent with the Warrant Agreement, the Strategic Partner and the Company entered into a Share Purchase Agreement (the “Purchase Agreement”). Under the Purchase Agreement, the Strategic Partner purchased one share of the Company’s non-voting \$0.001 par value per share Series G common stock for \$0.01. Upon exercise of the Series W Warrant, the Strategic Partner would have received one share of voting, \$0.001 par value, Series W common stock. Per the Warrant Agreement, the exercise price of the Series W Warrant was \$630.0 million plus adjustments for the Company’s cash, working capital, indebtedness, and transaction expenses, subject to an escrow holdback of \$92.0 million and a shareholder representative holdback of \$0.5M. The Warrant Agreement also provided for potential aggregate milestone payments of up to \$827 million for various sales-based and operating milestones and \$185 million for certain regulatory milestones, either at the time of the Series W Warrant’s exercise or at dates subsequent, as defined in the Warrant Agreement. Upon notice of exercise of the Series W Warrant by the Strategic Partner and receipt of the required funds, a Special Redemption, as defined in the Company’s Articles of Incorporation, would have triggered automatic redemption of all the Company’s outstanding capital instruments, except for the Series G common stock and Series W common stock, and the Strategic Partner would have acquired the Company.

Special Redemption

On October 25, 2017, the Company adopted the 12th Amended and Restated Articles of Incorporation (the “Amendment”). Under Article IV of the Amendment, if the Strategic Partner had exercised the Series W Warrant, an automatic redemption, conversion, termination and cancellation of all then outstanding shares of the Company’s capital stock, options and warrants would have occurred without any further action required. Immediately prior to the automatic redemption, all outstanding preferred shares would have converted to common shares, unvested stock options would have accelerated and became fully vested and all stock options would have terminated along with any preferred stock warrants outstanding. Shareholders, option holders and warrant holders would have had the right to receive the initial per share price less the strike price as defined in the Warrant Agreement. The Strategic Partner would have advanced (through an exchange agent) the funds to the Company, which would then have disbursed the funds to all shareholders, option holders and warrant holders. If the Series W Warrant was terminated or expired unexercised, Article IV of the Amendment would terminate and would be of no further force and effect.

In December 2020, management determined that exercise of the Series W Warrant was no longer probable, at which point further accretion to redemption value of common stock, preferred stock and stock options ceased.

On March 31, 2021, the Series W Warrant terminated as the Strategic Partner did not provide notice of exercise. A gain of \$5.0 million was recorded on the expiration of the Series W Warrant in the accompanying condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2021. Upon termination, amounts recorded in temporary equity for common stock and stock options were reclassified to common stock and additional paid-in capital within permanent equity as these instruments were no longer redeemable.

Note 8 – Convertible Preferred Stock and Stockholders’ Deficit

Convertible Preferred Stock

The Amendment authorized eight classes of preferred stock, Series A through F, the “Prior Preferred Stock” and Series G and H, the “Senior Preferred Stock”. All of the Company’s convertible preferred stock has been classified as temporary equity on the accompanying condensed consolidated balance sheets, as all such preferred stock is redeemable either at the option of the holder or upon an event outside the control of the Company (i.e., a change in control). The redeemable convertible preferred stock was previously redeemable per the Special Redemption (see Note 7) or upon certain change in control events (including liquidation, sale or transfer of control of the Company); however, all change in control events are outside of the Company’s control. In the event of the Special Redemption, the holders would have received redemption proceeds as defined in the Warrant Agreement. In the event of liquidation, holders of the convertible preferred stock may have the right to receive its liquidation preference under the terms of the Company’s Amendment.

As a result of management's determination that the Special Redemption was probable, but not certain, the Company began accreting to the expected redemption value of the redeemable convertible preferred stock in October 2017. In December 2020, management determined that the Special Redemption was no longer probable, at which point accretion to redemption value ceased. As of March 31, 2021, the Series W Warrant expired unexercised, and all redemption provisions of the Special Redemption lapsed.

The following table summarizes information related to issuance of the Company's preferred stock (in thousands, except number of shares and per share amounts):

As of June 30, 2021							
	Par Value	Date of Issuance	Shares Price at Issuance	Shares Authorized(1)	Shares Issued and Outstanding(1)	Liquidation Preference	Carrying Value (2) Share Capital
Series A	\$ 0.001	Feb-2000	\$ 40.81	355,921	355,903	\$ 14,523	\$ 13,535
Series B	\$ 0.001	May-2003	\$ 9.07	1,741,452	1,741,399	15,795	39,715
Series C	\$ 0.001	Feb-2007	\$ 12.92	1,168,344	1,168,311	15,086	28,136
Series D	\$ 0.001	Aug-2009	\$ 18.08	663,808	663,728	12,000	18,503
Series E	\$ 0.001	Oct-2011	\$ 20.66	353,339	353,327	7,300	10,350
Series F	\$ 0.001	May-2012	\$ 25.83	507,744	499,159	12,891	18,305
Series G	\$ 0.001	Jun-2015	\$ 12.40	5,832,685	5,788,878	71,759	135,682
Series H	\$ 0.001	Feb-2017	\$ 12.40	5,949,499	3,805,567	47,174	89,074
				<u>16,572,792</u>	<u>14,376,272</u>	<u>\$ 196,528</u>	<u>\$ 353,300</u>

As of December 31, 2020							
	Par Value	Date of Issuance	Shares Price at Issuance	Shares Authorized(1)	Shares Issued and Outstanding(1)	Liquidation Preference	Carrying Value (2) Share Capital
Series A	\$ 0.001	Feb-2000	\$ 40.81	355,921	355,903	\$ 14,523	\$ 13,535
Series B	\$ 0.001	May-2003	\$ 9.07	1,741,452	1,741,399	15,795	39,715
Series C	\$ 0.001	Feb-2007	\$ 12.92	1,168,344	1,168,311	15,086	28,136
Series D	\$ 0.001	Aug-2009	\$ 18.08	663,808	663,728	12,000	18,503
Series E	\$ 0.001	Oct-2011	\$ 20.66	353,339	353,327	7,300	10,350
Series F	\$ 0.001	May-2012	\$ 25.83	507,744	499,159	12,891	18,305
Series G	\$ 0.001	Jun-2015	\$ 12.40	5,832,685	5,788,878	71,759	135,682
Series H	\$ 0.001	Feb-2017	\$ 12.40	5,949,499	3,805,567	47,174	89,074
				<u>16,572,792</u>	<u>14,376,272</u>	<u>\$ 196,528</u>	<u>\$ 353,300</u>

- (1) The shares authorized, issued and outstanding do not reflect any anti-dilution provisions of Series C, Series D, Series E and Series F as a result of the Series G financing.
- (2) The carrying value reflects the gross proceeds received from the sale of the preferred stock less issuance costs and the fair value at issuance of preferred stock warrants classified as a liability, plus accretion of redemption value.

Common Stock

Each share of common stock is entitled to one vote. Common stock reserved for future issuance consisted of the following:

	June 30, 2021	December 31, 2020
Conversion of preferred stock	14,850,993	14,851,007
Preferred stock warrants	225,945	225,945
Common stock warrant	—	1
Stock options issued and outstanding under the 2006 and 2015 plans	4,570,118	4,201,935
Total shares of common stock reserved	<u>19,647,056</u>	<u>19,278,888</u>

Note 9 – Stock-Based Compensation Expense

As of June 30, 2021 and December 31, 2020, the Company had two stock-based incentive compensation plans, the Calhoun Vision, Inc. 2015 Equity Incentive Plan and the Calhoun Vision, Inc. 2006 Stock Plan (collectively the “Plans”).

Option awards are generally 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: 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 3 years. The purpose of the Plans 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.

Prior to the Company's IPO in July 2021, the Company's board of directors, with input from management, considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to: (i) third-party valuations of the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of the Company's convertible preferred stock relative to those of the Company's common stock; (v) the Company's operating results and financial condition, including the Company's levels of available capital resources; (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions and (viii) the lack of marketability of the Company's common stock. After completion of the Company's IPO in July 2021, the fair value of common stock is based on the closing price of the Company's common stock as reported on the Nasdaq Global Select Market.

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions 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—Since 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. The 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 is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

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.

A summary of stock option activities for the six months ended June 30, 2021 is as follows:

	Shares Available for Grant	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Avg Remaining Contractual Life (Years)
Options outstanding as of December 31, 2020	252,310	4,201,935	\$ 9.57		6.46
Issued	575,490				
Granted	(734,127)	734,127	\$ 15.64	\$ 9.01	
Exercised		(310,760)	\$ 4.29	\$ 1.92	
Forfeited	40,634	(40,634)	\$ 15.47	\$ 10.75	
Expired	14,550	(14,550)			
Options outstanding as of June 30, 2021	<u>148,857</u>	<u>4,570,118</u>	\$ 10.83		6.68
Exercisable as of June 30, 2021		<u>3,001,219</u>	\$ 8.30		5.43

As of June 30, 2021 and December 31, 2020 the intrinsic value of options vested was \$37.8 million and \$26.2 million, respectively, and of all options outstanding was \$45.8 million and \$26.4 million, respectively. During the six months ended June 30, 2021 and 2020, the total cash received from the exercise of stock options was \$1.3 million and \$881,000, respectively. The total fair value less strike price of these options was \$3.5 million and \$2.5 million, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 540	\$ 556	\$ 1,137	\$ 914
Selling, general and administrative	686	363	1,149	523
Cost of goods sold	180	164	359	269
	<u>\$ 1,406</u>	<u>\$ 1,083</u>	<u>\$ 2,645</u>	<u>\$ 1,706</u>

As of June 30, 2021 and December 31, 2020, there were 1,568,899 and 1,177,165 unvested options, respectively. Total unrecognized expense related to unvested stock options was approximately \$13.4 million and \$9.8 million as of June 30, 2021 and December 31, 2020, respectively. Amounts are expected to be recognized over a weighted average period of approximately 2.8 and 2.9 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:

	Six Months Ended June 30, 2021	
	Range	Weighted Average
Expected volatility	62.3% to 63.7%	63.6%
Risk-free interest rate	0.6% to 1.6%	1.1%
Expected life (in years)	5.52 to 10.00 years	6 years
Expected dividend yield	0.0%	0.0%
Grant date fair value	\$15.60 to \$19.94	\$15.64

Note 10 – Income Taxes

The Company maintains a full valuation allowance against its net deferred tax assets as of June 30, 2021 and December 31, 2020 based on the current assessment that it is not more likely than not these future benefits will be

realized before expiration. No material income tax expense or benefit has been recorded given the valuation allowance position and projected taxable losses in the jurisdictions where the Company files income tax returns.

The Company has not experienced any significant increases or decreases to its unrecognized tax benefits since December 31, 2020 and does not expect any within the next 12 months.

The Company is subject to U.S. federal and various states income taxes. The federal returns for tax years 2017 through 2020 remain open to examination and the state returns remain subject to examination for tax years 2016 through 2020. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authorities. All other state jurisdictions remain open to examination.

Note 11 – 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 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 June 30, 2021 and December 31, 2020 the Company held three leases for office, manufacturing and warehouse facilities in Aliso Viejo, California. The three leases are for 19,680, 42,106 and 48,036 square feet and expire on June 30, 2023, September 30, 2024 and January 31, 2026, respectively. For one of the facilities operating leases, the lessor provided \$900,000 in tenant allowances.

The following table presents the lease balances within the condensed consolidated balance sheets (in thousands):

Leases	Classification	June 30, 2021	December 31, 2020
Assets			
Operating	Operating leases right-of-use assets	4,749	\$ 5,319
Finance	Property and equipment, net	43	58
Total lease assets		<u>4,792</u>	<u>5,377</u>
Liabilities			
Current			
Operating	Lease liabilities	1,344	1,247
Finance	Lease liabilities	21	27
Noncurrent			
Operating	Long-term lease liabilities	4,347	5,042
Finance	Long-term lease liabilities	27	37
Total lease liabilities		<u>\$ 5,739</u>	<u>\$ 6,353</u>

For the three and six months ended June 30, 2021 and 2020, the components of operating and finance lease expenses were as follows (in thousands):

Lease Cost	Classification	Three Months Ended June 30,		Six Months Ended June 30,	
		2021	2020	2021	2020
Operating lease cost	Cost of goods sold	\$ 3	\$ 2	\$ 7	\$ 6
	Research and development	79	35	158	64
	Selling, general and administrative expenses	402	414	803	720
Finance lease cost	Amortization of right-of-use asset included in Research and development expenses	—	42	—	83
	Amortization of right-of-use asset included in Selling, general and administrative expenses	7	13	14	25
Finance lease cost	Interest expense	1	4	3	9

Maturities of the Company's operating and finance lease liabilities as of June 30, 2021 were as follows (in thousands):

Year Ended December 31,	Operating Leases	Finance Leases
2021 (remainder)	\$ 934	\$ 13
2022	1,881	23
2023	1,682	18
2024	1,456	—
2025	951	—
2026	79	—
Total lease payments	6,983	54
Less: imputed interest	1,292	6
Total lease liabilities	\$ 5,691	\$ 48

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 June 30, 2021 and December 31, 2020 were:

Lease Term and Discount Rate	June 30, 2021	December 31, 2020
Weighted average remaining lease term (years)		
Operating leases	3.75	4.21
Finance leases	2.15	2.42
Weighted average discount rate		
Operating leases	10.5%	10.5%
Finance leases	10.5%	10.5%

Note 12 – Commitments and Contingencies

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 June 30, 2021 and December 31, 2020, 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.

Note 13 – Subsequent Events

On July 6, 2021, the Company re-incorporated in Delaware. This jurisdictional change had no impact to the capital structure, stockholder rights, assets, or liabilities of the Company.

On July 28, 2021, the Company's Board of Directors and stockholders adopted and approved the Company's 2021 Equity Incentive Plan ("2021 Plan"). 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, or RSUs, and performance awards to employees, directors, and consultants and subsidiary corporations' employees and consultants. The 2015 Plan was terminated immediately prior to effectiveness of the 2021 Plan with respect to the grant of future awards. The number of shares of the Company's common stock available for issuance under the 2021 Plan is equal to 7,260,406 shares of common stock plus up to 4,840,271 shares of common stock remaining under the 2015 Plan and 2006 Plan.

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 our board of directors approved the 2021 Plan, by a number equal to the lesser 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 our immediately preceding fiscal year; or (iii) such lesser number of shares of our common stock as the administrator may determine.

On July 28, 2021, the Company's Board of Directors and stockholders adopted and approved the Company's 2021 Employee Stock Purchase Plan ("2021 ESPP"). The number of shares of the Company's common stock available for issuance under the 2021 ESPP is equal to 484,027 shares of common stock.

The number of common shares reserved for issuance under the 2021 ESPP will be increased automatically on the first day of each fiscal year beginning with our 2020 fiscal year, by a number equal to the lesser of: (i) 1,452,081 shares; (ii) 1% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year; or (iii) such other amount as the administrator may determine.

Each of the Company's 2021 Plan and 2021 ESPP provides for annual automatic increases in the number of shares reserved thereunder, and the 2021 Plan also provides for increases to the number of shares that may be granted thereunder based on awards under the 2015 Plan ("2015 Plan") or 2006 Stock Plan ("2006 Plan") that expire, are forfeited, or otherwise repurchased by the Company.

On July 30, 2021, the Board of Directors approved the issuance of 640,567 equity awards to the Company's named executive officers and certain non-employee directors, consisting of 17,577 restricted stock units and 622,990 stock option awards. The awards will vest over one to four years of service.

On August 3, 2021, the Board of Directors approved the issuance of equity awards to certain non-employee directors, consisting of 40,134 restricted stock units. The awards will vest over one to three years of service.

On August 31, 2021, the Board of Directors approved the issuance of 768,520 equity awards to employees, consisting of 600,018 restricted stock units and 168,502 stock option awards. The awards will generally vest over four years of service.

Item 2: MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2020, included in our prospectus dated July 29, 2021 filed with the U.S. Securities and Exchange Commission, pursuant to Rule 424(b)(4) under the Securities Act. 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 “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. See “Special Note Regarding Forward-Looking Statements.”

We are a commercial-stage medical technology company dedicated to improving the vision of patients following cataract surgery. Our proprietary RxSight system, comprised of our LAL, LDD and accessories, is the first and only commercially available IOL technology that enables doctors to customize and optimize visual acuity for patients after cataract surgery. Our LAL is made of proprietary photosensitive material that changes shape in response to specific patterns of ultraviolet light generated by our LDD. With the RxSight system, the surgeon performs a standard cataract procedure to implant the LAL, determines refractive error with patient input after healing is complete, and then uses the LDD to modify the lens with the exact amount of visual correction needed to achieve the patient’s desired vision outcomes. Alternative IOL technologies, in contrast, are not adjustable following the procedure and therefore require patients to make pre-operative choices about their visual preferences, which can often result in patient dissatisfaction when visual outcomes fail to meet expectations. We designed our RxSight system to maximize patient and doctor satisfaction through superior visual outcomes. In the pivotal study that formed the basis for our FDA approval, the observed rate of eyes with 20/20 or better uncorrected distance visual acuity for our LAL was 70.1%. This compares favorably to the results of pivotal studies with similar study designs and patient populations that supported FDA approval of Alcon’s Acrysof Toric (38.4%), and J&J’s Tecnis Toric (43.6%). We began commercializing our solution in the United States in the third quarter of 2019 and are focused on establishing the RxSight system as the standard of care for premium IOL procedures. As of June 30, 2021, we had an installed base of 130 LDDs in ophthalmology practices, and since our inception, surgeons have performed over 11,000 surgeries with our RxSight system.

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 products are also approved for sale in Europe and Mexico. We are not actively marketing our products for sale in Europe or Mexico; however, we have approval in both for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error. We have one customer in Germany and one in Mexico, both of which have participated in our clinical studies and perform commercial cases. We compete in the IOL market in the U.S. We are a Delaware corporation, headquartered in Aliso Viejo, California, and have one wholly owned subsidiary. Our subsidiary is located in Amsterdam, Netherlands, which has one wholly owned subsidiary in Germany and a registered branch in the United Kingdom.

Our commercial strategy is focused on a “land and expand” model through which we aim to drive new customer adoption, which generally begins with the sale of an LDD, and then helps the customer incorporate the LAL into their practice to drive utilization and premium procedure growth. We believe this commercial strategy over time may provide a degree of predictability in terms of our commercial growth and a consumable revenue stream from sales of our LALs. We are currently focused on driving adoption with surgeons performing a high volume of premium cataract procedures. Market Scope estimates that there are approximately 4,000 surgeons that perform cataract surgeries in the United States as of 2020, and we estimate that approximately 1,600 surgeons performed approximately 70 to 80% of the premium procedures in the United States in 2020. We believe this provides an attractive and concentrated market opportunity addressable with a focused sales force. We currently employ a sales team that, as of June 2021 includes 6 sales directors, and a group of over 40 clinical specialists, field service and customer service personnel. We believe 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. While we intend to initially focus our growing commercial efforts in the U.S., in the future, we may selectively pursue commercial expansion in Asia, Europe,

Australia or other geographies with significant market opportunity for premium IOLs, leveraging our CE and FDA approvals.

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 its 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.

On July 29, 2021, we completed our IPO, which resulted in the issuance and sale of 8,248,549 shares of common stock, including 898,549 shares sold pursuant to the exercise of the underwriters' over-allotment option at the IPO price of \$16.00 per share. We received net proceeds of approximately \$120.0 million from the IPO, after deducting underwriters' discounts and commissions of \$9.2 million and offering costs of \$2.7 million.

Prior to our IPO, our primary sources of capital had been private placements of preferred stock, a structured transaction with a strategic partner, debt financing and revenue from sales of our products. Since inception, we raised a total of \$191.3 million in net proceeds from private placements of preferred stock, \$120 million from a strategic partner, approximately \$39.2 million in net proceeds from a credit facility, and approximately \$11.0 million from issuance of common stock primarily from stock option exercises. As of June 30, 2021, we had cash and cash equivalents of \$41.7 million, short-term investments of \$20.0 million, long-term debt of \$39.5 million and an accumulated deficit of \$450.9 million. We generated sales of \$8.4 million and had a net loss of \$20.3 million for the six months ended June 30, 2021, compared to sales of \$5.6 million and a net loss of \$29.4 million for the six months ended June 30, 2020.

We intend to continue to make significant investments in our sales and marketing organization, primarily sales representatives, clinical applications specialists and technical service personnel to support new customers and upgrades and practice development personnel to facilitate adoption of use of our LALs among existing accounts. We will expand our marketing efforts with additional advertising and 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 of directors and expenses for compliance with public-company reporting requirements. Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years.

Facility lease agreements

We currently lease three facilities housing our headquarters, manufacturing, research and development and administrative offices in Aliso Viejo, California. The facility leases are for approximately 109,822 square feet in the aggregate. The leases terminate, 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; and (iii) March 31, 2023 with two options to extend for five years each.

COVID-19 pandemic

We are subject to the continuing risks related to the public health crises, primarily the global pandemic associated with COVID-19. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to most countries, and all 50 states within the United States. The COVID-19 outbreak has negatively impacted and may continue to negatively impact our operations and revenues and overall financial condition, similar to other medical device manufacturers, by decreasing the number of our products sold. RxSight has a limited commercial history, as all but eight months of commercial history has occurred during the COVID-19 crisis. Total IOL procedure volume dropped 17% in the US and 25% globally from 2019 to 2020 due principally to the COVID-19 pandemic, as health care organizations globally have prioritized the treatment of patients with COVID-19. In the United States, governmental authorities had recommended, and in certain cases required, that elective, specialty and other

procedures and appointments, be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges may continue for the duration of the pandemic, which is uncertain, and will reduce our revenue while the pandemic continues.

Numerous state and local jurisdictions imposed, and in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our headquarters is located, issued “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in our headquarters closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of training and other events, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions to our business and supply chain include restrictions on our personnel and personnel of partners to travel and access customers for training and case support; delays in approvals by regulatory bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our RxSight system. In addition, even after the “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19 were significantly reduced in the second quarter of 2021, we continue to experience disruptions to our business, including patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus.

As we continue to actively advance our clinical, discovery and research programs, we are in close contact with the third parties we engage with, who are primarily located in the United States, and are assessing the impact of the COVID-19 pandemic on each of our programs, expected timelines and costs on an ongoing basis. In light of ongoing developments relating to the COVID-19 pandemic, the focus of healthcare providers on fighting the virus, and consistent with the FDA’s industry guidance for conducting clinical trials, we and our contract research organizations have made certain adjustments to the operation of our clinical trials in an effort to ensure the monitoring and safety of patients and minimize risk to trial integrity during the pandemic and generally. Other COVID-related guidance recently released by the FDA includes statistical considerations for clinical trials conducted during the COVID-19 public health emergency and post marketing adverse event reporting for medical products during a pandemic. We may need to make further adjustments in the future, including implementation of new policies and procedures.

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 further 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 our RxSight systems sold after the pandemic has ended.

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, LALs implanted and the number of doctors performing surgery with our products are indicators of our ability to drive adoption and generate revenue. We believe these are important metrics for our business. Due to our limited commercial history, all but eight months of which have occurred during the COVID-19 pandemic, we are not yet able to 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 installed at the end of each period are important metrics as they represent an installed base into which we can sell our LALs.

	2019				2020				2021	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
LDDs Sold	—	—	10*	9	15	15	20*	23	13	25
Installed Base at End of Period	—	—	10	19	34	49	69	92	105	130

* One LDD placed for rent Q3 2019 at a university & one LDD converted from clinical to commercial use in Q3 2020

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. While an important metric, the COVID-19 pandemic and severe weather in the first quarter 2021 impacted trends in our business. In the second quarter of 2020, the number of our LALs sold decreased as compared to the first quarter of 2020 as ambulatory surgery centers (ASCs), where most cataract surgeries are performed, were closed to elective surgeries for six or more weeks. In the third quarter 2020, LALs sold increased as compared to the second quarter of 2020, reflecting, we believe, some resurgence of surgeries when ASCs re-opened, with sales of LALs in the fourth quarter of 2020 continuing to increase sequentially, despite seasonal holidays. During the first quarter of 2021, however, the U.S. saw a resurgence in COVID-19 cases attributed to holiday travel and gatherings and severe weather in Texas and other southern states, resulting in reduced LAL sales for such period.

	2019				2020				2021	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
LALs Sold	—	26	336	575	719	662	1,513	1,577	1,567	1,825

Components of results of operations

Sales

Our revenue consists 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 (UV protective glasses and LAL insertion devices). Revenue is derived from sales of products primarily in the U.S. and sales to a single customer in each of Germany and Mexico. 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 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. The Company deferred revenue of \$380,000 and \$345,000 related to such service agreements as of June 30, 2021 and December 31, 2020, respectively. Revenue for such service agreements will be recognized over the term of each contract.

For the three and six months ended June 30, 2021, and 2020, revenue from contracts with customers consisted of the following:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
LDD (including training)	\$ 2,965	\$ 2,050	\$ 4,802	\$ 4,209
LAL	1,792	619	3,321	1,290
Accessories and Service Warranty	140	37	258	95
	<u>\$ 4,897</u>	<u>\$ 2,706</u>	<u>\$ 8,381</u>	<u>\$ 5,594</u>

For the three months ended June 30, 2021, we had one customer who individually accounted for approximately 13% of revenue. For the six months ended June 30, 2021, we had no customer who individually accounted for 10% or more of revenue. For the three months ended June 30, 2020, we had one customer who individually accounted for

approximately 54% of revenue. For the six months ended June 30, 2020, we had one customer who individually accounted for approximately 39% of revenue.

Cost of sales

Cost of sales consists 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, including 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 revenue. 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 close to 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, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, 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 (including legal, audit and tax fees), 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, 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 compensation and benefits (including stock-based compensation), 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 R&D 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.

Change in fair value of warrants

Change in fair value of warrants consists of gains and losses resulting from the remeasurement of the fair value of our preferred stock warrant liabilities at each balance sheet date. We continued to record adjustments to the estimated fair value of the preferred stock warrants until the conversion of the underlying convertible preferred stock into common stock which occurred upon the completion of its IPO in July 2021.

Interest expense

Interest expense consists 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, net

Interest and other income, net consists primarily of interest income earned on our cash and cash equivalents.

Accretion to redemption value of redeemable preferred stock and preferred stock options

Due to the Special Redemption provision in place in our Articles of Incorporation and until the unexercised Series W Warrant expiration on March 31, 2021, all equity instruments were redeemable and evaluated as probable of redemption through early December 2020. No accretion was calculated during the three and six months ended June 30, 2021. For common and preferred stock, the value of the accretion was calculated as the estimated future redemption amount accreted to the estimated redemption date using the effective interest rate. For stock options the value of accretion was calculated at the estimated future redemption amount less the strike price, recognized over the same period as the corresponding service period for which stock-based compensation is recognized.

Comprehensive income (loss)

All components of comprehensive income (loss), including net income (loss), are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income 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 June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021, and 2020, together with the dollar increase or decrease and percentage change in those items.

(in thousands, except share amounts, per-share data and percentages)	Three months ended June 30		Change	
	2021	2020	(\$)	(%)
Sales	\$ 4,897	\$ 2,706	\$ 2,191	81.0%
Cost of sales	5,709	3,180	2,529	79.5
Gross loss	\$ (812)	\$ (474)	\$ (338)	71.3%
Operating expenses:				
Selling, general and administrative	6,502	3,249	3,253	100.12
Research and development	6,563	5,084	1,479	29.1
Total operating expenses	13,065	8,333	4,732	56.8
Loss from operations	\$ (13,877)	\$ (8,807)	\$ (5,070)	57.6%
Other income (expense), net:				
Change in fair value of warrants	1,214	(4,178)	5,392	(129.1)%
Interest expense	(826)	(4)	(822)	20,550.0
Interest and other income	15	147	(132)	(89.8)
Loss before income taxes	(13,474)	(12,842)	(632)	4.9
Income tax expense	3	40	(37)	(92.5)
Net loss	\$ (13,477)	\$ (12,882)	\$ (595)	4.6%
Accretion to redemption value of redeemable preferred stock and redeemable stock options	—	(4,097)	4,097	(100.0)
Net loss attributable to common stockholders	(13,477)	(16,979)	3,502	(20.6)
Other comprehensive income (loss)				
Unrealized gain on short-term investments	(4)	(112)	108	(96.4)
Foreign currency translation loss	1	3	(2)	(66.7)
Total other comprehensive income (loss)	(3)	(109)	106	(97.2)
Comprehensive loss	\$ (13,480)	\$ (12,991)	\$ (489)	3.8%

Sales

Sales increased by \$2.2 million to \$4.9 million for the three months ended June 30, 2021, from \$2.7 million for the three months ended June 30, 2020. The increase in total sales was primarily due to sales of 1,163 more LALs with an increased average selling price and 10 more LDDs.

Cost of sales

Cost of sales increased by \$2.5 million to \$5.7 million for the three months ended June 30, 2021, from \$3.2 million for the three months ended June 30, 2020, primarily due to the increase in the number of LALs and LDDs sold. The increase was impacted by the recording of a \$1.7 million reserve for excess LAL inventory as a result of the recent introduction of an updated LAL including our ActivShield technology. Gross margin increased to (16.6)% in the three months ended June 30, 2021 from (17.5)% for the three months ended June 30, 2020 due to improved operating leverage.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$3.3 million to \$6.5 million for the three months ended June 30, 2021, from \$3.2 million for the three months ended June 30, 2020, an increase of 100%. This increase was primarily attributable to an increase in selling and marketing personnel costs of \$1.6 million due mainly to additional headcount as well as increased travel costs of \$0.4 million when compared to the three months ended June 30, 2020, due to temporary reduction in travel costs caused by COVID-19, as well as increased consulting and temporary personnel expenses of \$0.3 million. General and administrative temporary labor and consulting costs increased by approximately \$0.5 million driven by temporary personnel costs as well as an increase in consulting expenses in preparation for our IPO in July 2021. General and administrative personnel expenses also increased by \$0.3 million due primarily to an increase in headcount as well as temporary reductions in salaries that were in place for the three months ended June 30, 2020.

Research and development expenses

Research and development expenses increased by \$1.5 million to \$6.6 million for the three months ended June 30, 2021, from \$5.1 million for the three months ended June 30, 2020, an increase of 29%. This increase was primarily attributable to increased material costs of \$1.0 million, which included \$0.7 million in expensed LALs and an increase of \$0.2 million in personnel costs due primarily to higher incentive pay as well as temporary reductions in salaries that were in place for the three months ended June 30, 2020, as well as an increase in clinical study expense of \$0.2 million.

Other income (expense), net

Other income (expense), net, increased by \$4.4 million to \$0.4 million for the three months ended June 30, 2021 from a \$4.0 million loss for the three months ended June 30, 2020 due to the change in the fair value of liability classified warrants of \$5.4 million partially offset by reduced interest income of \$0.1 million and an increase in interest expense of \$0.8 million interest expense on our term loan.

Accretion to redemption value of redeemable preferred stock and redeemable stock options

Accretion to redemption value of redeemable preferred stock and redeemable stock options was \$0.0 million for the three months ended June 30, 2021, and \$4.1 million for the three months ended June 30, 2020, due to the expiration of the Common W warrant liability on March 31, 2021.

Other comprehensive income (loss)

Other comprehensive income (loss) decreased by \$0.1 million to \$0.0 million for the three months ended June 30, 2021, from income of \$0.1 million for the three months ended June 30, 2020, due primarily to a decrease of \$0.1 million in the unrealized gain on short-term investments.

Comparison of the six months ended June 30, 2021, and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021, and 2020, together with the dollar increase or decrease and percentage change in those items:

(in thousands, except share amounts, per-share data and percentages)	Six months ended June 30		Change	
	2021	2020	(\$)	(%)
Sales	\$ 8,381	\$ 5,594	\$ 2,787	49.8%
Cost of sales	8,074	5,989	2,085	34.8
Gross profit (loss)	\$ 307	\$ (395)	\$ 702	(177.7)%
Operating expenses:				
Selling, general and administrative	12,113	6,948	5,165	74.3
Research and development	13,206	10,861	2,345	21.6
Total operating expenses	25,319	17,809	7,510	42.2
Loss from operations	\$ (25,012)	\$ (18,204)	\$ (6,808)	37.4%
Other income (expense), net:				
Change in fair value of warrants	1,214	(11,585)	12,799	(11047.9)%
Expiration of warrant	5,018	—	5,018	0.0
Interest expense	(1,524)	(9)	(1,515)	16,833.3
Interest and other income	32	459	(427)	(93.0)
Loss before income taxes	(20,272)	(29,339)	9,067	(30.9)
Income tax expense	10	45	(35)	(77.8)
Net loss	\$ (20,282)	\$ (29,384)	\$ 9,102	(31.0)%
Accretion to redemption value of redeemable preferred stock and redeemable stock options	-	(8,343)	8,343	(100.0)
Net loss attributable to common stockholders	(20,282)	(37,727)	17,445	(46.2)
Other comprehensive income (loss)				
Unrealized gain (loss) on short-term investments	3	(35)	38	(108.6)
Foreign currency translation gain	(3)	2	(5)	(250.0)
Total other comprehensive income (loss)	-	(33)	33	(100.0)
Comprehensive loss	\$ (20,282)	\$ (29,417)	\$ 9,135	(31.1)%

Sales

Sales increased by \$2.8 million to \$8.4 million for the six months ended June 30, 2021, from \$5.6 million for the six months ended June 30, 2020. The increase in sales was due to sales of 2,011 more LALs with an increased average selling price and eight more LDDs sold. In mid-March 2020, ambulatory surgery centers (ASCs), where most cataract surgeries were performed, were closed to elective surgeries for six or more weeks, contributing to the increase when comparing the six months 2021 and 2020.

Cost of sales

Cost of sales increased by \$2.1 million to \$8.1 million for the six months ended June 30, 2021, from \$6.0 million for the six months ended June 30, 2020, due to the increase in the number of products sold and associated service warranties. The increase was also driven by the recording of a \$1.7 million reserve for excess LAL inventory as a result of the recent introduction of an updated LAL including our ActivShield technology. Gross margin increased to 3.7% for the six months ended June 30, 2021, from a 7.1% loss due to improved operating leverage on a higher volume of units sold.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$5.2 million to \$12.1 million for the six months ended June 30, 2021, from \$6.9 million for the six months ended June 30, 2020. The increase was primarily driven

by an increase in selling and marketing personnel related expenses of \$2.7 million due mainly to additional headcount, increased travel costs of \$0.3 million due the temporary reduction in selling and marketing travel costs during the six months ended June 30, 2020 caused by COVID-19, an increase in general and administrative personnel costs of \$0.6 million, higher general and administrative audit, tax, and legal costs and \$0.6 million higher selling, general and administrative stock-based compensation expenses.

Research and development expenses

Research and development expenses increased by \$2.3 million to \$13.2 million for the six months ended June 30, 2021, from \$10.9 million for the six months ended June 30, 2020, an increase of 22%. This increase was primarily attributable to an increase of \$0.7 million in personnel costs due primarily to increased personnel headcount and reinstatement of incentive pay, increased material costs of \$1.4 million, which included \$0.7 million in expensed LALs, as well as an increase in stock-based compensation expense of \$0.2 million.

Other income (expense), net

Other income (expense), net, increased by \$15.9 million to \$4.7 million for the six months ended June 30, 2021, from a \$11.1 million loss for the six months ended June 30, 2020, due primarily to the change in fair value of warrant liabilities of \$17.8 million, offset by a decrease in interest income of \$0.4 million due to lower cash and short-term investment balances and an increase in interest expense of \$1.5 million due to higher interest expense on our term loan.

Accretion to redemption value of redeemable preferred stock and redeemable stock options

Accretion to redemption value of redeemable preferred stock and redeemable stock options decreased by \$8.3 million to \$0.0 million for the six months ended June 30, 2021, from \$8.3 million for the six months ended June 30, 2020, due to management no longer accreting common stock, preferred stock and stock options to redemption value in 2021 after it was determined in December 2020 that exercise of the Series W Warrant was no longer probable.

Other comprehensive income (loss)

Other comprehensive income (loss) increased by \$0.03 million to \$0.0 million for the six months ended June 30, 2021, from (\$0.03) million for the six months ended June 30, 2020, due primarily to reduction in the unrealized gain on 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 for at least the next several years. As of June 30, 2021, we had cash, cash equivalents and short-term investments of \$61.7 million. For the six months ended June 30, 2021, and 2020, our loss from operations were \$25.0 million and \$18.2 million, respectively. We had an accumulated deficit of \$450.9 million as of June 30, 2021.

Prior to our IPO completed in July 2021, our primary sources of capital were private placements of preferred stock, a structured transaction with a strategic partner, debt financing and revenue from sales of our products.

Funding requirements

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

- our revenue growth;
- our research and development efforts;
- our sales and marketing activities;
- our ability to raise additional funds 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;
- debt service requirements;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

Based on our current planned operations, we expect that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations for the next 12 months after the date our most recent financial statements were issued. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations. We may require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings and/or debt financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us, if at all. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating activities, which may have a material adverse effect on our business and/or results of operations and financial condition. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

See the section of this Quarterly Report on Form 10-Q titled "Risk Factors" 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:

	Six months ended June 30, (unaudited)	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (22,231)	\$ (20,028)
Investing activities	33,680	23,702
Financing activities	16,391	857
Effect of foreign exchange rate on cash, cash equivalents and restricted cash	(3)	2
Net increase in cash, cash equivalents and restricted cash	<u>\$ 27,837</u>	<u>\$ 4,533</u>

Cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2021, was \$22.2 million, consisting primarily of a net loss of \$20.3 million, a non-cash gain on expiration of an unexercised warrant of \$5.0 million, an increase in operating assets and liabilities of \$2.3 million, partially offset by non-cash stock-based compensation of \$2.6 million, provision for excess and obsolete inventory of \$1.7 million, and depreciation and amortization of \$1.9 million.

Net cash used in operating activities for the six months ended June 30, 2020, was \$20.0 million, consisting primarily of a net loss of \$29.4 million, an increase in operating assets and liabilities of \$5.5 million, offset by the

non-cash change in fair value of liability classified warrants of \$11.6 million, depreciation of \$1.8 million and stock-based compensation of \$1.7 million.

Cash used in investing activities

Net cash provided by investing activities for the six months ended June 30, 2021, was \$33.7 million, consisting of net maturities of short-term investments of \$35.0 million, offset by net purchases of property and equipment of \$1.3 million.

Net cash provided by investing activities for the six months ended June 30, 2020, was \$23.7 million, consisting of net maturities of short-term investments of \$25.1 million, offset by net purchases of property and equipment of \$1.4 million.

Cash from financing activities

Net cash from financing activities for the six months ended June 30, 2021, was \$16.4 million, consisting primarily of proceeds from a draw on the Company's term loan of \$15.0 million and proceeds from stock options exercised of \$1.3 million.

There were no significant financing cash flow activities in the six months ended June 30, 2020.

Contractual obligations and commitments

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 \$0.6 million and \$0.4 million as of December 31, 2019 and December 31, 2020.

Term Loan

In October 2020, we entered into a loan and security agreement, or the Credit Agreement, with Bank of America, as collateral agent, and Oxford Finance LLC, or Oxford Finance, as lender. The Credit Agreement provides for a tranche one loan advance in the amount of \$25.0 million, which was fully funded on the closing date by the lender, a second tranche of \$5.0 million in the first quarter of 2021, which was advanced on March 29, 2021, and a third tranche of \$10.0 million in the second quarter of 2021, which was advanced on June 28, 2021. The Credit Agreement also provides for an additional two tranches in the amount of \$5.0 million each in 2021, subject to remaining in compliance with the terms of the credit facility. A final tranche in an amount of \$10.0 million is available in the first quarter of 2022, subject to our achievement of a revenue milestone and remaining in compliance with the terms of the credit facility. We refer to our tranche one loan advance, tranche two loan advance, tranche three loan advance, tranche four loan advance, tranche five loan advance, and tranche six loan advance collectively as our credit facility.

The credit facility is secured by substantially all of our personal property other than our intellectual property, but includes any accounts receivable, other amounts owed and any proceeds of intellectual property. We also entered into a negative pledge arrangement with the collateral agent and lenders where we agreed not to encumber any of our intellectual property. Outstanding borrowings under the credit facility bear interest at an annual rate equal to the greater of (i) the Wall Street Journal 30-day LIBOR plus 9.09% and 0.16% or (ii) 9.25%. At our election, we may also switch to an interest rate equal to 10.25% plus the greater of (i) The Wall Street Journal Prime rate or (ii) 7%. The interest rate resets monthly on the last day of the month prior to the month in which interest accrues, and an actual/360-day convention applies. If we are considered to be in default, additional interest of 5% applies. We are required to make monthly payments of interest only through December 1, 2023, or the interest-only period; provided that the interest-only period maybe extended to December 1, 2024.

The Term Loan requires 36 months of interest-only payments, followed by 23-months of amortization. If the Company is in compliance with the Performance to Plan covenant through October 31, 2023, the interest-only period is extended by 12 months, and the amortization period is reduced by 11 months. Payments are due on the first day of each month in arrears. All unpaid amounts under the Term Loan mature on October 1, 2025.

We may repay the Term Loan at any time without penalty; however, the loan must be prepaid in full or in specific increments and amounts prepaid may not be subsequently reborrowed. The loan may also be accelerated by the lender in the event of a default.

Borrowings under the credit facility are pre-payable at any time without penalty; however, the loan must be prepaid in full or in part one time in an amount not less than \$5.0 million and amounts prepaid may not be subsequently reborrowed. If the loan is not fully prepaid by December 31, 2021, the Company will become subject to an additional fee (the “Exit Fee”). The fee is 3% of the original loan amount if prepaid between January 1, 2022, and October 31, 2022 (\$750k); 4% if prepaid between November 1, 2022 and October 31, 2023 (\$1.0 million); and 5% (\$1.25 million) if paid subsequently, including at maturity. The loan may be accelerated by Oxford in the event of a default. The credit facility also includes certain customary affirmative and negative covenants, including certain financial covenants if the lenders make us the additional tranche advances. We were in compliance with all covenants under the credit facility as of June 30, 2021.

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. While our significant accounting policies are more fully described in the notes to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies 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.

There were no material changes to our critical accounting policies or in the methodology used for estimates from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Prospectus of July 29, 2021.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

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 Quarterly Report on Form 10-Q 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, presenting only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus, 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 prospectus 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 this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Qualitative and Quantitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates and foreign currency exchange rates.

Interest Rate Risk

Our cash, cash equivalents and marketable securities as of June 30, 2021 consisted of \$20.0 million, invested in government securities as well as \$41.7 million invested in bank deposits and money market funds. Our historical interest income has not fluctuated significantly. We do not believe that a hypothetical 10% change in interest rates would have a material impact on our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. As of June 30, 2021, we had \$40.0 million in variable rate debt outstanding. Our Credit Agreement bears interest at an annual rate equal to the greater of (i) the Wall Street Journal prime rate plus 9.09% or (ii) 9.25%. A hypothetical change in interest rates of 10% would have resulted in a change of \$0.1 million in interest expense in for the three months ended June 30, 2021.

Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar and our sales outside the United States are primarily denominated in Euros and GBP. For the years ended December 31, 2020 and 2019, approximately 0.3% and 0.5%, respectively, of our sales were denominated in currencies other than U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United States and Europe. If our operations in countries outside of the United States grows, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. In addition, because we conduct business in currencies other than U.S. dollars, but report

our results of operations in U.S. dollars, we also face remeasurement exposure to fluctuations in currency exchange rates, which could hinder our ability to predict our future results and earnings and could impact our results of operations. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies. We do not believe that a hypothetical 10% change in the relative value of the U.S. dollar to other currencies would have a material impact on our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a material effect on our financial results during the periods presented.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2021.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended June 30, 2021 that has materially affected, or is 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.

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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. 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 for the foreseeable 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.

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 on 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.
- 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.

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.

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 may adversely affect our business.

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 light adjustable lenses and light delivery devices. 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 product, 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 for the foreseeable 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 for the foreseeable future. We reported losses from operations of \$46.1 million and \$35.4 million for the years ended December 31, 2019 and 2020, respectively, and \$13.9 million for the three months ended June 30, 2021. As a result of these losses, as of June 30, 2021, we had an accumulated deficit of \$450.9 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 additional costs associated with being a public company.

The net losses that we incur may fluctuate significantly 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 substantial net losses and negative cash flows from operations for at least the next several years. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- our research and development efforts;
- our sales and marketing activities;
- our success in leveraging future strategic partnerships;
- our ability to raise additional funds 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 employees and the need and ability to hire additional management and sales, scientific and medical personnel;

- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- debt service requirements;
- 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.

As of June 30, 2021, and December 31, 2020, we had \$61.7 million and \$69.0 million, respectively, in cash, cash equivalents and marketable securities. While we believe that our existing cash, cash equivalents and marketable securities 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 Quarterly Report on Form 10-Q, but we cannot assure you that we will be able to generate sufficient liquidity as and when needed. 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.

The terms of our credit facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the credit facility 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 Credit Agreement with Oxford Finance, provides for a five-year \$60.0 million term-loan facility, of which \$40.0 million has been drawn as of June 30, 2021. \$10.0 million of the term-loan facility is available in additional draws during 2021 and \$10.0 million will be available in the first quarter of 2022 if we reach certain revenue milestones.

Our payment obligations under the Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the Credit Agreement 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.

Commencing in 2022, the Credit Agreement requires us to achieve certain revenue levels as compared to our board approved operating plan in order to avoid a default or to access additional funds. When we are subject to this covenant, there can be no assurance of our ability to maintain compliance with this covenant as of any future date.

Our obligations under the Credit Agreement 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 Credit Agreement 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.

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 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, or 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, 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 system and our products and on the willingness of patients, 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, 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 spectacles;
- 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, Bausch + Lomb, Hoya Corporation and Carl Zeiss AG. 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 spectacles until final lock-in which is approximately 4-5 weeks after surgery. They will also be required to return for an additional 2-3 clinic visits compared to traditional 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 a single manufacturing facility, and should this facility 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 three facilities expire at the end of September 30, 2029 (including a five year option to extend), January 31, 2041 (including three-five year options to extend) and June 30, 2033 (including

two extensions to extend for 5 years each), and 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, although we believe there is potential to improve on the current reimbursement profile for our products in the future, 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;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- 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 U.S. Foreign Corrupt Practices Act (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.

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 in public health insurance coverage and government reimbursement rates for our products could affect the adoption of our products and our future revenue.

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, Centers for Medicare & Medicaid Services (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 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 December 31, 2020, we had federal net operating loss carryforwards (NOLs) of approximately \$230 million, which will begin to expire in various years ranging from 2021 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 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 net 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. Additionally, California recently enacted legislation limiting our ability to use our state NOLs for taxable years 2020, 2021, and 2022.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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 competitive 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 U.S. Patent and Trademark Office, or 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 U.S. 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 U.S. 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 U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, 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 U.S. Patent and Trademark Office, or 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 U.S. 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.

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 Food, Drug and Cosmetic Act, or 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 Medical Device Reporting, or 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 has a CE Mark 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 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, or 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, or 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, or 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. The Supreme Court of the United States held oral arguments on the Fifth Circuit Court case in November 2020. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, upholding the ACA. It is unclear how this Supreme Court decision, future litigation, and healthcare measures promulgated by the Biden administration will impact the implementation of 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 2030 unless additional congressional action is taken. These Medicare sequester reductions have been suspended from May 1, 2020 through the end of 2021 due to the COVID-19 pandemic. 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 U.S. 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 U.S. 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 Patient Protection and Affordable Care Act of 2010, as amended by the health Care and Education Reconciliation Act of 2010 (collectively, 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, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; additionally, effective January 1, 2022, for data reported to CMS in 2022, these reporting obligations with respect to payments and transfers of value made to covered recipients in the previous year, or data collected in 2021, will extend to include certain non-physician providers, such as physician assistants, nurse practitioners, and other mid-level practitioners; 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, or 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 Centers for Medicare and Medicaid Services (CMS) as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. 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 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). The new regulations replace predecessor directives and emphasize a global convergence of regulations. With the transition from the Medical Devices Directive, or 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 U.S. and international privacy, data protection and other laws, and subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil 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 the California Consumer Privacy Act (the "CCPA") in January 2020 which requires certain companies that process information on 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 California Privacy Rights Act of 2020 (“CPRA”). Effective beginning January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify 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 General Data Protection Regulation (“GDPR”), which was adopted by the European Union (“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. The interpretations of the GDPR by local data protection authorities in EU member states, along with the complexity of the new data protection regime itself, will leave the interpretation and enforcement of the law unclear in the near term, with potential inconsistencies across the EU member states. The implementation and enforcement of the GDPR 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. 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. As of January 1, 2021, we are also 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. These recent developments will require us to review and amend the legal mechanisms by which we make and/or receive personal data transfers.

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”). We rely on transfer mechanisms permitted under these laws, including EU Standard Contract Clauses. Such mechanisms have received heightened regulatory and judicial scrutiny in recent years. If we cannot rely on existing mechanisms for transferring personal data from the EEA, the United Kingdom or other jurisdictions, we could be prevented from transferring personal data of users or employees in those regions. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

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 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 recent years, including 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. If a prolonged government shutdown occurs, it 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 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, each component of which has received a CE mark and 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 blanket orders covering the medium term of 18 – 24 months for the majority of our supplier base. 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. 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, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, 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. While we have taken measures to mitigate business continuity risk, including increasing standard lead times, payment of expedite fees, issuance 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 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. 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 this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, 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;
- expiration of market stand-off or lock-up agreements;
- general economic, industry and market conditions; 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 “Risk Factors” section, 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 stock is currently traded on Nasdaq, but we can provide no assurance that we will be able to maintain an active trading market on Nasdaq or any other exchange in the future. If an active trading market does not develop is not maintained, or if we fail to satisfy the continued listing standards of Nasdaq 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. We currently have 27,313,004 outstanding shares of common stock based on the number of shares outstanding as of August 1, 2021.

Holders of an aggregate of 15,076,938 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

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.

Following the completion of our IPO, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 36% of our voting 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 will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this Quarterly Report on Form 10-Q;
- 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 to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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 will incur increased costs as a result of operating as a public company, and our management will be required to devote 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 will incur significant legal, accounting and other expenses that we did not incur as a private company, 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 will be 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, beginning with our second annual report on Form 10-K after we become a public company, we will be 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. 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 have broad discretion in the use of the net proceeds from our Initial Public Offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our Initial Public Offering, and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply the net proceeds in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from our Initial Public Offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 restated certificate of incorporation and restated 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 restated certificate of incorporation and restated 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 amended and restated 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 amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State 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 amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

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. 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 amended and restated 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 against any person in connection with any offering of the Company's securities, including but not limited to any auditor, underwriter, selling shareholder, 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.

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 will be authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation will authorize 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. 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. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax legislation.

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. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to most countries, and all 50 states within the United States. 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 number of our RxSight systems sold, similar to other ophthalmic procedures, has decreased as health care organizations globally have prioritized the treatment of patients with COVID-19. For example, in the United States, governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments, including those related to cataract treatments, be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges may continue for the duration of the pandemic, which is uncertain, and will reduce our revenue and continue to interrupt the commercialization of our products while the pandemic continues. Further, once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with doctors and surgeries to be performed at ophthalmic practices and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking to receive, or who have received, our LAL will have to navigate limited provider capacity. We believe this limited provider capacity could have an adverse effect on our sales following the end of the pandemic.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our headquarters is located, issued “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in the temporary closing of our headquarters, slowdowns and delays, travel restrictions and cancellation of

events, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on our personnel and personnel of partners to travel and access customers for training and case support; delays in approvals by regulatory bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our RxSight system. In addition, even after the “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19 are lifted, we may continue to experience disruptions to our business, including as a result of patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus.

As we continue to actively advance our clinical programs and discovery and research programs, we are in close contact with the third parties we engage with and are assessing the impact of the COVID-19 pandemic on each of our programs, expected timelines and costs on an ongoing basis. In light of ongoing developments relating to the COVID-19 pandemic, the focus of healthcare providers on fighting the virus, and consistent with the FDA’s industry guidance for conducting clinical trials issued in March 2020, updated subsequently, we and our contract research organizations have made certain adjustments to the operation of our clinical trials in an effort to ensure the monitoring and safety of patients and minimize risk to trial integrity during the pandemic and generally. Other COVID-related guidance recently released by FDA includes statistical considerations for clinical trials during the COVID-19 public health emergency and post-marketing adverse event reporting for medical products during a pandemic. We may need to make further adjustments in the future, including implementation of new policies and procedures.

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 further 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.

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.

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, 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 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. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the commercialization of our RxSight system and the further development of our current and future products could 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 employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such actual or perceived access, disclosure or other security breach or loss of information (whether affecting us or one of our third-party service providers) could result in legal claims proceedings, regulatory investigations, liability under laws that protect the privacy of personal information, significant regulatory penalties or other fines, 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, malware or ransomware), 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 misappropriately regulated, protected, or personally identifiable information, and may purposefully or inadvertently cause a breach 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 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 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, 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.

Adverse worldwide economic conditions, including those related to the COVID-19 pandemic, 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 keep limited components, sub-assemblies, materials and finished products on hand. 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, 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.

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

Recent Sales of Unregistered Securities

From April 1, 2021 through June 30, 2021, we granted to our employees and consultants options to purchase an aggregate of 7,260 shares of our common stock under our 2015 Equity Incentive Plan, at an exercise price of \$19.94 per share. On July 30, 2021, after the quarter ended, we granted each of our executive officers options to purchase an aggregate of 622,990 shares of our common stock under our 2021 Equity Incentive Plan, at an exercise price of \$16.00 per share.

From April 1, 2021 through June 30, 2021, we issued and sold to our employees, and consultants an aggregate of 30,215 shares of our common stock upon the exercise of options issued under our 2006 Stock Plan and 2015 Equity Incentive Plan at exercise prices ranging from \$3.93 to \$15.08, for an aggregate exercise price of \$0.1 million.

On August 3, 2021, certain of our stockholders cash exercised 63,728 warrants to purchase our Series H Preferred Stock at the exercise price of \$12.40 per share, and certain of our stockholders completed a cashless exercise of warrants to purchase 36,533 Series H Preferred Stock on August 3, 2021. The aggregate 100,261 shares of Series H Preferred Stock were subsequently converted into 100,261 shares of common stock prior to the closing of the IPO.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales and issuances of the above securities were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

On July 23, 2021, we effected a reverse stock split (the "Reverse Split") of our common stock (excluding Series G and Series W common stock) and convertible preferred stock on a 1-for-10.33 basis. The par values of the common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. No fractional shares were credited to stockholders as a result of the Reverse Split. Instead, any fractional shares owed to any of our stockholders as a result of the Reverse Split are to be paid in cash, on the basis of our \$16.00 per share IPO price, by a third-party paying agent.

Use of Proceeds

On August 3, 2021, after the quarter end, we completed our IPO, with a subsequent partial exercise of the underwriter's option to purchase additional shares. We issued and sold an aggregate of 8,248,549 shares of common stock, par value \$0.001 per share, at an offering price of \$16.00 per share. We received aggregate net proceeds of \$120.0 million, after deducting underwriters' discounts and commissions of \$9.2 million and estimated offering expenses of \$2.7 million.

We intend to use the net proceeds we received from our IPO to support our operations, including for commercial expansion, to fund product development, research activities and clinical development, and for working capital and general corporate purposes. We may use a portion of such net proceeds to invest in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. However, we do not have agreements or commitments for any material acquisitions or investments at this time. The representatives of the underwriters and joint book-running managers of our IPO were J.P. Morgan Securities LLC and BofA Securities, Inc. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to director offer letters and our outside director compensation policy.

There has been no material change in the planned use of the IPO proceeds as described in our prospectus dated July 29, 2021, as filed with the SEC pursuant to Rule 424(b) under the Securities Act (File No. 333-257790).

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 Quarterly Report on Form 10-Q unless otherwise stated.

EXHIBIT INDEX

Exhibit Number	Description	Form	Incorporated by Reference		Filing Date
			File No.	Exhibit	
3.1	<u>Amended and Restated Certificate of Incorporation of the Registrant.</u>	S-1	333-257790	3.2	July 9, 2021
3.2	<u>Amended and Restated Bylaws of the Registrant.</u>	S-1	333-257790	3.3	July 9, 2021
4.1	<u>Specimen stock certificate of the Registrant.</u>	S-1/A	333-257790	4.2	July 26, 2021
10.1+	<u>Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.</u>	S-1	333-257790	10.1	July 9, 2021
10.2+	<u>2015 Equity Incentive Plan of the registrant, as amended, and forms of agreement thereunder.</u>	S-1/A	333-257790	10.2	July 26, 2021
10.3+	<u>2021 Equity Incentive Plan of the registrant, as amended, and forms of agreement thereunder.</u>	S-1/A	333-257790	10.3	July 26, 2021
10.4+	<u>2021 Employee Stock Purchase Plan of the registrant.</u>	S-1/A	333-257790	10.4	July 26, 2021
10.5	<u>Loan and Security Agreement, by and among the Registrant, Oxford Finance LLC and the lenders listed on Schedule 1.1 thereto, dated as of October 29, 2020.</u>	S-1	333-257790	10.5	July 9, 2021
10.6	<u>Consent and First Amendment to Loan and Security Agreement, by and among the Registrant, Oxford Finance LLC and the lenders listed on Schedule 1.1 thereto, dated as of July 6, 2021.</u>	S-1/A	333-257790	10.6	July 26, 2021
10.7#	<u>License Agreement by and between the Registrant and the California Institute of Technology, dated as of July 28, 2015.</u>	S-1	333-257790	10.6	July 9, 2021
10.8#	<u>Exclusive License Agreement between the Regents of the University of California and the Registrant, dated as of March 1, 2000, as amended on May 29, 2008, December 5, 2013, November 10, 2016, April 4, 2017, June 21, 2017 and May 21, 2019.</u>	S-1	333-257790	10.7	July 9, 2021
10.9	<u>License and Maintenance Agreement between QAD, Inc. and its subsidiaries and the Registrant, dated as of October 29, 2015.</u>	S-1	333-257790	10.8	July 9, 2021

10.10	<u>QAD Hosted On Premise Project Proposal between Strategic Information Group and the Registrant, dated as of October 29, 2015.</u>	S-1	333-257790	10.9	July 9, 2021
10.11	<u>Cloud Services Agreement between QAD, Inc. and its subsidiaries and the Registrant, dated as of May 28, 2021.</u>	S-1	333-257790	10.10	July 9, 2021
10.12	<u>Lease, dated as of October 27, 2015, by and between the Registrant and Accuride International Inc., as amended by that certain First Amendment to Lease, dated November 23, 2015, that certain Second Amendment to Lease, dated December 22, 2015, that certain Third Amendment to Lease, dated January 18, 2016, and that certain Fourth Amendment to Lease, dated November 12, 2016, for premises located at 100-150 Columbia, Suites 100 and 200, Aliso Viejo, California 92656.</u>	S-1	333-257790	10.11	July 9, 2021
10.13	<u>Lease, dated as of March 27, 2020, by and between Pacific Park Investments, Inc. and the Registrant, for premises located at 75 Columbia, Aliso Viejo, California 92656.</u>	S-1	333-257790	10.12	July 9, 2021
10.14	<u>Lease, dated as of January 10, 2018, by and between the Registrant and Clifford D. Downs, as amended b that certain Commencement Date Memorandum dated as of February 22, 2018, for premises located at 5 Columbia, Aliso Viejo, California 92656.</u>	S-1	333-257790	10.13	July 9, 2021
10.15+	<u>Confirmatory Employment Letter, by and between the Registrant and Ron Kurtz, dated as of July 8, 2021.</u>	S-1	333-257790	10.14	July 9, 2021
10.16+	<u>Confirmatory Employment Letter, by and between the Registrant and Shelley Thunen, dated as of July 8, 2021.</u>	S-1	333-257790	10.15	July 9, 2021
10.17+	<u>Confirmatory Employment Letter, by and between the Registrant and Eric Weinberg, dated as of July 8, 2021.</u>	S-1	333-257790	10.16	July 9, 2021
10.18+	<u>Confirmatory Employment Letter, by and between the Registrant and Ilya Goldshleger, dated as of July 8, 2021.</u>	S-1	333-257790	10.17	July 9, 2021
10.19+	<u>Change in Control and Severance Agreement, by and between the Registrant and Ron Kurtz, dated as of July 8, 2021.</u>	S-1	333-257790	10.18	July 9, 2021
10.20+	<u>Change in Control and Severance Agreement, by and between the Registrant and Shelley Thunen, dated as of July 8, 2021.</u>	S-1	333-257790	10.19	July 9, 2021
10.21+	<u>Change in Control and Severance Agreement, by and between the Registrant and Eric Weinberg, dated as of July 8, 2021.</u>	S-1	333-257790	10.20	July 9, 2021

10.22+	Change in Control and Severance Agreement, by and between the Registrant and Ilya Goldshleger, dated as of July 8, 2021.	S-1	333-257790	10.21	July 9, 2021
10.23	Consulting Agreement, by and between the Registrant and Yelroc Consulting, Inc., dated as of January 1, 2019, as amended by that certain Amendment No. 1 to Consulting Agreement, dated as of December 16, 2020.	S-1	333-257790	10.22	July 9, 2021
10.24	Termination Agreement, by and between the Registrant and Yelroc Consulting, Inc., dated as of August 3, 2021.	S-1/A	333-257790	10.24	July 26, 2021
10.25	Consulting Agreement, by and between the Registrant and Daniel Schwartz, M.D., dated as of January 1, 2019, as amended by that certain Amendment No. 1, dated as of December 16, 2020.	S-1	333-257790	10.23	July 9, 2021
10.26	Amended and Restated Secured Full Recourse Promissory Note, by and between the Registrant and Daniel Schwartz, dated as of April 18, 2019.	S-1	333-257790	10.24	July 9, 2021
10.27	Share Forfeiture and Release Agreement, by and between the Registrant and Daniel Schwartz, dated as of July 23, 2021.	S-1/A	333-257790	10.27	July 26, 2021
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XXBRL 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).

* + Indicates management contract or compensatory plan.

Portions of the exhibit have been omitted as the Registrant has determined that: (i) the omitted information is not material; and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Blend Labs, 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 Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**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)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - b) (Paragraph omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a));
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my 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: September 9, 2021

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)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - b) (Paragraph omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a));
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my 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: September 9, 2021

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 June 30, 2021, as filed with the Securities and Exchange Commission (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 as of and for the period covered by the Report.

Date: September 9, 2021

By: _____ /s/ Ron Kurtz, M.D.
Ron Kurtz, M.D.
Chief Executive Officer
(Principal Executive 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 June 30, 2021, as filed with the Securities and Exchange Commission (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 as of and for the period covered by the Report.

Date: September 9, 2021

By: _____ /s/ Shelley Thunen

Shelley Thunen
Chief Financial Officer
(Principal Financial Officer)
