

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended April 3, 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: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

1212 Terra Bella Avenue
Mountain View, California
(Address of principal executive offices)

77-0210467
(I.R.S. Employer
Identification Number)

94043-1824
(Zip Code)

Registrant's telephone number, including area code: (650) 940-4700

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

Title of Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value \$0.01 per share	IRIX	Nasdaq Global Market

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

The number of shares of common stock, \$0.01 par value, issued and outstanding as of May 6, 2021 was 15,625,800.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential,” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our future financial performance, including our expectations regarding our revenue, cost of revenue, gross profit or gross margin, operating expenses (including changes in sales and marketing, research and development and general and administrative expenses), and our ability to achieve and maintain future profitability;
- the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand of our products, business operations, and results of operations;
- our ability to raise additional capital;
- customer acceptance and purchase of our existing products and new products;
- our ability to maintain and expand our customer base;
- competition from other products;
- the impact of foreign currency exchange rate and interest rate fluctuations on our results and sales;
- the pace of change and innovation in the markets in which we participate and the competitive nature of those markets;
- our business strategy and our plan to build our business;
- our ability to effectively manage our growth;
- the success of our strategic partnership with Topcon;
- our costs of manufacturing and reliance on third party manufacturers;
- our ability to forecast and meet product demand;
- our ability to discover defects in our products and systems;
- our international expansion and sales strategy;
- our operating results and cash flows;
- our beliefs and objectives for future operations;
- our relationships with third parties;
- our ability to maintain, protect, and enhance our intellectual property rights;
- our ability to maintain, protect, and enhance our information technology systems and data;
- our ability to maintain our facilities in good working order;
- our ability to recover the carrying value of goodwill;
- the impact of expensing stock options and other equity awards;
- our ability to successfully defend litigation brought against us;
- our ability to indemnify our directors and officers;
- our ability to repay indebtedness and have indebtedness forgiven;
- our ability to successfully expand in our existing markets and into new markets;
- sufficiency of cash to meet cash needs for at least the next 12 months;
- our ability to comply with laws, policies, and regulations that currently apply or become applicable to our business both in the United States and internationally;

- our ability to attract and retain qualified employees and key personnel, and source suppliers;
- the future trading prices of our common stock; and
- our ability to pay dividends in the future.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events, and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events, or circumstances could differ materially from those described 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 such statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to conform such statements to actual results or revised expectations, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

As used in this Quarterly Report on Form 10-Q, the terms “Company,” “IRIDEX,” “we,” “us” and “our” refer to IRIDEX Corporation, and its consolidated subsidiaries.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

IRIDEX Corporation
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands except share and per share data)

ASSETS	<u>April 3, 2021</u>	<u>January 2, 2021 (1)</u>
Current assets:		
Cash and cash equivalents	\$ 27,993	\$ 11,626
Accounts receivable, net of allowance for doubtful accounts of \$250 as of April 3, 2021 and \$244 as of January 2, 2021	8,185	7,289
Inventories	7,042	5,714
Prepaid expenses and other current assets	1,001	730
Total current assets	<u>44,221</u>	<u>25,359</u>
Property and equipment, net	719	449
Intangible assets, net	2,349	68
Goodwill	965	533
Operating lease right-of-use assets, net	1,228	1,428
Other long-term assets	77	132
Total assets	<u>\$ 49,559</u>	<u>\$ 27,969</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,687	\$ 1,148
Accrued compensation	1,873	1,965
Accrued expenses	1,447	990
Other current liabilities	2,274	816
Current portion of PPP loan	2,185	1,249
Accrued warranty	124	166
Deferred revenue	1,812	938
Operating lease liabilities	1,345	1,409
Total current liabilities	<u>12,747</u>	<u>8,681</u>
Long-term liabilities:		
PPP loan	312	1,248
Accrued warranty	81	81
Deferred revenue	10,653	289
Operating lease liabilities	95	282
Other long-term liabilities	22	22
Total liabilities	<u>23,910</u>	<u>10,603</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding 15,522,809 and 13,899,683 shares as of April 3, 2021 and January 2, 2021, respectively	165	148
Additional paid-in capital	84,419	74,181
Accumulated other comprehensive income (loss)	19	(19)
Accumulated deficit	(58,954)	(56,944)
Total stockholders' equity	<u>25,649</u>	<u>17,366</u>
Total liabilities and stockholders' equity	<u>\$ 49,559</u>	<u>\$ 27,969</u>

(1) Derived from the audited consolidated financial statements included in the Annual Report on Form 10-K filed with the SEC for the year ended January 2, 2021.

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

IRIDEX Corporation
Condensed Consolidated Statements of Operations
(Unaudited, in thousands except per share data)

	Three Months Ended	
	April 3, 2021	March 28, 2020
Total revenues	\$ 11,959	\$ 9,021
Cost of revenues	7,020	5,105
Gross profit	4,939	3,916
Operating expenses:		
Research and development	1,165	719
Sales and marketing	2,982	3,152
General and administrative	2,633	1,698
Total operating expenses	6,780	5,569
Loss from operations	(1,841)	(1,653)
Other income, net	(161)	9
Loss from operations before provision for income taxes	(2,002)	(1,644)
Provision for income taxes	8	7
Net loss	\$ (2,010)	\$ (1,651)
Net loss per share:		
Basic	\$ (0.14)	\$ (0.12)
Diluted	\$ (0.14)	\$ (0.12)
Weighted average shares used in computing net loss per common share:		
Basic	14,346	13,786
Diluted	14,346	13,786

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

IRIDEX Corporation
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited, in thousands)

	<u>Three Months Ended</u>	
	<u>April 3, 2021</u>	<u>March 28, 2020</u>
Net loss	\$ (2,010)	\$ (1,651)
Foreign currency translation adjustments	38	2
Comprehensive loss	<u>\$ (1,972)</u>	<u>\$ (1,649)</u>

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

IRIDEX Corporation
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited, in thousands, except share data)

For the three months ended April 3, 2021	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances, January 2, 2021	13,899,683	\$ 148	\$ 74,181	\$ (19)	\$ (56,944)	\$ 17,366
Issuance of common stock, net of issuance costs	1,618,122	16	9,862			9,878
Issuance of common stock under stock option plan	3,082	1	16			17
Employee stock-based compensation expense			366			366
Release of restricted stock, net of taxes paid	1,922		(6)			(6)
Other comprehensive income				38		38
Net loss					(2,010)	(2,010)
Balances, April 3, 2021	<u>15,522,809</u>	<u>\$ 165</u>	<u>\$ 84,419</u>	<u>\$ 19</u>	<u>\$ (58,954)</u>	<u>\$ 25,649</u>

For the three months ended March 28, 2020	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 28, 2019	13,785,233	\$ 147	\$ 73,093	\$ 80	\$ (50,615)	\$ 22,705
Employee stock-based compensation expense			95			95
Release of restricted stock, net of taxes paid	2,736		(2)			(2)
Other comprehensive income				2		2
Net loss					(1,651)	(1,651)
Balances, March 28, 2020	<u>13,787,969</u>	<u>\$ 147</u>	<u>\$ 73,186</u>	<u>\$ 82</u>	<u>\$ (52,266)</u>	<u>\$ 21,149</u>

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

IRIDEX Corporation
Condensed Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Three Months Ended	
	April 3, 2021	March 28, 2020
Operating activities:		
Net loss	\$ (2,010)	\$ (1,651)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	140	143
Stock-based compensation	366	95
Provision for doubtful accounts	—	42
Changes in operating assets and liabilities:		
Accounts receivable	(900)	2,292
Inventories	943	(35)
Prepaid expenses and other current assets	(271)	(290)
Operating lease right-of-use assets	200	302
Other long-term assets	53	11
Accounts payable	539	(1,091)
Accrued compensation	(91)	(681)
Accrued expenses	458	(28)
Accrued warranty	(42)	(140)
Deferred revenue	11,238	(108)
Operating lease liabilities	(251)	(343)
Other liabilities	1,458	29
Net cash provided by (used in) operating activities	<u>11,830</u>	<u>(1,453)</u>
Investing activities:		
Acquisition of property and equipment	(73)	(68)
Cash paid for business combination, net	(5,343)	—
Net cash used in investing activities	<u>(5,416)</u>	<u>(68)</u>
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	9,878	—
Proceeds from stock option exercise	17	—
Taxes paid related to net share settlements of equity awards	(6)	(2)
Net cash provided by (used in) financing activities	<u>9,889</u>	<u>(2)</u>
Effect of foreign exchange rate changes	64	9
Net decrease in cash and cash equivalents	16,367	(1,514)
Cash and cash equivalents, beginning of period	11,626	12,653
Cash and cash equivalents, end of period	<u>\$ 27,993</u>	<u>\$ 11,139</u>
Supplemental disclosure of non-cash activities:		
Transfer of inventory to property and equipment	\$ 27	\$ 48

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

IRIDEX Corporation
Notes to Unaudited Condensed Consolidated Financial Statements

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of IRIDEX Corporation (“IRIDEX”, the “Company”, “we”, “our”, or “us”) have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the financial statements have been included.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, together with management’s discussion and analysis of the Company’s financial condition and results of operations, contained in our Annual Report on Form 10-K for the fiscal year ended January 2, 2021, which was filed with the Securities and Exchange Commission (“SEC”) on March 23, 2021. The results of operations for the three months ended April 3, 2021 and March 28, 2020 are not necessarily indicative of the results for the fiscal year ending January 1, 2022 or any future interim period. The three months ended April 3, 2021 and March 28, 2020, each had 13 weeks. For purposes of reporting the financial results, the Company’s fiscal years end on the Saturday closest to the end of December. Periodically, the Company includes a 53rd week to a year in order to end that year on the Saturday closest to the end of December.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended January 2, 2021, which was filed with the SEC on March 23, 2021.

Financial Statement Presentation.

The unaudited condensed consolidated financial statements include the accounts of the Company and our wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that 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 that are not readily apparent from other sources. Actual results may differ from these estimates. In addition, any change in these estimates or their related assumptions could have an adverse effect on our operating results.

Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumables, service, and support activities. We also derive revenue from royalties from third parties which are typically based on licensees’ net sales of products that utilize our technology. Our revenue is recognized in accordance with Accounting Standards Codification (“ASC”) 606, “Revenue from Contracts with Customers.”

The Company has the following revenue transaction types: (1) Product Sale Only, (2) Laser Advantage Program (“LAP”), (3) Service Contracts, (4) System Repairs (outside of warranty), (5) Royalty Revenue and (6) Exclusive Distribution Rights.

- (1) **Product Sale Only:** The Company’s products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes. The Company’s products are currently sold for use by ophthalmologists specializing in the treatment of glaucoma and retinal diseases. Inside the United States and Germany the products are sold directly to the end users. In other countries outside of the United States and Germany, the Company utilizes independent, third-party distributors to market and sell the Company’s products. There is no continuing obligation subsequent to the shipment to these distributors.

The Company recognizes revenue from product sale at a point in time. When a system or disposables are sold without any additional deliverables, the Company recognizes revenue using the five-step model: (1) identifying the contract with the customer, (2) identifying the performance obligations in the contract, (3) determining expected transaction price, (4) allocating the transaction price to the distinct performance obligations in the contract, and (5) recognizing revenue when (or as) the performance obligations are satisfied.

- (2) LAP Program: The Company sometimes enters into LAP contracts with customers. Under the LAP program, the system is given away free of charge and title is transferred after the customer purchases the minimum required number of boxes of probes (classified as disposables). Customers with older machines have the ability to trade in their old machines for the most current laser equipment offered in the program (Cyclo G6 Laser) and receive a discount on the program's minimum purchase requirements. Under ASC 606, this non-cash consideration must be included in the transaction price. However, the Company has determined that there is no value associated with the old machines and the trade in is essentially offered to encourage customers to purchase more consumables under the program.

The Company recognizes revenue from product sales under the LAP program at a point in time. The Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

- (3) Service Contracts: The Company offers a standard two-year warranty on all system sales. The Company also offers a service contract which is sold to customers in incremental, one-year periods which begin subsequent to the expiration of the standard two-year warranty. The customer can opt to purchase the service contract at the time of the system sale or after the initial system sale.

The Company recognizes revenue from service contracts ratably over the service period. Revenue recognition for the sale of a service contract is largely dependent on the timing of the sale as follows:

- a. Service Contract Sale in Conjunction with System Sale: If the customer opts to purchase a service contract at the time of the system sale, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.
 - b. Service Contract Sale Subsequent to System Sale: If the customer opts to purchase a service contract after the initial system sale, the Company determines the amount of time that has elapsed since the initial system sale. If the service contract is purchased within 60 days of the initial sale, the Company considers this sale to be an additional element of the original sale and allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation. If the service contract is purchased subsequent to sixty days after the initial sale, the sale of the service contract is deemed a separate contract and is deferred at the selling price and recognized ratably over the extended warranty period as the performance obligation is satisfied.
- (4) System Repairs (outside of warranty): Customers will occasionally request repairs from the Company subsequent to the expiration of the standard warranty and outside of a service contract.

The Company recognizes revenue from system repairs (outside of warranty) at a point in time. When the customer requests repairs from the Company subsequent to the expiration of the standard warranty and outside of a service contract, these repair contracts are considered separate from the initial sale, and as such, revenue is recognized as the repair services are rendered and the performance obligation satisfied.

- (5) Royalty Revenue: The Company has royalty agreements with two customers related to sale of the Company's intellectual property. Under the terms of these agreements, the customer is to remit a percentage of sales to the Company.

Since these arrangements are for sales-based licenses of intellectual property, for which the guidance in paragraph ASC 606-10-55-65 applies, the Company recognizes revenue only as the subsequent sale occurs. However, the Company notes that such sales being reported by the licensee with a quarter in arrear, such revenue is recognized at the time it is reported and paid by the licensee given that any estimated variable consideration would have to be fully constrained due to the unpredictability of such estimate and the unavoidable risk that it may lead to significant revenue reversals.

- (6) Exclusive Distribution Rights: In March 2021, Company entered into a distribution agreement with Topcon Corporation ("Topcon"), pursuant to which the Company granted Topcon the exclusive right to distribute the Company's retina and glaucoma products in certain geographies outside the United States. The exclusivity arrangement with Topcon obligates the Company to provide training, customer support, and exclusive territorial rights to Topcon for certain international regions, for a period of 10 years, commencing upon regulatory approval to transfer existing (non-exclusive) distribution rights from the current distributors in those regions to Topcon. The agreement further stipulates that \$2.0 million of arrangement fee is to be refunded to Topcon in the event that regulatory approval for the Japan region is not obtained within nine months from the date of execution of the agreement. The Company has the right to terminate the exclusive distribution rights granted to Topcon for any of the regions at any point in time during the 10-year exclusivity term for a termination fee that is based on a multiple of 1.2X the revenue generated by the Company in 2019 for the respective region. Management has determined that the exclusivity rights, training, and customer support represents a single combined performance obligation for each region, to be recognized as exclusivity fee revenue on a straight-line basis over

the 10-year period for each region, commencing on the date that regulatory approval is obtained for each region, based on the Standalone Selling Price ("SSP") for such combined performance obligation for each region. The estimated fair value of the exclusive distribution rights for all regions combined totaled approximately \$14.8 million. Of this amount, management has fully-constrained the arrangement fee allocated to the Japan and Spain regions (totaling approximately \$3.5 million, of which \$1.5 million was recorded as customer deposit under other current liabilities) because of significant uncertainty regarding obtaining the necessary regulatory approvals and termination of existing distributor relationships in those regions. As of April 3, 2021, no revenue related to the exclusive distribution rights was recorded for the three months then ended.

The Company elected the practical expedient allowing it to not recognize as a contract asset the commission paid to its salesforce on the sale of its products as an incremental cost of obtaining a contract with a customer but rather recognize such commission as expense when incurred as the amortization period of the asset that the Company would have otherwise recognized is one year or less.

Leases.

We determine if an arrangement is a lease at inception. Operating leases are included in Operating lease right-of-use ("ROU") assets, net and Operating lease liabilities in our condensed consolidated balance sheets. As of April 3, 2021 and as of January 2, 2021, the Company was not a party to finance lease arrangements.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on information available at commencement date in determining the present value of lease payments. We use the implicit rate when readily determinable. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Under the available practical expedient, we account for the lease and non-lease components as a single lease component.

Concentration of Credit Risk.

Our cash and cash equivalents are deposited in demand and money market accounts. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and therefore, bear minimal risk.

We market our products to distributors and end-users throughout the world. Sales to international distributors are generally made on open credit terms and letters of credit. Management performs ongoing credit evaluations of our customers and maintains an allowance for potential credit losses. Historically, we have not experienced any significant losses related to individual customers or a group of customers in any particular geographic area. For the three months ended April 3, 2021, no single customer accounted for more than 10% of total revenues. For the three months ended March 28, 2020, one customer accounted for more than 10% of total revenues, representing 13%. As of April 3, 2021, two customers accounted for over 10% of our accounts receivable, representing 13% and 12%, respectively. As of January 2, 2021, one customer accounted for more than 10% of our accounts receivable, representing 13%.

Taxes Collected from Customers and Remitted to Governmental Authorities.

Taxes collected from customers and remitted to governmental authorities are recognized on a net basis in the accompanying condensed consolidated statements of operations.

Shipping and Handling Costs.

Our shipping and handling costs billed to customers are included in revenues and the associated expense is recorded in cost of revenues for all periods presented.

Deferred Revenue.

Deferred revenue represents contract liabilities and exclusivity fees. Revenue related to service contracts is deferred and recognized on a straight-line basis over the period of the applicable service contract. Costs associated with these service arrangements are recognized as incurred. Revenue related to exclusivity fees is deferred and recognized over the related exclusivity period.

A reconciliation of the changes in the Company's deferred revenue balance for the three months ended April 3, 2021 and March 28, 2020 is as follows:

	Three Months Ended	
	April 3, 2021	March 28, 2020
Balance, beginning of period	\$ 1,227	\$ 1,810
Additions to deferral	11,665	433
Revenue recognized	(427)	(535)
Deductions from reserves	-	(6)
Balance, end of period	12,465	1,702
Non-current portion of deferred revenue	10,653	320
Current portion of deferred revenue	<u>\$ 1,812</u>	<u>\$ 1,382</u>

During both the three months ended April 3, 2021 and March 28, 2020, approximately \$0.4 million were recognized pertaining to amounts deferred as of January 2, 2021 and December 28, 2019. As of April 3, 2021, approximately \$10.3 million and \$0.9 million of the non-current portion of deferred revenue and current portion of deferred revenue, respectively, pertains to exclusivity fee deferred revenue.

Warranty.

The Company currently provides a two-year full warranty on its products. The associated costs of these warranties are accrued for upon shipment of the products. The Company's warranty policy is applicable to products which are considered defective in their performance or fail to meet the product specifications. Warranty costs are reflected in the condensed consolidated statements of operations as cost of revenues.

A reconciliation of the changes in the Company's warranty liability for the three months ended April 3, 2021 and March 28, 2020 is as follows:

	Three Months Ended	
	April 3, 2021	March 28, 2020
Balance, beginning of period	\$ 247	\$ 536
Accruals for product warranties	19	31
Cost of warranty claims	(21)	(78)
Adjustment to pre-existing warranties	(40)	(93)
Balance, end of period	<u>\$ 205</u>	<u>\$ 396</u>

Reclassifications.

Certain reclassifications have been made to the prior year financial statements included in these condensed consolidated financial statements to conform to the current year presentation. The reclassifications had no impact on previously reported total assets, total liabilities and net loss or accumulated deficit.

Recently Adopted Accounting Standards.

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" as part of its initiative to reduce complexity in the accounting standards. The standard eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies and simplifies other aspects of the accounting for income taxes. The Company adopted ASU 2019-12 in fiscal year 2021 and the standard did not have a material impact on its condensed consolidated financial statements.

3. Significant Transactions

On March 2, 2021, the Company entered into a series of strategic transactions with Topcon, headquartered in Tokyo Japan, pursuant to which (i) the Company purchased substantially all of the tangible and intangible assets of Topcon Medical Laser Systems, Inc. ("TMLS") related to laser products previously manufactured and sold by TMLS, including the Pattern Scanning Laser (PASCAL) products, under the tradename "PASCAL" altogether, the "PASCAL Business", (ii) Topcon acquired an equity interest in the Company, comprised of the issuance of 1,618,122 shares of the Company's common stock at \$6.18 per share (as determined based on the average of the Nasdaq Official Closing Price of the Company's common stock for the five trading days immediately preceding March 2, 2021), and (iii) the Company granted Topcon the exclusive right to distribute certain of its products (including the PASCAL laser products) in certain international regions (the "Exclusive Distribution Rights") and (iv) Topcon and the Company entered into the Manufacturing Services Agreement regarding transition of regulatory authorizations relating to, and manufacturing and supply of,

the PASCAL products for a specified post-closing transition period. The transaction is expected to result in net proceeds to the Company of approximately \$19.5 million (of which \$17.5 million was received on March 10, 2021 with the remaining \$2.0 million expected to be received later only if, as of the exclusive distribution rights start date, the Company has (A) begun the process of transferring to Topcon the exclusive distribution right in Japan, which process shall be evidenced by a copy of a written notice or letter sent by the Company to the existing distributor in Japan under which it has exercised its right of termination or non-renewal in accordance with the terms of the applicable existing distributor agreement and (B) used its commercially reasonable efforts to obtain a written acknowledgement by such existing distributor to assign and transfer all supporting documents in such existing distributor's possession that are necessary for Topcon to effectuate the transfer of exclusive distribution rights to Topcon in Japan.). The net proceeds have been allocated on a fair value basis as follows (in thousands):

1) Sale of equity interest (before issuance costs)	\$ 10,000
2) Grant of exclusive distribution rights	14,800
3) Purchase of tangible and intangible assets	<u>(5,343)</u>
Net Proceeds	<u>\$ 19,457</u>

The purchase of tangible and intangible assets has been recognized as an acquisition of a business with the relative fair value of the net consideration allocated to the tangible and intangible assets based on their preliminary estimated fair values as of the acquisition date.

Refer to Note 2. Summary of Significant Accounting Policies for the recognition of revenue under ASC 606 for the grant of exclusive distribution rights.

Acquisition of substantially all of TMLS' assets including the rights to the PASCAL product.

On March 10, 2021, the Company completed the purchase of substantially all of the tangible and intangible assets of TMLS, which was an established leader in manufacturing and selling laser products under the tradename "PASCAL". The acquisition has been recognized as an acquisition of a business and the purchase price (approximately \$5.3 million) has been preliminarily allocated to tangible and identified intangible assets acquired based on their estimated fair values. As additional information becomes available, the Company may further revise the preliminary purchase price allocation during the remainder of the measurement period (which will not exceed 12 months from March 10, 2021). Any such revisions or changes may be material.

The following table presents the preliminary allocation of the total purchase price:

	Estimated Fair Value (in thousands)
Inventory	\$ 2,319
Computers and Software	102
Manufacturing and Office Equipment	112
Other tangible assets	78
Developed Technology	900
In-process Research and Development (IPR&D)	1,000
Trade names and Trademarks	300
Customer Relationships	100
Goodwill	<u>432</u>
Total	<u>\$ 5,343</u>

Developed technology relates to PASCAL products, a pattern scanning laser used for retinal treatments, and was valued using the multi-period excess earnings method under the income approach. This method reflects the present value of the projected cash flows that are expected to be generated by the developed technology less charges representing the contribution of other assets to those cash flows. The economic useful life is estimated to be 7 years, as determined based on the technology cycle related to the developed technology, and the estimated cash flows over the forecast period.

IPR&D pertains to an upcoming release of PASCAL products and has been valued using the multi-period excess earnings method under the income approach.

Trade names and Trademarks pertain to the "PASCAL" trade name, and the fair value was determined by applying the relief-from-royalty method under the income approach. The economic useful life is estimated to be 9 years, based on the expected life of the trade name and the cash flows anticipated over the forecast period.

Customer relationships represent the fair value of future projected revenue that will be derived from sales of products to existing customers of the TMLS Business, with an estimated useful life of 7 years.

Goodwill is primarily attributable to the assembled workforce and anticipated synergies and economies of scale expected from the integration of the TMLS Business. Substantially all goodwill is deductible for tax purposes.

4. Inventories

The components of the Company's inventories as of April 3, 2021 and January 2, 2021 are as follows:

	April 3, 2021	January 2, 2021
Raw materials	\$ 3,827	\$ 2,236
Work in process	534	548
Finished goods	2,681	2,930
Total inventories	<u>\$ 7,042</u>	<u>\$ 5,714</u>

5. Goodwill and Intangible Assets

Goodwill.

The carrying value of goodwill was \$1.0 million and \$0.5 million as of April 3, 2021 and January 2, 2021, respectively.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. The Company reviews goodwill for impairment on an annual basis or whenever events or changes in circumstances indicate the carrying value may not be recoverable. The Company performs an annual impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceed the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, income tax effects from any tax-deductible goodwill carrying amount of the reporting unit should be considered when measuring the goodwill impairment loss, if applicable. The Company has determined that it has a single reporting unit for purposes of performing its goodwill impairment test. As the Company uses the market approach to assess impairment, its common stock price is an important component of the fair value calculation. If the Company's stock price continues to experience significant price and volume fluctuations, this will impact the fair value of the reporting unit and can lead to potential impairment in future periods. The Company performed its annual impairment test during the second quarter of fiscal year 2020 and determined that its goodwill was not impaired.

In March 2021, the Company recorded approximately \$0.4 million goodwill in connection with its purchase of the PASCAL Business. As of April 3, 2021, the Company had not identified any factors that indicated there was an impairment of its goodwill and determined that no additional impairment analysis was then required.

Intangible Assets.

The following table summarizes the components of gross and net intangible asset balances (in thousands):

	April 3, 2021			Remaining Amortization Life	January 2, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Customer relationships	\$ 340	\$ 177	\$ 163	5.77 Years	\$ 240	\$ 172	\$ 68
Developed technology	900	11	889	6.92 Years			
Trade names	300	3	297	8.92 Years			
In-process R&D	1,000	—	1,000	Not applicable			
	<u>\$ 2,540</u>	<u>\$ 191</u>	<u>\$ 2,349</u>		<u>\$ 240</u>	<u>\$ 172</u>	<u>\$ 68</u>

For the three months ended April 3, 2021 and March 28, 2020, amortization expense totaled \$19 thousand and \$4 thousand, respectively.

The amortizations of customer relationships and trade names were charged to sales and marketing expense. The amortization for developed technology was charged to research and development expense. Future estimated amortization expense excluding in-process R&D (in thousands):

Fiscal Year:		
2021 (nine months)	\$	144
2022		192
2023		192
2024		192
2025		180
Thereafter		449
Total	\$	<u>1,349</u>

6. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.
- Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The carrying amounts of the Company's financial assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses as of April 3, 2021 and January 2, 2021, approximate fair value because of the short maturity of these instruments. The carrying amount of the Company's PPP loan as of April 3, 2021, approximates its fair value based on the specified interest rate.

As of April 3, 2021 and January 2, 2021, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above were as follows:

(in thousands)	As of April 3, 2021				As of January 2, 2021			
	Fair Value Measurements				Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	\$ 27,657	\$ —	\$ —	\$ 27,657	\$ 11,051	\$ —	\$ —	\$ 11,051

The Company's Level 1 financial assets are money market funds whose fair values are based on quoted market prices. The Company does not have any Level 2 and Level 3 financial assets or liabilities.

7. PPP Loan

On April 23, 2020, the Company qualified for and received a loan pursuant to the Paycheck Protection Program, a program implemented by the U.S. Small Business Administration under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, from a qualified lender (the "PPP Lender"), for an aggregate principal amount of approximately \$2.5 million (the "PPP Loan"). The PPP Loan bears interest at a fixed rate of 1.0% per annum, with the first six months of interest deferred, has a term of two years, and is

unsecured and guaranteed by the U.S. Small Business Administration. The principal amount of the PPP Loan is subject to forgiveness under the Paycheck Protection Program upon the Company's request to the extent that the PPP Loan proceeds are used to pay expenses permitted by the Paycheck Protection Program, including payroll costs, covered rent and mortgage obligations, and covered utility payments incurred by the Company. On September 22, 2020, the Company submitted the PPP Loan forgiveness application for the entire amount of approximately \$2.5 million. The accrued interest is \$23 thousand as of April 3, 2021. The Company cannot provide assurance that principal and interest amounts under the PPP Loan will be forgiven. To the extent that all or part of the PPP Loan is not forgiven, the Company will be required to pay interest on the PPP Loan at a rate of 1.0% per annum, and starting in September 2021 principal and interest payments will be required through the maturity date in April 2022. The terms of the PPP Loan provide for customary events of default including, among other things, payment defaults, breach of representations, and insolvency events.

The U.S. Department of the Treasury has announced that it will conduct audits for PPP loans that exceed \$2 million. Should the Company be audited or reviewed by the U.S. Department of the Treasury or the U.S. Small Business Administration as a result of the SBA Loan or filing the application for forgiveness or otherwise and receive an adverse outcome in such an audit, we could be required to return the full amount of the SBA Loan and may potentially be subject to civil and criminal fines and penalties.

8. Commitments and Contingencies

COVID-19.

The COVID-19 pandemic has created and may continue to create significant uncertainty in global markets, which has disrupted and harmed, and may continue to disrupt and harm, the Company's business, financial condition, and results of operations. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including but not limited to the duration and spread of the outbreak, duration of local, state and federal issued public health orders, impact on our customers and our sales cycles, impact on our employees and impact on regional and worldwide economies and markets in general, all of which are uncertain and cannot be predicted.

Operating Lease Commitments.

Our operating lease commitments consist of facility and office equipment leases. Operating lease expenses for the three months ended April 3, 2021 and March 28, 2020 were approximately \$0.3 million during each period. The weighted average discount rate used in calculating the present value of lease payments was 5.4%. As of April 3, 2021, the weighted average remaining lease term for our operating leases was 1.1 years.

The following represents maturities of operating lease liabilities as of April 3, 2021 (in thousands):

Fiscal Year	Operating Lease Payments
Remainder of 2021 (9 months)	\$ 1,131
2022	302
2023	50
2024	3
2025	—
Total lease payments	1,486
Less: Imputed interest	(46)
Total lease liabilities	\$ 1,440

On April 30, 2021, the First Amendment to that certain Triple Net Lease dated April 26, 2017 between the Company and ZIC 1212 Terra Bella LLC ("First Amendment") was executed, among other things, to reduce the portion of premises leased by the Company and extend the lease term through August 31, 2024.

Pursuant to the First Amendment, the base monthly rent for the reduced premises of approximately 29,830 square feet, ranges from \$84,121 to \$93,070, for the period May 1, 2021 to August 31, 2024. The Company is also responsible for the payment of certain operating expenses and taxes during the term. The Lease provides the landlord with a termination right, which can be exercised by the landlord by giving written notice to the Company at least thirty (30) months prior to the effective date of the termination.

Purchase Commitments.

Our purchase commitments consist primarily of non-cancellable purchase commitments with vendors to manufacture certain components and ophthalmic instrumentation. As of April 3, 2021, our future minimum payments through fiscal year 2022 for our purchase commitments were approximately \$13.9 million.

Indemnities.

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 parties (generally our business partners or customers) in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to our products. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments that we could be required to make under these agreements 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 estimated fair value of these agreements is minimal.

We have entered into indemnification agreements with our directors and officers that may require us to indemnify our directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature. These agreements also require us to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified and to make good faith determination whether or not it is practicable for us to obtain directors and officers insurance. We currently have directors and officers liability insurance.

Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

9. Stockholders' Equity and Stock-Based Compensation

Stock-Based Compensation

The Company accounts for stock-based compensation granted to employees and directors, including employees stock option awards, restricted stock and restricted stock units ("RSUs") in accordance with ASC 718, "Compensation – Stock Compensation" ("ASC 718"). Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee's service period. The Company recognizes compensation expense on a ratable basis over the requisite service period of the award.

The Company values options using the Black-Scholes option pricing model. Time-based RSUs are valued at the grant date fair value of the underlying common shares. Performance-based RSUs without market conditions are valued at grant date fair value of the underlying common shares. Performance-based RSUs granted with market conditions and performance-based stock options with market conditions are valued using the Monte Carlo simulation model. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, including the option's expected term and the price volatility of the underlying stock. The Monte Carlo simulation model incorporates assumptions for the holding period, risk-free interest rate, stock price volatility and dividend yield.

2008 Equity Incentive Plan.

The terms of awards granted during the three months ended April 3, 2021 were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended January 2, 2021.

The following table shows stock-based compensation expense included in the condensed consolidated statements of operations for the three months ended April 3, 2021 and March 28, 2020:

(in thousands)	Three Months Ended	
	April 3, 2021	March 28, 2020
Cost of revenues	\$ 47	\$ 24
Research and development	36	(31)
Sales and marketing	98	39
General and administrative	185	63
	<u>\$ 366</u>	<u>\$ 95</u>

Stock-based compensation expense capitalized to inventory was immaterial for the three months ended April 3, 2021 and March 28, 2020.

As of April 3, 2021, there was \$1.6 million of total unrecognized compensation cost, net of expected forfeitures, related to non-vested stock-based compensation arrangements. The cost is expected to be recognized over a weighted average period of 2.02 years.

Summary of Stock Options.

The following table summarizes stock options information during the three months ended April 3, 2021:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding as of January 2, 2021	1,649,540	\$ 4.67	
Granted	16,000	4.90	
Exercised	(3,082)	5.29	
Canceled or forfeited	(99,061)	4.54	
Outstanding as of April 3, 2021	1,563,397	\$ 4.68	\$ 4,538

The weighted average grant date fair value of the options granted was \$2.74 and \$1.05 per share for the three months ended April 3, 2021 and March 28, 2020, respectively.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock-based awards (options) with the following weighted average assumptions:

	Three Months Ended	
	April 3, 2021	March 28, 2020
Average risk free interest rate	0.74%	0.46%
Expected life (in years)	4.45 years	4.55 years
Dividend yield	—%	—%
Average volatility	72%	57%

Performance stock options granted with market conditions are valued using a Monte Carlo simulation model in combination with a Black-Scholes option pricing model.

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of the Company's stock price history over a period commensurate with the expected term of the options, trading volume of the Company's stock, look-back volatilities and Company-specific events that affected volatility in a prior period. The expected term of employee stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the history of exercises and cancellations on all past option grants made by the Company, the contractual term, the vesting period and the expected remaining term of the outstanding options. The risk-free interest rate is based on the U.S. Treasury interest rates whose term is consistent with the expected life of the stock options. No dividend yield is included as the Company has not issued any dividends and does not anticipate issuing any dividends in the future.

Information regarding stock options outstanding, vested, expected to vest, and exercisable as of April 3, 2021 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
Options outstanding	1,563,397	\$ 4.68	5.82	\$ 4,538
Options vested and expected to vest	1,353,572	\$ 4.78	5.61	\$ 3,875
Options exercisable	447,476	\$ 7.11	3.57	\$ 658

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of April 3, 2021, that would have been received by option holders had all option holders exercised their stock options as of that date. This amount changes based on the fair market value of the Company's common stock. The total intrinsic value of options exercised for the three months ended April 3, 2021 and March 28, 2020 was approximately \$6 thousand and \$0 thousand, respectively.

Summary of RSUs and Awards

Information regarding RSUs activity for the three months ended April 3, 2021 is summarized below:

	<u>Number of Shares</u>
Outstanding as of January 2, 2021	524,851
RSUs granted	6,450
RSUs released	(2,833)
RSUs forfeited	(54,312)
Outstanding as of April 3, 2021	<u>474,156</u>

10. Income Taxes

Provision for Income Tax.

The Company calculates its interim tax provision in accordance with the provisions of ASC 740-270, *Income Taxes; Interim Reporting*. For interim periods, the Company estimates its annual effective income tax rate and applies the estimated rate to the year-to-date income or loss before income taxes. The Company also computes the tax provision or benefit related to items reported separately and recognizes the items net of their related tax effect in the interim periods in which they occur. The Company also recognizes the effect of changes in enacted tax laws or rates in the interim periods in which the changes occur. The Company recorded a provision for income tax of \$8 thousand and \$7 thousand for the three months ended April 3, 2021 and March 28, 2020, respectively.

Deferred Income Taxes.

The Company accounts for income taxes in accordance with ASC topic 740, *Income Taxes* (“ASC 740”), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. As of the first quarter of fiscal year 2021, based on the Company’s recent history of losses and its forecasted losses, management believes on the more likely than not basis that a full valuation allowance is required. Accordingly, the Company continues to provide a full valuation allowance on its federal and states deferred tax assets.

Uncertain Tax Positions.

The Company accounts for its uncertain tax positions in accordance with ASC 740. As of January 2, 2021, the Company had \$1.2 million of unrecognized tax benefits, none of the unrecognized tax benefits would result in a change in the Company’s effective tax rate if recognized in future years.

The Company is not aware of any other uncertain tax positions that could result in significant additional payments, accruals, or other material deviation in this estimate during the fiscal year.

CARES Act.

On March 27, 2020, the CARES Act was signed into law. The CARES Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. These provisions are not expected to have a material effect on the Company’s consolidated financial statements. The Company obtained a PPP Loan. A portion, or all, of the PPP Loan may be forgiven. The Company cannot provide assurance that principal and interest amounts under the PPP Loan will be forgiven. If the PPP Loan is forgiven, the Company may qualify to not include the debt forgiveness income as taxable income. Given the Company has a full valuation allowance, the impact of the PPP Loan is not expected to be material.

The Company is subject to United States federal income tax as well as to income taxes in state jurisdictions. The Company’s federal and state income tax returns are open to examination by tax authorities for three years and three-to-five years, respectively.

11. Computation of Basic and Diluted Net Loss Per Common Share

Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding during the period. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options, and the release (vesting) of RSUs and awards and are calculated under the treasury stock method. Common stock equivalent shares from unexercised stock options, and unvested RSUs and awards are excluded from the computation for periods in which we incur a net loss or if the exercise price of such options is greater than the average market price of our common stock for the period as their effect would be anti-dilutive.

For the three months ended April 3, 2021 and March 28, 2020, potential shares from stock options and RSUs totaling 1,635,558 and 1,215,607 shares, respectively, were excluded from the computation of diluted weighted average shares outstanding.

A reconciliation of the numerator and denominator of basic and diluted net loss per common share is provided as follows:

(in thousands except per share data)	Three Months Ended	
	April 3, 2021	March 28, 2020
Numerator:		
Net loss	\$ (2,010)	\$ (1,651)
Denominator:		
Weighted average shares of common stock (basic)	14,346	13,786
Weighted average shares of common stock (diluted)	14,346	13,786
Per share data:		
Basic net loss per share	\$ (0.14)	\$ (0.12)
Diluted net loss per share	\$ (0.14)	\$ (0.12)

12. Business Segments

The Company operates in one segment, ophthalmology. The Company develops, manufactures and markets medical devices. Our revenues arise from the sale of consoles, delivery devices, consumables, service, and support activities.

Revenue information shown by product group is as follows:

(in thousands)	Three Months Ended	
	April 3, 2021	March 28, 2020
Cyclo G6	\$ 3,349	\$ 2,923
Retina	6,660	4,134
Other(1)	1,950	1,964
Total revenues	\$ 11,959	\$ 9,021

(1) Includes service contract revenues of \$299 and \$315 recognized during the three months ended April 3, 2021 and March 28, 2020, respectively. Other also includes revenues from paid service, royalty, freight and legacy G probes.

Revenue information shown by geographic region, based on the sales destination, is as follows:

(in thousands)	Three Months Ended	
	April 3, 2021	March 28, 2020
United States	\$ 5,564	\$ 4,441
Europe	2,417	1,984
Rest of Americas	804	403
Asia/Pacific Rim	3,174	2,193
Total revenues	\$ 11,959	\$ 9,021

Revenues are attributed to countries based on the location of end customers.

Other than the United States, Japan accounted for more than 10% of the Company's revenues during the three months ended April 3, 2021, representing 17%. Other than the United States, Japan accounted for more than 10% of the Company's revenues during the three months ended March 28, 2020, representing 13%. The United States accounted for 46.5% and 49.2% of revenues for the three months ended April 3, 2021 and March 28, 2020, respectively. International sales accounted for 53.5% and 50.8% of revenues for the three months ended April 3, 2021 and March 28, 2020, respectively.

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

Overview

IRIDEX Corporation is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures used to treat sight-threatening eye conditions, including glaucoma and retinal diseases. Certain of our products are powered by our proprietary MicroPulse technology, which is a method of delivering laser energy using a mode which chops the continuous wave laser beam into short, microsecond-long laser pulses. Our products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes.

Our laser consoles consist of the following product lines:

- **Glaucoma** – This product line includes our Cyclo G6 laser system used for the treatment of glaucoma;
- **Medical Retina** – Our medical retina product line includes our IQ 532 and IQ 577 laser photocoagulation systems, which are used for the treatment of diabetic macular edema and other retinal diseases; and
- **Surgical Retina** – Our surgical retina line of products includes our OcuLight TX, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. These systems are often used in vitrectomy procedures, which are used to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments.

Our business generates recurring revenues through sales of consumable products, predominantly single-use laser probe devices and other instrumentation, as well as repair, servicing and extended service contracts for our laser systems. Our laser probes consist of the following product lines:

- **Glaucoma** – Probes used in our glaucoma product line include our patented MicroPulse P3 (“MP3”) probe and G-Probe; and
- **Surgical Retina** – Our surgical retina probes include our EndoProbe family of products used in vitrectomy procedures.

Ophthalmologists typically use our laser systems in hospital operating room (“OR”) and ambulatory surgical centers (“ASCs”), as well as their offices and clinics. In the ORs and ASCs, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a consumable, single use MP3 probe, G-Probe or EndoProbe.

Our products are sold in the United States and Germany predominantly through a direct sales force and internationally (aside from Germany) primarily through independent distributors.

Sales to international distributors are made on open credit terms or letters of credit and are currently denominated in U.S. dollars and accordingly, are not subject to risks associated with currency fluctuations. However, increases in the value of the U.S. dollars against any local currencies could cause our products to become relatively more expensive to customers in a particular country or region, leading to reduced revenue or profitability in that country or region. Sales to direct end users transacted through our German office are denominated in Euros and are subject to risks associated with the currency fluctuations.

Cost of revenues consists primarily of our direct manufacturing costs which includes the cost of components and sub-systems, assembling, packaging, shipping and testing components at our facility, direct labor and associated overhead, warranty, royalty and amortization of intangible assets and depot service costs. For certain of our products, we are responsible for the cost of the fully assembled product that is manufactured by a third-party.

Research and development expenses consist primarily of personnel costs, materials to support new product development and research support provided to clinicians at medical institutions developing new applications which utilize our products and regulatory expenses. Research and development costs have been expensed as incurred.

Sales and marketing expenses consist primarily of costs of personnel, sales commissions, travel expenses, advertising and promotional expenses.

General and administrative expenses consist primarily of costs of personnel, legal, accounting and other public company costs, insurance and other expenses not allocated to other departments.

Impact of COVID-19 to our Business

The COVID-19 pandemic continues to create significant uncertainty in global markets, which has disrupted and harmed, and may continue to disrupt and harm, the Company’s business, financial condition, and results of operations. The extent of the impact of COVID-19 on the Company’s operational and financial performance will depend on certain developments, including but not limited to the duration and spread of the outbreak, duration of local, state and federal issued public health orders, impact on our customers and our sales cycles, impact on our employees and impact on regional and worldwide economies and markets in general, all of which are uncertain and cannot be predicted.

We expect our results of operations to be impacted for so long as the COVID-19 pandemic continues.

For more information on risks associated with the COVID-19 outbreak, see the section titled “Risk Factors” in Item 1A of Part II.

Results of Operations

The following table sets forth certain operating data as a percentage of revenues:

	Three Months Ended	
	April 3, 2021	March 28, 2020
Total revenues	100.0%	100.0%
Cost of revenues	58.7%	56.6%
Gross margin	41.3%	43.4%
Operating expenses:		
Research and development	9.7%	8.0%
Sales and marketing	24.9%	34.9%
General and administrative	22.0%	18.8%
Total operating expenses	56.6%	61.7%
Loss from operations	(15.3%)	(18.3%)
Other income, net	(1.3%)	0.1%
Loss from operations before provision for income taxes	(16.6%)	(18.2%)
Provision for income taxes	0.1%	0.1%
Net loss	(16.7%)	(18.3%)

The following comparisons are between the three months ended April 3, 2021 and March 28, 2020:

Revenues.

(in thousands)	Three Months Ended April 3, 2021	Three Months Ended March 28, 2020	Change in \$	Change in %
Cyclo G6	\$ 3,349	\$ 2,923	\$ 426	14.6%
Retina	6,660	4,134	2,526	61.1%
Other	1,950	1,964	(14)	(0.7%)
Total revenues	\$ 11,959	\$ 9,021	\$ 2,938	32.6%

Our total revenues increased by \$2.9 million, or 32.6%, from \$9.0 million to \$12.0 million. Revenues from retina products increased 61.1%, primarily due to inclusion of PASCAL product revenue from our acquisition of TMLS assets and strength of Iridex Retina products, particularly in the international markets. Revenues from Cyclo G6 products increased 14.6%, as a result of strong performance of our Cyclo G6 Probes in both the US and Internationally. Other revenues, comprised of service, royalty, freight and legacy G probes, was flat year over year.

While we believe that demand for our products remains and our outlook has improved, the overall capital expenditure landscape within hospitals, surgi-centers and physician offices is still being impacted by the general level of uncertainty brought on by COVID-19. Until this stabilizes, we anticipate capital expenditures may continue to be deferred.

Gross Profit and Gross Margin.

Gross profit increased by \$1.0 million, or 26.1%, from \$3.9 million to \$4.9 million. Gross margin decreased by 2.1 percentage points from 43.4% to 41.3%. The decrease in gross margin was primarily attributable to a shift in geographic mix and product mix.

Gross margins are expected to fluctuate due to changes in the relative proportion of domestic and international sales, the product mix of sales, introduction of new products, manufacturing variances, total unit volume changes that lead to greater or lesser production efficiencies and other factors.

Research and Development.

Research and development (“R&D”) expenses increased by \$0.4 million, or 62.0%, from \$0.7 million to \$1.2 million. The increase in spending was primarily attributable to increased level of spending on laser systems and inclusion of R&D expense from our acquisition of PASCAL Business.

Sales and Marketing.

Sales and marketing expenses decreased by \$0.2 million, or 5.4%, from \$3.2 million to \$3.0 million. The decrease was primarily attributable to ongoing pause in marketing activities due to COVID-19 relative to prior year.

General and Administrative.

General and administrative expenses increased by \$0.9 million, or 55.1%, from \$1.7 million to \$2.6 million. The increase in spending was primarily attributable to an increase in legal and consulting expenses associated with PASCAL Business acquisition and execution of the Exclusive Distribution agreement with Topcon.

Other Income (Expense), Net.

Other expense, net was \$0.2 million, compared to other income, net of \$9 thousand. Other income (expense), net, consisted primarily of interest income or expense, foreign currency gain or loss.

Income Taxes.

We recorded an income tax provision of \$8 thousand and \$7 thousand, respectively.

Liquidity and Capital Resources.

Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing or to raise capital.

As of April 3, 2021, we had cash and cash equivalents of \$28.0 million and working capital of \$31.5 million compared to cash and cash equivalents of \$11.6 million and working capital of \$16.7 million as of January 2, 2021.

Net cash provided by operating activities was \$11.8 million in the three months ended April 3, 2021 compared to net cash used in operating activities of \$1.5 million in the three months ended March 28, 2020. The increase in net cash provided by operating activities, expressed in direct cash flow terms, was primarily due to the payment received for the distribution exclusivity fee and timing of vendor payments.

For the three months ended April 3, 2021, net cash used in investing activities was \$5.4 million, which consisted primarily of the purchase of PASCAL Business. Net cash used in investing activities for the three months ended March 28, 2020 was \$0.1 million, which consisted of capital expenditures.

For the three months ended April 3, 2021, net cash provided by financing activities was \$9.9 million, primarily from the net proceeds arising from the issuance of common stock. For the three months ended March 28, 2020, net cash used in financing activities was immaterial.

We have historically funded our operations primarily through sales of our products to customers, and through common stock and borrowing arrangements. As of April 3, 2021, our principal sources of liquidity consisted of cash and cash equivalents of \$28.0 million. We have incurred net losses over the last several years, and as of April 3, 2021, have an accumulated deficit of approximately \$58.9 million. We expect to continue to incur operating losses and negative cash flows from operations through April 2, 2022.

We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs over the next 12 months. Our future capital requirements will depend on many factors, including our growth rate, the timing and extent of our spending to support research and development activities, the timing and cost of establishing additional sales and marketing capabilities, the introduction of new and enhanced products and our costs to implement new manufacturing technologies. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us or at all. Any debt financing obtained by us in the future could also involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. Additionally, if we raise additional funds through further issuances of equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to grow or support our business and to respond to business challenges could be significantly limited.

Off-Balance Sheet Arrangements.

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information called for by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Principal Executive Officer and our Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and our Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of April 3, 2021. Based on the foregoing, our Principal Executive Officer and our Principal Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Risk Factor Summary

Our business operations are subject to numerous risks, factors and uncertainties outside of our control that could cause our actual results to be harmed, including risks regarding the following:

General economic factors

- the COVID-19 pandemic and responsive measures;
- the success of our partnership with Topcon; and
- natural disasters, economic downturns, public health crises or political crises.

Operational factors

- our relationship with our strategic partner and distributor, Topcon;
- quality control and production issues;
- the complexity of our laser systems;
- defects in our laser systems;
- costs, sales volumes, results of operations, and revenues;
- direct and independent sales forces and a network of international distributors to sell our products;
- our growth;
- dependence on international sales;
- new products and applications and improving existing products;
- fluctuations in our sales and operating results;
- the ophthalmology market;
- competition in our industry;
- the collaborative relationships used to enhance products and applications;
- the loss of key personnel;
- meeting product demand;
- dependence on sole source and limited source suppliers;
- disruptions to our information technology system and breaches of data security;
- maintaining relationships with health care providers;
- the misuse of our products;
- our reputation and brand;
- the inability of our customers to obtain credit or material increases in interest rates; and
- recalls of our products.

Regulatory and Legal factors

- healthcare reform measures;
- third-party coverage and reimbursement policies;
- compliance with healthcare laws;
- our compliance with potential governmental, regulatory and other legal proceedings relative to advertising, promotion and marketing;
- patents and proprietary rights related to our intellectual property;
- compliance with government regulations, including the FDA's quality system regulation and laser performance standards;
- regulatory approval for clinical trials;
- compliance with product liability claims;

- developments in trade policies;
- tax laws;
- federal, state and foreign laws; and
- environmental requirements.

Financing and Transactional Risks

- our ability to repay indebtedness and have indebtedness forgiven;
- efforts to acquire additional companies or product lines;
- divestitures of our businesses or product lines;
- raising additional capital; and
- provisions in our charter documents, Delaware law and contractual provisions that could delay or prevent an acquisition or sale of our company.

Governance Risks and Risks related to Ownership of our Common Stock

- the volatility of the trading price of our common stock;
- our intention not to pay dividends for the foreseeable future;
- the publication of research about us by analysts;
- the concentration of ownership of our common stock; and
- our ability to maintain an effective system of internal control over financial reporting.

Factors That May Affect Future Results

In addition to the other information contained in this Quarterly Report on Form 10-Q, we have identified the following risks and uncertainties that may have a material adverse effect on our business, common stock price, financial condition or results of operations. You should carefully consider the risks described below before making an investment decision.

Risks Relating to our Business

The effects of the COVID-19 pandemic have disrupted, and may continue to significantly disrupt, our operations, including our ability to manufacture and supply products and perform research and development activities, our customers' usage of our products as demand declines in elective surgeries in response to COVID-19, all of which have had and expected to continue to have a material and adverse effect on our business, future revenues and financial condition. We are unable to predict the extent to which the pandemic and related impacts will continue to adversely impact our business operations, financial performance, results of operations, financial position and the achievement of our strategic objectives.

Our business, results of operation and financial performance have been negatively impacted by the COVID-19 pandemic and related public health responses, such as shelter-in-place orders, social distancing protocols, and travel restrictions in many of the countries and regions in which we have operations or manufacturing partners. Due to these impacts and measures, we have experienced and may continue to experience significant and unpredictable reductions in the demand for our products as healthcare customers divert medical resources and priorities towards the treatment of diseases related to COVID-19. In addition, our customers may delay, cancel or redirect planned capital expenditures in order to focus resources on COVID-19 or in response to economic disruption related to COVID-19. For example, during the fiscal year ended January 2, 2021, we experienced significant decline in treatment and procedure volume worldwide, as healthcare systems diverted resources to meet the increasing demands of managing COVID-19. In addition, the American College of Surgeons, U.S. surgeon general, and medical societies are evaluating the risks of minimally invasive surgeries in the presence of infectious diseases, which we expect will continue to negatively impact the usage of our products and the number of ophthalmic treatments and procedures performed. If these recommendations continue to remain in place and the volume of elective procedures remains low, our results of operations and financial condition will continue to be adversely affected.

As a result of the COVID-19 outbreak around the world, we have adopted several measures including instructing employees to work from home while under shelter-in-place orders, slowing our manufacturing operations, and restricting non-critical business travel by our employees. In April and May of 2020, following shelter-in-place orders, the Company operated with limited personnel at our facilities to continue essential operations. In June 2020, we implemented return-to-work phases in conjunction with a social distancing protocol to safely continue essential operations to best meet customer demands in light of the pandemic. This pandemic has caused disruption and delays in our ability to operate and manufacture, test and assemble products in our internal facilities, particularly in our Mountain View, California facility, and has limited our ability to continue certain research and development activities which could materially and adversely affect our ability to develop new products and technologies on the timelines we previously anticipated.

The COVID-19 pandemic has created economic uncertainty and volatility in the financial markets around the world, resulting in an economic downturn that has affected and will likely continue to affect demand for our products and impact our results of operations. As a result, this may lead to a period of regional, national, and global economic slowdown or regional, national, or global recessions that would curtail or delay spending by hospitals and affect demand for our products as well as increase the risk of customer defaults or delays in payments. Our customers may terminate or amend their agreements for the purchase, lease, or service of our products due to bankruptcy, lack of liquidity, lack of funding, operational failures, or other reason. The ultimate impact of the COVID-19 pandemic on our operations and financial performance depends on many factors that are not within our control, including, but not limited, to: the recommendations by medical authorities on whether hospitals should and may perform elective surgical procedures; hospitals abilities and willingness to devote resources to elective surgical procedures; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic (including restrictions on travel and transport and workforce pressures); the impact of the pandemic and actions taken in response on global and regional economies, travel, and economic activity; the availability of federal, state, local or non-U.S. funding programs; general economic uncertainty in key global markets and financial market volatility; global economic conditions and levels of economic growth; and the pace of recovery when the COVID-19 pandemic subsides. Although the magnitude of the impact of COVID-19 on our business operations remains uncertain and difficult to predict, and this remains a highly dynamic situation, we have experienced and will continue to experience in subsequent periods, disruptions to our business that will likely continue to adversely impact our business, financial condition and results of operations.

We may not be successful in our strategic partnership with Topcon Corporation and the relationship may divert resources away from existing operations or expose us to liabilities, which could adversely affect our business, results of operations and financial condition.

On March 2, 2021, we entered into a series of strategic transactions with Topcon Corporation (“Topcon”) Topcon America Corporation (the “Investor”) and Topcon Medical Laser Systems, Inc., a subsidiary of Topcon (the “Seller”), which included an asset purchase agreement with the Seller, pursuant to which we acquired substantially all the assets (except for cash and cash equivalents) of the Seller, including rights to the PASCAL product (the “Asset Purchase Agreement”), (ii) Topcon and our company entered into a distribution agreement dated March 2, 2021, pursuant to which we granted Topcon the exclusive right to distribute our retina and glaucoma products in certain geographies outside the United States (the “Distribution Agreement”), (iii) pursuant to an investment agreement dated March 2, 2021 (the “Investment Agreement”) the Investor acquired 1,618,122 shares of the our Common Stock for an aggregate purchase price of \$10 million (the “Shares”).

Pursuant to the Asset Purchase Agreement, the transferred assets include substantially all of the Seller’s assets including the rights to the PASCAL product (the “Transferred Assets”). We assumed only those liabilities arising after the closing in connection with the Transferred Assets. In the Asset Purchase Agreement, our company and the Seller made certain customary representations and warranties and agreed to certain customary covenants. The Agreement provides that our company and the Seller will each indemnify the other for losses arising from certain breaches of the Agreement and for certain other liabilities subject to customary caps and deductibles. If there are claims under the indemnification provisions for which we are liable we will need to use some or all our cash to settle those claims.

Pursuant to the Distribution Agreement, we appointed Topcon as the exclusive distributor of our glaucoma and retina products, including PASCAL product, in certain countries outside of the United States. Topcon agreed to use commercially reasonable efforts to commercialize our products in each region throughout the territory, including achieving certain sales baselines by product category and region. If Topcon fails to achieve the baselines in a region, we will have the right to, subject to payment of a fee, terminate Topcon’s appointment in such region. The Distribution Agreement and Topcon’s appointment will, unless terminated earlier, continue on a country-by-country basis for a period of ten (10) years from the date exclusivity is granted. The Distribution Agreement includes customary termination rights and effects of termination, including a termination for convenience right in favor of Topcon and, subject to payment of a fee, a termination right in our favor upon a change of control of our company.

As a result of the Distribution Agreement, we anticipate terminating our relationships with our current distributors in certain geographies and using Topcon as our exclusive distributor. If we are unable to terminate our existing relationships with current distributors, or if Topcon is unable to generate as much revenue under the Distribution Agreement as we receive from our current distributors, our business, results of operations and financial condition could be adversely affected. If there are claims under the indemnification provisions of the Distribution Agreement for which we are liable or we are unable to terminate our relationships with our current distributors, we will need to use some or all our cash to settle those claims or make payments to Topcon pursuant to the terms of the Distribution Agreement.

We are investing a substantial amount of time, resources and efforts in connection with our relationship with Topcon, including commercializing our products in certain geographies and working to achieve certain sales baselines by product category and region. All of these actions divert resources away from our other initiatives and operations particularly with respect to product sales in the United States. These efforts may not result in the anticipated additional products, efficiencies or revenues for our company, which could adversely affect our business, operating results and financial condition as a result.

We have incurred indebtedness under the CARES Act which may be subject to audit, may not be forgivable and may eventually have to be repaid. Any repayment of such indebtedness may limit the funds available to us and may restrict our flexibility in operating our business or otherwise adversely affect our results of operations.

In April 2020, the Company received an aggregate principal amount of approximately \$2.5 million U.S. Small Business Administration Loan (the "SBA Loan") pursuant to the Payroll Protection Program ("PPP"), established under the CARES Act. The SBA Loan is subject to forgiveness under the PPP upon the Company's request to the extent that the proceeds are used to pay expenses permitted by the PPP, including payroll costs, covered rent and mortgage obligations, and covered utility payments. In September 2020, the Company submitted an application for forgiveness of the entire amount due on the loan. Amounts outstanding under the loan will bear a fixed interest rate of 1.00% per annum with a maturity date of April 22, 2022, two years from commencement date. All payments are deferred for 18 months for the Company with interest accruing over the entire period of the SBA Loan. The U.S. Department of the Treasury has announced that it will conduct audits for PPP loans that exceed \$2 million. Should we be audited or reviewed by the U.S. Department of the Treasury or the U.S. Small Business Administration as a result of the SBA Loan or filing an application for forgiveness or otherwise, such audit or review could result in the diversion of management's time and attention, generate negative publicity and cause us to incur legal and reputational costs. If we were to be audited and receive an adverse outcome in such an audit, we could be required to return the full amount of the SBA Loan and may potentially be subject to civil and criminal fines and penalties. We may not have the resources to repay the SBA Loan if required to do so by the federal government.

The Company cannot provide assurance that the principal and interest amounts under the PPP Loan will be forgiven. If all or substantially all of the SBA Loan is not forgiven or it is subsequently determined that it must be repaid, we may be required to use a substantial portion of our cash flows from operations to pay interest and principal on the SBA Loan. Although we currently have no intention of repaying the SBA Loan, we may decide to repay it in the future. Any such repayment of the SBA Loan will reduce the funds available to us for working capital, capital expenditures, and other corporate purposes and may limit our ability to obtain additional financing for working capital, capital expenditures, expansion plans, and other investments or divert funds that are otherwise necessary to run our business. We cannot assure you that our business will generate sufficient cash flow from operations or that future financing will be available to us in amounts sufficient to enable us to make required and timely repayments on our indebtedness, or to fund our operations. To date, we have used a substantial amount of cash for operating activities, and we cannot assure you when we will begin to generate cash from operating activities in amounts sufficient to service our debt. Additionally, though we believe we are eligible for the SBA Loan under the PPP, our receipt of the SBA Loan could result in negative publicity, or expose us to liability under the federal False Claims Act, which prohibits the known filing of a false claim or the known use of false statements to obtain payment from the federal government, if it is determined that we were in fact not eligible to take the SBA Loan in the first instance.

In addition, although we are reviewing and may seek additional available benefits under the CARES Act, we cannot predict the manner in which such benefits will be allocated or administered and we cannot assure you that we will be able to access such benefits in a timely manner or at all. Certain of the benefits under the CARES Act have not previously been administered on the present scale or at all. Government or third party program administrators may be unable to cope with the volume of applications in the near term and any benefits we receive may not be as extensive as those for which we apply, may impose additional conditions and restrictions on our operations or may otherwise provide less relief than we contemplate. If the U.S. government or any other governmental authority agrees to provide additional crisis relief assistance that we accept, it may impose certain requirements on the recipients of the aid, including restrictions on executive officer compensation, dividends, prepayment of debt, limitations on debt and other similar restrictions that will apply for a period of time after the aid is repaid or redeemed in full. We cannot assure you that any such government crisis relief assistance will not significantly limit our corporate activities or be on terms that are favorable to us. Such restrictions and terms could adversely impact our business and limit our operations and revenue as a result.

We face quality control and other production issues that could materially and adversely impact our sales and financial results and the acceptance of our products.

The manufacture of our infrared and visible laser consoles and related delivery devices is a highly complex and precise process. We may experience manufacturing difficulties, quality control issues or assembly constraints.

If our sales increase substantially, we may need to increase our production capacity and may not be able to do so in a timely, effective or cost-efficient manner. We may not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations.

In the past several years, we have experienced supply chain, production and training issues as we have expanded our product lines and sales volumes, and may experience similar issues in the future as we continue to grow our business. For example, we have contracted with a manufacturing company located in Wuhan, China for certain laser systems scheduled for release in the first half of 2021. Due to the COVID-19 outbreak, release of our manufacturing process and launch of these new laser systems may be delayed or disrupted, and we may need to incur costs to replace or shift this manufacturing process elsewhere. These issues have caused, and may in the future cause, us to reduce or delay the shipment of our products and incur costs to service or replace products already shipped to

customers. We have also incurred, and may in the future incur, additional costs to rectify or prevent similar issues in the future. Our efforts to address these supply chain, production and training issues may not be successful, and if we are unable to address these issues in a timely and cost-effective manner, product shipments to our customers could be delayed, our sales levels may suffer and manufacturing and operational costs may increase, any of which would negatively impact our business, results of operations and financial condition.

Some of our laser systems are complex in design and may contain defects that are not detected until deployed by our customers, which could increase our costs and reduce our revenues.

Laser systems are inherently complex in design and require regular maintenance. The manufacture of our lasers, laser products and systems involves a highly complex and precise process. As a result of the technical complexity of our products, changes in our or our suppliers' manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in a material adverse effect on our ability to achieve acceptable manufacturing yields and product reliability. To the extent that we do not achieve such yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on certain of our product sales, and allowances for estimated warranty costs are recorded during the period of sale. The determination of such allowances requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. We currently establish warranty reserves based on historical warranty costs. If actual return rates and/or repair and replacement costs differ significantly from our estimates, adjustments to recognize additional cost of revenues may be required in future periods.

Our customers may discover defects in our products after the products have been fully deployed and operated under peak stress conditions. In addition, some of our products are combined with products from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

- loss of customers;
- increased costs of product returns and warranty expenses;
- damage to our brand reputation;
- failure to attract new customers or achieve market acceptance;
- diversion of development and engineering resources; and
- legal actions by our customers.

The occurrence of any one or more of the foregoing factors could seriously harm our business, financial condition and results of operations.

We rely on our direct and independent sales forces and international distributors to sell our products and if we lose our sales force or distributor relationships, it could harm our business.

Our ability to sell our products and generate revenues depends upon our direct and independent sales forces within the United States, direct sales force in Germany and relationships with independent international distributors. Currently our direct and independent sales forces within the United States consist of approximately 16 employees and one independent representative, respectively and our direct sales force in Germany consists of one employee. Our international independent distributors are managed by a team of five people. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are largely dependent on the efforts of these third parties. If any distributor breaches the terms of its distribution agreement with us or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory could be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may harm our revenues and our ability to maintain market share. Similarly, our independent contractor and distributor agreements are generally terminable at will by either party and independent contractors and distributors may terminate their relationships with us, which would affect our sales and results of operations. Any loss of the members of our existing direct or indirect sales organizations, or any failure to execute on our plans to further develop our sales function, could have an adverse impact on our business, results of operations and financial condition. Additionally, our sales forces' operations have been disrupted by the COVID-19 pandemic, as many are no longer allowed to travel and must instead perform their services from home, which could have an impact on their ability to sell and distribute our products.

Growth in our sales and marketing organization may create operational challenges without immediately offsetting benefits.

We have increased and continue to increase our internal sales and marketing functions. This growth may place a significant strain on our management, operating and financial systems and our sales, marketing, training and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced

or replaced. For example, if we are unable to provide adequate training for our expanding sales force, our ability to fully utilize new sales and marketing resources may be adversely impacted, we could suffer reputational harm and our ability to maintain our installed base of customers may be negatively impacted. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

It can take six months or longer before our internal sales representatives are fully trained and productive in selling our product to prospective clients. This ramp up period presents a number of operational challenges as the cost of recruiting, hiring and carrying new sales representatives cannot be offset by the revenue such new sales representatives produce until after they complete their ramp up periods. If we cannot reliably develop our sales representatives to a productive level, or if we lose productive representatives in whom we have heavily invested, our future growth rates and revenue may suffer.

We depend on international sales for a significant portion of our operating results.

We derive, and expect to continue to derive, a large portion of our revenues from international sales. For the first fiscal quarter of fiscal year 2021, our international sales were \$6.4 million, or 53.5% of total revenues. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. All of our international revenues and costs for the first fiscal quarter of fiscal year 2021 have been denominated in U.S. dollars except for sales transacted through our German subsidiary. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our U.S. dollar-denominated products more expensive and thus less competitive in foreign markets and may negatively affect our reported revenue in any particular reporting period. Our international operations and sales are subject to a number of risks and potential costs, including:

- the impact of the COVID-19 pandemic on the global economy and financial markets;
- fluctuations in foreign currency exchange rates;
- product and production issues;
- performance of our international channel of distributors;
- longer accounts receivable collection periods;
- impact of recessions in global economies and availability of credit;
- political and economic instability;
- change in international regulatory agreements and requirements;
- trade sanctions and embargoes;
- impact of international conflicts, terrorist and military activity, civil unrest;
- foreign certification requirements, including continued ability to use the “CE” mark in Europe, and other local regulatory requirements;
- differing local product preferences and product requirements;
- cultural differences;
- changes in foreign medical reimbursement and coverage policies and programs;
- reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- potentially adverse tax consequences, such as those related to changes in tax laws or tax rates or their interpretations;
- protectionist, adverse and changing foreign governmental laws and regulations;
- greater risk of our employees failing to comply with both U.S. and foreign laws, including anti-trust regulations, the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and any trade regulations designed to ensure fair trade practices; and
- compliance costs and risks of non-compliance with multiple regulatory regimes governing the production, marketing, sale and use of our products.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations.

As we expand our existing international operations, we may encounter new risks in addition to the above factors. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we

may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenues, profitability and the price of our common stock.

If we fail to develop and successfully introduce new products and applications or fail to improve our existing products, our business prospects and operating results may suffer.

Our ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, which may include clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. In addition, our research and development process has been slowed by the impact of COVID-19, and should the COVID-19 economic restrictions worsen, it could delay and disrupt our research and development processes even further.

Successful commercialization of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns.

Our ability to market and sell new products is subject to government regulation, including approval or clearance by the FDA and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

We are exposed to risks associated with worldwide economic slowdowns and related uncertainties.

We are subject to macro-economic fluctuations in the U.S. and worldwide economy. Concerns about consumer and investor confidence, volatile corporate profits and reduced capital spending, international conflicts, terrorist and military activity, civil unrest and pandemic illness could reduce customer orders or cause customer order cancellations. For example, the COVID-19 pandemic has and may continue to cause adverse impacts on global economic activity which could negatively impact our business. In addition, political and social turmoil related to international conflicts and terrorist acts may put further pressure on economic conditions in the United States and abroad.

Weak economic conditions and declines in consumer spending and consumption may harm our operating results. Purchases of our products are often discretionary. During uncertain economic times, customers or potential customers may delay, reduce or forego their purchases of our products and services, which may impact our business in a number of ways, including lower prices for our products and services and reducing or delaying sales. There could be a number of follow-on effects from economic uncertainty on our business, including insolvency of key suppliers resulting in product delays, delays in customer payments of outstanding accounts receivable and/or customer insolvencies, counterparty failures negatively impacting our operations, and increasing expense or inability to obtain future financing.

If economic uncertainty persisted, or if the economy entered a prolonged period of decelerating growth, our results of operations may be harmed.

Our operating results may fluctuate from quarter to quarter and year to year.

Our sales and operating results may vary significantly from quarter to quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- general economic uncertainties and political concerns, including the impact of COVID-19;
- changes in the prices at which we can sell our products, including the impact of changes in exchange rates;
- introduction of new products, product enhancements and new applications by our competitors, including new drugs, entry of new competitors into our markets, pricing pressures and other competitive factors;
- any delays or reductions in product shipments, or product recalls, resulting from manufacturing, distribution or other operational issues;
- the timing of the introduction and market acceptance of new products, product enhancements and new applications;
- changes in demand for our existing line of ophthalmology products;
- the cost and availability of components and subassemblies, including the willingness and ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;

- our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- fluctuations in our product mix within ophthalmology products and foreign and domestic sales;
- the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- our long and highly variable sales cycle;
- changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products;
- variances in shipment volumes as a result of product, supply chain and training issues; and
- increased product innovation costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors. For example, our European sales during the third quarter are generally lower due to many businesses being closed for the summer vacation season.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarters. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

We rely on continued market acceptance of our existing products and any decline in sales of our existing products would adversely affect our business and results of operations.

We currently market visible and infrared medical laser systems and delivery devices to the ophthalmology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon a number of factors including the following:

- the impact of COVID-19 pandemic on timing of ophthalmic treatment procedures;
- acceptance of product performance, features, ease of use, scalability and durability, including with respect to our MicroPulse laser photocoagulation systems;
- recommendations and opinions by ophthalmologists, other clinicians, and their associated opinion leaders;
- marketing and clinical study outcomes;
- price of our products and prices of competing products and technologies, particularly in light of the current macro-economic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;
- availability of competing products, technologies and alternative treatments; and
- level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation, including our Cyclo G6 probe and EndoProbe devices. Our ability to increase recurring revenues from the sale of consumable products will depend primarily upon the features of our current products and product innovation, the quality of, ease of use and prices of our products, including the relationship to prices of competing products. The level of our service revenues will depend on the quality of service we provide and the responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices, consumables or services may have a material adverse effect on our business, results of operations and financial condition.

We face strong competition in our markets and expect the level of competition to grow in the foreseeable future.

Competition in the market for laser systems and delivery devices used for ophthalmic treatment procedures is intense and is expected to increase. This market is also characterized by technological innovation and change. We compete by providing features and services that are valued by our customers such as: enhanced product performance and clinical outcomes, ease of use, durability, versatility, customer training services and rapid repair of equipment.

Our principal ophthalmic laser competitors are Alcon, Inc., Novartis AG, Bausch Health Companies Inc., Carl Zeiss Meditec AG, Ellex Medical Lasers, Ltd., Lumenis Ltd., Nidek Co. Ltd., Quantel Medical SA, OD-OS GmbH and A.R.C. Laser GmbH. We also compete with alternative glaucoma surgical device companies such as Alcon, Inc., Allergan, Inc., Glaukos Corporation, New

World Medical, Inc. and Ivantis, Inc. Pharmaceuticals represent alternative treatments to our laser procedures. Some of our principal pharmaceutical competitors are Alcon, Inc., Allergan, Inc., Astellas Pharma Inc., Pfizer Inc., Regeneron Pharmaceuticals, Inc., Roche Holdings Ltd. (Genentech) and Bausch Health Companies Inc. Some of our competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical device companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the conditions targeted by us, or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Our ability to raise capital in the future may be limited, and future sales and issuances of securities could negatively affect our stock price and dilute the ownership interest of our existing investors.

Our business and operations may consume resources faster than we anticipate. We may need in the future to raise additional funds through future equity or debt financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. Additional financing may not be available on favorable terms, if at all. If adequate funds are not available on acceptable terms, we may be unable to invest in future growth opportunities, which could seriously harm our business and operating results. Future sales or issuances of securities by us could decrease the value of our common stock, dilute stockholders' voting power and reduce future potential earnings per share.

To raise capital, we may sell common stock, convertible securities or other equity-linked securities in one or more transactions at prices and in a manner we determine from time to time. If we sell additional equity securities, our existing stockholders may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. We may also issue debt securities, which may impose restrictive covenants on our operations or otherwise adversely affect the holdings or the rights of our stockholders.

We may sell shares or other securities in any offering at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing investors.

Our operating results may be adversely affected by uncertainty regarding healthcare reform measures and changes in third-party coverage and reimbursement policies.

Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as governmental programs and private insurance plans, for the health care services provided to their patients. Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding reimbursement of medical procedures using our products and any healthcare reform measures. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act", and the current U.S. presidential administration has announced certain policy changes that could impact the availability of benefits under the Affordable Care Act. For example, tax reform legislation enacted at the end of 2017 eliminated the tax penalty for individuals who did not maintain sufficient health insurance coverage beginning in 2019 (the "individual mandate"). We anticipate continued Congressional interest in modifying provisions of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to or any repeal of the Affordable Care Act, with respect to certain of its provisions or in its entirety or related administrative policies. Various healthcare reform proposals have also emerged at the state level.

We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Furthermore, existing legislation and regulation related to the health care industry and third-party coverage reimbursement, including the Affordable Care Act, has been subject to judicial challenge, and may be subject to similar challenges from time to time in the future (such as the ongoing *California v. Texas* case). Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

Third-party payers are increasingly scrutinizing and continue to challenge the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have

generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.

While we do not bill directly to Medicare, Medicaid or other third-party payors, because payment is in many cases available for our products from such payors, many healthcare laws place limitations and requirements on the manner in which we conduct our business (including our sales and promotional activities and interactions with healthcare professionals and facilities) and could result in liability and exposure for us. The laws that may affect our ability to operate include (i) the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of “implied certification” where the government and qui tam relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted “off-label,” lacked necessary clearance or approval, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and disclosures requirements such as the federal Sunshine Act, now known as Open Payments; and/or (iv) state law equivalents of each of the above federal laws, including, without limitation anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Compliance with Open Payments, commonly known as the Sunshine Act, has presented a number of challenges to companies such as ours, in terms of interpretation of the law and its implementation. Under the Sunshine Act, Centers for Medicare & Medicaid Services (“CMS”) has the potential to impose penalties of up to \$1.15 million per year for violations, depending on the circumstances, although enforcement has been negligible to date. Payments reported under the Sunshine Act also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute and other healthcare laws. The risk that we are our being found in violation of these laws may be increased by the fact that we do not have a formal healthcare compliance program in place. Further, while safe harbors may in some instances be available and utilized by companies to reduce risks associated with the Anti-Kickback Statute and certain other healthcare laws, we have not necessarily utilized such safe harbors nor fully followed all elements required to claim the benefit of such safe harbors in all possible instances. Any action against us for violation of these laws, 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.

We depend on collaborative relationships to develop, introduce and market new products, product enhancements and new applications.

We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and innovation and clinical testing of our products. Commercially, we currently have a distribution and licensing agreement with Alcon for our GreenTip SoftTip Cannula. Sales of and royalties from the GreenTip SoftTip Cannula are dependent upon the sales performance of Alcon, which depends on their efforts and is beyond our control. The failure to obtain any additional future clinical or commercial collaborations and the resulting failure or success of such collaboration relationships could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

If we cannot increase our sales volumes, reduce our costs or introduce higher margin products to offset potential reductions in the average unit price of our products, our operating results may suffer.

The average unit price of our products may decrease in the future in response to changes in product mix, competitive pricing pressures, new product introductions by our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes or through new product introductions, our net revenues will decline. In addition, to maintain our gross margins we must continue to reduce the manufacturing cost of our products. If we cannot maintain our gross margins our business could be seriously harmed, particularly if the average selling price of our products decreases significantly without a corresponding increase in sales.

Our promotional practices are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion and marketing that could have a significant negative effect on our business.

We are subject to governmental oversight and associated civil and criminal enforcement relating to drug and medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. In the United States, we are subject to potential enforcement from the FDA, the U.S. Federal Trade Commission, the Department of Justice, the CMS, other divisions of the Department of Health and Human Services and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies, alleging off-label marketing and other violations. We may be subject to liability based on the actions of individual employees and contractors carrying out activities on our behalf, including sales representatives who may interact with healthcare professionals.

If we fail to manage growth effectively, our business could be disrupted which could harm our operating results.

We have experienced and may in the future experience growth in our business, both organically and through the acquisition of businesses and products. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product innovation and clinical trials for new applications and products. We must also be prepared to expand our work force and to train, motivate and manage additional employees as the need for additional personnel arises. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to effectively manage future growth could have a material adverse effect on our business, results of operations and financial condition.

We rely on patents and proprietary rights to protect our intellectual property and business.

Our success and ability to compete is dependent, in part, upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. As of April 3, 2021, our patent portfolio includes 25 active United States patents and seven active foreign patents on the technologies related to our products and processes. In addition, as of April 3, 2021, we have eight patent applications pending in the United States and 14 foreign patent applications pending. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Patents have a limited lifetime and once a patent expires competition may increase.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain industry standard provisions requiring such individuals to assign to us, without additional consideration, any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Also, our trade secrets may become known to or independently developed by competitors.

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage.

Numerous patents are held by others, including academic institutions and our competitors. Patent applications filed in the United States generally will be published eighteen months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, both within the United States and internationally, we cannot provide assurance that our technology does not infringe any patents or patent applications held by third parties. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable.

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop non-infringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

If we lose key personnel or fail to integrate replacement personnel successfully, our ability to manage our business could be impaired.

Our future success depends upon the continued service of our key management, technical, sales, and other critical personnel. Our officers and other key personnel are employees-at-will, and we cannot provide assurance that we will be able to retain them. Key personnel have left our company in the past, and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

Efforts to acquire additional companies or product lines may divert our managerial resources away from our business operations, and if we complete additional acquisitions, we may incur or assume additional liabilities or experience integration problems.

As part of our growth strategy, we seek to acquire businesses or product lines for various reasons, including adding new products, adding new customers, increasing penetration with existing customers, adding new manufacturing capabilities or expanding into new geographic markets. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These efforts could divert the attention of our management and key personnel from our business operations. If we complete future acquisitions, we may also experience:

- difficulties integrating any acquired products into our existing business;
- difficulties in integrating an acquired company's technologies, services, employees, customers, partners, business operations and administrative and software management systems with ours;
- delays in realizing the benefits of the acquired products;
- diversion of our management's time and attention from other business concerns;
- adverse customer reaction to the product acquisition; and
- increases in expenses.

Moreover, we cannot assure you that the anticipated benefits of any acquisition or investment would be realized or that we would not be exposed to unknown liabilities. In connection with these types of transactions, we may issue additional equity securities that would dilute the ownership interest of existing investors or earnings per share, use cash that we may need in the future to operate our business, incur debt on terms unfavorable to us or that we are unable to repay, incur large charges or substantial liabilities, encounter difficulties integrating diverse business cultures and become subject to adverse tax consequences, substantial depreciation or deferred compensation charges. These challenges related to acquisitions or investments could adversely affect our business, operating results and financial condition.

If we fail to accurately forecast demand for our product and component requirements for the manufacture of our product, we could incur additional costs or experience manufacturing delays and may experience lost sales or significant inventory carrying costs.

We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain or manufacture the necessary components, materials, and fully assembled products. Lead times for components and fully assembled products vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such products. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. If we underestimate demand for our product and consequently, our components, materials and fully assembled products requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

We depend on sole source or limited source suppliers.

We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components and fully-assembled products on a purchase order basis. Some of our suppliers and manufacturers are sole or limited source suppliers. In addition, some of these suppliers are relatively small private companies whose operations may be disrupted or discontinued at any time. There are risks associated with the use of independent manufacturers, including the following:

- the impact of COVID-19 on global supply chains and market stability;
- unavailability of shortages or limitations on the ability to obtain supplies of components and products in the quantities that we require, or that satisfy the environmental requirements to which we are subject;
- delays in delivery or failure of suppliers to deliver critical components and products on the dates we require;
- failure of suppliers to manufacture and assemble components and products to our specifications, and potentially reduced quality; and
- inability to obtain components and products at acceptable prices.

Our business and operating results may suffer from the lack of alternative sources of supply for critical sole and limited source components and fully-assembled products. The process of qualifying suppliers is complex, requires extensive testing with our products, and may be lengthy, particularly as new products are introduced. New suppliers would have to be educated in our production processes. In addition, the use of alternate components may require design alterations to our products and additional product testing under FDA and relevant foreign regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components or products may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to decline. Establishing our own capabilities to manufacture these components or products would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components or fully-assembled products in the quantity and quality desired and at the prices we have budgeted.

If our facilities were to experience catastrophic loss, our operations would be seriously harmed.

Our facilities could be subject to catastrophic loss such as fire, flood, unpredictable power outages, or earthquake. All of our research and development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. California can experience earthquakes, catastrophic wildfires, and intermittent power outages. Any such loss at any of our facilities caused by fires, flooding, power outages, or earthquakes could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records and corporate records, communicate with staff and external parties and operate other critical functions, including sales and manufacturing processes. Our information technology systems are potentially vulnerable to disruption due to breakdown or malicious intrusion and computer viruses. If we were to experience a prolonged system disruption in our information technology systems, it could negatively impact the coordination of our sales, planning and manufacturing activities, which could adversely affect our business. In addition, in order to maximize our information technology efficiency, we have physically consolidated our primary corporate data and computer operations. This concentration, however, exposes us to a greater risk of disruption to our internal information technology systems. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable time frame.

In addition, our information technology systems are potentially vulnerable to cyber-attacks or other data security breaches-whether by employees or others-which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of sensitive and confidential information of our employees, customers, suppliers and others, any of which could have a material adverse effect on our business, financial condition and results of operations.

While we have implemented a number of protective measures, including firewalls, antivirus and malware detection tools, patches, log monitors, routine back-ups, system audits, routine password modifications and disaster recovery procedures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events, and in some cases we may be unaware of an incident or its magnitude and effects. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

If we fail to maintain our relationships with health care providers, customers may not buy our products and our revenue and profitability may decline. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for healthcare compliance risks.

We market our products to numerous health care providers, including physicians, hospitals, ambulatory surgery centers, government affiliated groups and group purchasing organizations. We have developed and strive to maintain close relationships with members of each of these groups who assist in product research and development and advise us on how to satisfy the full range of surgeon and patient needs. We rely on these groups to recommend our products to their patients and to other members of their organizations. The failure of our existing products and any new products we may introduce to retain the support of these various groups could have a material adverse effect on our business, financial condition and results of operations. In addition, our interactions, communications, and financial relationships with these individuals and entities present potential healthcare compliance risks.

We are subject to government regulations which may cause us to delay or withdraw the introduction of new products or new applications for our products.

The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the FD&C Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the product must be shown to meet regulatory requirements established by the FD&C Act and implemented by the FDA. Unless otherwise exempt, a device manufacturer must obtain marketing “clearance” through the 510(k) premarket notification process, or “approval” through the lengthier premarket approval application (“PMA”) process. Not all devices are eligible for the 510(k) clearance process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the PMA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory clearance or approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes a broad range of additional requirements on medical device companies. Our products must be produced in compliance with the Quality System Regulation (“QSR”) and our manufacturing facilities are subject to establishment registration and device listing requirements from the FDA, and similar requirements from certain state authorities, and ongoing periodic inspections by the FDA, including unannounced inspections for compliance with applicable requirements. We are subject to monitoring, recordkeeping, and reporting obligations for medical device adverse events and malfunctions; notification of our products’ defects or failure to comply with the FDA’s laser regulations; and reporting of recalls, corrections, or removals of our products. The FDA also imposes requirements for the labeling of our products, and places limitations on claims we are permitted to make about our products in promotional labeling. The Federal Trade Commission has jurisdiction over the advertising of all of our products, which are non-restricted devices, and exercises oversight in coordination with the FDA.

Noncompliance with the applicable requirements can result in, among other things, regulatory citations (including “483 Observations”) and Warning Letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations. Such enforcement action can also result in negative publicity.

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products “CE” marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directives and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. There are a number of major regulatory changes occurring in the regulation of medical devices in the EU. A new revision of the quality system regulation (ISO 13485:2016) has been released that substantially increases the requirements for a medical device quality system. The Medical Device Regulation (“MDR”) will replace the current medical device directives (93/42/EEC), and it substantially changes the way that medical devices are brought to market in the EU and how they maintain compliance throughout the product’s life cycle. Due to the UK’s exit from EU (“Brexit”), different rules will apply in Great Britain (England, Wales and Scotland), Northern Ireland and the EU after the Brexit transition period, which began January 1, 2021. Additionally, the new revision 4 of the clinical evaluation report guidance document (MEDDEV 2.7.1) severely restricts the use of substantial equivalence for new products, resulting in the need for formal clinical trial data for most new products. These changes will increase the cost for compliance and for product development, and they lengthen product introduction cycles. Failure to comply with these changes can have an adverse effect on our ability to release new products in a timely manner.

Any clinical trials necessary that we may undertake for regulatory approval or marketing reasons will be an expensive, lengthy, costly, and uncertain process, and could result in delays in new product introductions or even an inability to release a product.

We may be required to undertake clinical trials often required to obtain regulatory approvals or may choose to undertake such trials for marketing or other reasons. Clinical trials for products such as ours are complex and expensive and their outcomes are uncertain. Any clinical trials that we may undertake would require the investment of significant financial and administrative resources. Moreover, the results of clinical trials are uncertain, and inconclusive or negative results may not support, or may impair, the sale and adoption of our products. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products could produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA, or another regulatory authority could suspend or terminate clinical trials at any time if they or we believed the trial participants faced unacceptable health risks.

If we fail to comply with the FDA's quality system regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.

We are currently required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, which would cause our sales and business to suffer.

If we modify one of our FDA cleared devices, we may need to submit a new 510(k), or potentially a PMA, and if clearance or approval is not obtained, it would prevent us from selling our modified products or cause us to redesign our products.

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness 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 additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenues and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

Our products may be misused, which could harm our reputation and our business.

We market and sell our products for use by highly skilled physicians with specialized training and experience in the treatment of eye-related disorders. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions, nor do we supervise the procedures performed with our products. The physicians who operate our products are responsible for their use and the treatment regime for each individual patient. In addition, non-physicians, particularly in countries outside of the United States, or poorly trained or inexperienced physicians, may make use of our products. Our efforts to market our MicroPulse systems as a fovea-friendly alternative to traditional continuous wavelength systems or alternative treatment methods may result in users failing to implement adequate safety precautions and thereby increase the risks associated with the misuse of our product. The lack of training and the purchase and use of our products by non-physicians or poorly trained or inexperienced physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation, or otherwise cause our business to suffer.

Inability of customers to obtain credit or material increases in interest rates may harm our sales.

Some of our products are sold to health care providers in general practice. Many of these health care providers purchase our products with funds they secure through various financing arrangements with third-party financial institutions, including credit facilities and short-term loans. If availability of credit becomes more limited, or interest rates increase, these financing arrangements may be harder to obtain or become more expensive for our customers, which may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer.

Our products could be subject to recalls even after receiving FDA approval or clearance. A recall would harm our reputation and adversely affect our operating results.

The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in the design or manufacture of our products, or in other cases we may determine that we will recall a product because we have determined that the product is violative, in order to avoid further enforcement action and protect the public health.

A government mandated recall, or a voluntary recall by us, could occur as a result of actual or potential component failures, adverse event reports, manufacturing errors or design defects, including defects in labeling. Furthermore, we may from time to time initiate a recall of a component or set of components comprising a portion of our laser systems, which could increase customer returns, warranty claims and associated reserve levels. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales and financial results.

For example, on February 23, 2018, we initiated a worldwide voluntary recall of a specific laser accessory called the TruFocus LIO Premiere® ("LIO"). The LIO is a head-mounted indirect ophthalmoscope that connects to our laser console and is used to view and perform laser treatment on a patient's retina. This recall was prompted after we received reports of three adverse events from one physician in the U.S., resulting in focal cataracts and iris burns occurring during procedures in which the TruFocus LIO Premiere was used. We identified several potential root causes for the adverse events, including use error. On March 22, 2019, we provided the FDA with a request for termination of Recall Number Z-1075-2018. Our termination request is pending.

We obtained FDA clearance for an updated TruFocus LIO Premiere® device. The updated device includes expanded user instructions and minor design changes. Use of the updated LIO may result in adverse events, including those observed with the prior LIO device. If physician use of our updated LIO results in serious adverse events, we may have to initiate another recall or utilize additional resources to further evaluate the design of the LIO device. Furthermore, in light of the recall, we cannot provide any assurance that the updated LIO, once launched, will achieve market acceptance. We will be required to devote significant resources to launch and market the updated LIO and cannot provide any assurance that these activities will generate revenue as anticipated. If our revenue grows more slowly than we expect because of a delay in or a lack of market acceptance for our updated LIO, our business and financials will be adversely affected.

If product liability claims are successfully asserted against us, we may incur substantial liabilities that may adversely affect our business or results of operations.

We may be subject to product liability claims from time to time. Our products are highly complex and the risk of significant patient injury is more likely with products and procedures involving the eye. Use of our products incorrectly can result in temporary or permanent loss in vision, burns, scarring, blind spots or other injuries of the eye and we may periodically become subject to product liability lawsuits as a result. We believe we maintain adequate levels of product liability insurance to cover such claims subject to certain deductibles. However, product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

Significant developments resulting from recent and potential changes in United States trade policies could have a material adverse effect on us.

Certain of our materials may be subject to the effects of various trade agreements, treaties and tariffs. The prior U.S. presidential administration has imposed tariffs on various goods from various countries, including China, Canada and the European Union ("EU"). As a result, Canada, the EU, China and other countries responded with retaliatory tariffs on certain United States exports. We cannot predict the effect these and potential additional tariffs will have on our business, including in the context of escalating trade tensions. Further tariffs, additional taxes, or trade barriers, both domestically and internationally, may affect our selling and/or manufacturing costs and margins, the competitiveness of our products, or our ability to sell products or purchase necessary equipment and supplies, and consequently affect our business, results of operations, or financial conditions. To the extent that trade tariffs and other restrictions imposed by the United States increase the price of, or limit the amount of, raw materials and finished goods imported into the United States, the costs of our raw materials may be adversely affected and the demand from our customers for products and services may be diminished, which could adversely affect our revenues and profitability.

In addition, these potential developments and any market perceptions concerning these and related issues and the attendant regulatory uncertainty regarding, for example, the posture of governments with respect to international trade, could have a material adverse effect on global trade and economic growth which, in turn can adversely affect our business. Furthermore, changes in United States trade policy have resulted and could result in additional reactions from United States trading partners and other countries, including adopting responsive trade policies that make it more difficult or costly for us to export our products to those countries. We sell a significant majority of our products into countries outside the United States and we purchase a significant portion of equipment and supplies from suppliers outside the United States. These measures could also result in increased costs for goods imported into the U.S. or may cause us to adjust our worldwide supply chain. Any of these effects could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, may result in lowering our margin on products sold.

We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impacts on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the United States economy, which in turn could adversely impact our business, financial condition and results of operations.

Changes in U.S. tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

The comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”) was enacted in the United States on December 22, 2017 and includes, among other items, a reduction in the federal corporate income tax rate from 35% to 21%, certain interest expense deduction limitations and changes in the timing of certain taxable income. We are required to recognize the effect of the tax law changes in the period of enactment, such as re-measuring our U.S. deferred tax assets and liabilities and reassessing the net realizability of our deferred tax assets and liabilities.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) which provides guidance on accounting for the tax effects of the Tax Act. We have completed our analysis and accounting with respect to the Tax Act, and identified no additional changes from amounts previously recorded. However, changes in law, interpretations, and facts may result in adjustments to these amounts. Based on our net operating loss carryovers and valuation allowance, there is no impact to its consolidated financial statements as a result of the accounting for the tax effects of the Tax Act.

Subsequent legislations, guidance, regulations or audits that differ from our prior assumptions and interpretations, or other factors which were not anticipated at the time we estimated our tax provision could have a material adverse effect on our business, cash flow, results of operations or financial condition.

We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties. Additionally, challenges to or investigation into our practices could cause adverse publicity and be costly to respond to and thus could harm our business.

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of certain metals used in manufacturing which may stem from minerals (so called “conflict minerals”) which originate in the Democratic Republic of the Congo or adjoining regions. These metals include tantalum, tin, gold and tungsten. These metals are central to the technology industry and are present in some of our products as component parts. In most cases no acceptable alternative material exists which has the necessary properties. It is not possible to determine the source of the metals by analysis but instead a good faith description of the source of the intermediate components and raw materials must be obtained. The components which incorporate those metals may originate from many sources and we purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used, and components and assemblies which we buy may have a mix of sources as their origin. We are required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance we can obtain this information from intermediate producers not willing or not able to provide this information or further identify their sources of supply or to notify us if these sources change. These metals are subject to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

Divestitures of some of our businesses or product lines may materially and adversely affect our financial condition, results of operations or cash flows and require us to raise additional capital to replace revenue from those business units or product lines.

We evaluate the performance and strategic fit of all of our businesses and may sell businesses or product lines. Divestitures involve risks, including difficulties in the separation of operations, services, products and personnel, the diversion of management’s attention from other business concerns, the disruption of our business, the potential loss of key employees and the retention of uncertain environmental or other contingent liabilities related to the divested business. In addition, divestitures may result in significant asset impairment charges, including those related to goodwill and other intangible assets, and the loss of revenue which could have a material adverse effect on our financial condition and results of operations. In addition, we may need to raise additional capital to replace the revenue generated from the business or product line that is divested and we can provide no assurance that such capital will be available or available on terms that are acceptable to us. We cannot assure you that we will be successful in managing these or any other significant risks that we encounter in divesting a business or product line, and any divestiture we undertake could materially and adversely affect our business, financial condition, results of operations and cash flows, and may also result in a diversion of management attention, operational difficulties and losses.

If we fail to comply with environmental requirements, our business, financial condition, operating results and reputation could be adversely affected.

Our products and operations are subject to various federal, state, local and foreign environmental laws and regulations, including those governing the use, storage, handling, exposure to, and disposal of hazardous materials and a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use and disposal of our products. We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory documentation for our products. Failure to meet these standards could limit the ability to market our products in those regions which require compliance with such standards or subject us to fines and penalties. Examples of such standards include laws governing the hazardous material content of our devices and products, such as the EU

Directive 2015/863 which is known as “RoHS 3” and that relates to Restrictions on the Use of Certain Hazardous Substances and the EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment. Similar laws and regulations have been passed or are pending in several other jurisdictions and may be enacted in other regions, including in the United States, and we are, or may in the future be, subject to these laws and regulations.

Our failure to comply with past, present and future similar laws could result in reduced sales of our devices and products, inventory write-offs, reputational damage, penalties and other sanctions, any of which could harm our business and financial condition. We also expect that our devices and products will be affected by new environmental laws and regulations on an ongoing basis. New environmental laws and regulations will likely result in additional costs and may increase penalties associated with violations or require us to change the content of our devices and products or how they are manufactured, which could have a material adverse effect on our business, operating results and financial condition.

Risks Relating to Ownership of Our Common Stock

Our stock price has been and may continue to be volatile and an investment in our common stock could suffer a decline in value.

The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including changes in foreign currency exchange rates, quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. During the first quarter of fiscal year 2021, the trading price of our common stock fluctuated from a low of \$2.18 per share to a high of \$7.71 per share. There can be no assurance that our common stock trading price will not suffer declines. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes and therefore broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.

We expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings, financial condition, capital needs and other factors deemed relevant by the board of directors, and may be restricted by future agreements with lenders. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our market and our competitors. If no or few securities or industry analysts cover our company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes incorrect or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price or trading volume to decline.

Ownership of our common stock is concentrated among a few investors, which may affect the ability of a third party to acquire control of us. Substantial sales by such investors could cause our stock price to decline.

Our directors, executive officers, current five percent or greater stockholders and affiliated entities together beneficially own a significant portion of our common stock outstanding. Having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our board of directors through a proxy solicitation.

As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We may experience difficulty in meeting these reporting requirements in a timely manner, particularly if material weaknesses or significant deficiencies were to persist. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 while we are a “smaller reporting company” as defined in the Exchange Act. If we are unable to comply with the requirements of Section 404 in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities, which could require additional financial and management resources.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which could likely have a negative effect on the trading price of our common stock.

Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes-Oxley Act in a timely manner, that our internal controls are perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline.

Our charter documents, anti-takeover provisions of Delaware law, and contractual provisions could delay or prevent an acquisition or sale of our company.

Our certificate of incorporation empowers the board of directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the board of directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our certificate of incorporation and bylaws contain other provisions that could have an anti-takeover effect, including the following:

- the authorized number of directors may be changed only by resolution of our board of directors;
- only our board of directors is authorized to fill vacant directorships, including newly created seats;
- special meetings of our stockholders may be called only by our board of directors, the chairman of the board, chief executive officer or president, thus prohibiting a stockholder from calling a special meeting;
- stockholders must give advance notice to nominate directors or propose other business; and
- stockholders are not permitted to cumulate votes in the election of directors.

In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or prevent changes in our management.

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

Sales of Unregistered Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

<u>Exhibit No.</u>	<u>Exhibit Title</u>
10.1(1)	<u>Asset Purchase Agreement dated as of March 2, 2021, among the Company, Topcon Medical Laser Systems, Inc. and Topcon America Corporation.</u>
10.2(1)	<u>Distribution Agreement dated as of March 2, 2021, by and between the Company and Topcon Corporation.</u>
10.3(1)	<u>Investment Agreement dated as of March 2, 2021, by and between the Company and Topcon America Corporation.</u>
10.4(1)	<u>Registration Rights Agreement dated as of March 2, 2021, by and between the Company and Topcon America Corporation.</u>
31.1	<u>Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).</u>
32.1*	<u>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.</u>
32.2*	<u>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.</u>
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.CAL	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* The certification furnished in Exhibit 32.1 and 32.2 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

(1) Incorporated by reference to Exhibits filed with the Registrant’s Report on Form 8-K/A on March 4, 2021.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, MicroPulse, OcuLight, EndoProbe, MicroPulse P3, G-Probe, G-Probe Illuminate, TruFocus LIO Premiere, IQ 577, IQ532, Cyclo G6, and TxCell are our registered trademarks. All other trademarks or trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

SIGNATURES

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

IRIDEX Corporation (Registrant)

Date: May 12, 2021

By: /s/ DAVID I. BRUCE

Name: David I. Bruce

Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2021

By: /s/ FUAD AHMAD

Name: Fuad Ahmad

Title: Interim Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 13(a) or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David I. Bruce, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IRIDEX Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2021

By: /s/ DAVID I. BRUCE
Name: David I. Bruce
Title: President and Chief Executive Officer
(Principal Executive Officer)

**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**

I, David I. Bruce, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, certify that the Quarterly Report of IRIDEX Corporation on Form 10-Q for the fiscal quarter ended April 3, 2021 (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of IRIDEX Corporation.

Date: May 12, 2021

By: /s/ DAVID I. BRUCE
Name: David I. Bruce
Title: President and Chief Executive Officer
(Principal Executive Officer)

**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**

I, Fuad Ahmad, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, certify that the Quarterly Report of IRIDEX Corporation on Form 10-Q for the fiscal quarter ended April 3, 2021 (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of IRIDEX Corporation.

Date: May 12, 2021

By: /s/ FUAD AHMAD
Name: Fuad Ahmad
Title: Interim Chief Financial Officer
(Principal Financial Officer)