

**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 1, 2023

Or

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

For the transition period from _____ to _____

Commission file number: 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

The number of shares of common stock, \$0.01 par value, issued and outstanding as of May 4, 2023 was 16,007,161.

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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;
- macroeconomic conditions, including impact of the COVID-19 pandemic, foreign exchange fluctuation, inflation concerns, rising interest rates and recessionary fears, potential federal debt default and uncertainty in the global banking and financial services market, on our business and results of operations;
- 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 Corporation;
- 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;
- our ability to raise additional capital;
- 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. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission (“SEC”) as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in and should be read in conjunction with 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)

	April 1, 2023	December 31, 2022 ⁽¹⁾
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,048	\$ 13,922
Accounts receivable, net of allowance for credit losses of \$146 as of April 1, 2023 and \$0 as of December 31, 2022 ⁽²⁾	6,931	6,229
Receivable from related party	3,828	3,539
Inventories	11,241	10,608
Prepaid expenses and other current assets	1,650	1,468
Total current assets	34,698	35,766
Property and equipment, net	449	462
Intangible assets, net	1,894	1,977
Goodwill	965	965
Operating lease right-of-use assets, net	1,423	1,665
Other long-term assets	1,551	1,455
Total assets	\$ 40,980	\$ 42,290
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,546	\$ 3,858
Payable to related party	123	15
Accrued compensation	2,813	2,448
Accrued expenses	2,132	1,548
Other current liabilities	882	968
Accrued warranty	196	168
Deferred revenue	2,424	2,411
Operating lease liabilities	1,046	1,037
Total current liabilities	13,162	12,453
Long-term liabilities:		
Accrued warranty	124	106
Deferred revenue	11,312	11,742
Operating lease liabilities	472	732
Other long-term liabilities	26	26
Total liabilities	25,096	25,059
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 16,007,161 and 15,989,662 shares as of April 1, 2023 and December 31, 2022, respectively	169	169
Additional paid-in capital	87,312	86,802
Accumulated other comprehensive loss	(35)	(24)
Accumulated deficit	(71,562)	(69,716)
Total stockholders' equity	15,884	17,231
Total liabilities and stockholders' equity	\$ 40,980	\$ 42,290

- (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 December 31, 2022.
- (2) Prior to our adoption of Accounting Standard Update 2016-13, "Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" on January 1, 2023, the allowance for credit losses related to accounts receivable was not applicable and is therefore presented as \$0 at December 31, 2022. See Note 3 for additional details.

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 1, 2023	April 2, 2022
Total revenues	\$ 13,706	\$ 13,387
Cost of revenues	7,768	7,410
Gross profit	5,938	5,977
Operating expenses:		
Research and development	1,749	2,116
Sales and marketing	4,283	4,300
General and administrative	2,250	1,838
Total operating expenses	8,282	8,254
Loss from operations	(2,344)	(2,277)
Other income (expense), net	266	(94)
Loss from operations before provision for income taxes	(2,078)	(2,371)
Provision for income taxes	12	20
Net loss	\$ (2,090)	\$ (2,391)
Net loss per share:		
Basic	\$ (0.13)	\$ (0.15)
Diluted	\$ (0.13)	\$ (0.15)
Weighted average shares used in computing net loss per share:		
Basic	16,001	15,881
Diluted	16,001	15,881

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

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

	Three Months Ended	
	April 1, 2023	April 2, 2022
Net loss	\$ (2,090)	\$ (2,391)
Foreign currency translation adjustments	(11)	28
Comprehensive loss	<u>\$ (2,101)</u>	<u>\$ (2,363)</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 1, 2023	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 31, 2022	15,989,662	\$ 169	\$ 86,802	\$ (24)	\$ (69,716)	\$ 17,231
Adoption of ASU 2016-13					244	244
Issuance of common stock under stock option plan	17,499	—	37			37
Stock-based compensation expense			473			473
Other comprehensive loss				(11)		(11)
Net loss					(2,090)	(2,090)
Balances, April 1, 2023	<u>16,007,161</u>	<u>\$ 169</u>	<u>\$ 87,312</u>	<u>\$ (35)</u>	<u>\$ (71,562)</u>	<u>\$ 15,884</u>

For the three months ended April 2, 2022	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balances, January 1, 2022	15,876,171	\$ 168	\$ 85,255	\$ 45	\$ (62,169)	\$ 23,299
Issuance of common stock under stock option plan	6,063	—	14			14
Stock-based compensation expense			384			384
Release of restricted stock, net of taxes paid	3,073	—	(8)			(8)
Other comprehensive income				28		28
Net Loss					(2,391)	(2,391)
Balances, April 2, 2022	<u>15,885,307</u>	<u>\$ 168</u>	<u>\$ 85,645</u>	<u>\$ 73</u>	<u>\$ (64,560)</u>	<u>\$ 21,326</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 1, 2023	April 2, 2022
Operating activities:		
Net loss	\$ (2,090)	\$ (2,391)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	144	119
Amortization of operating lease right-of-use assets	242	233
Stock-based compensation	473	384
Changes in operating assets and liabilities:		
Accounts receivable	(453)	(434)
Receivable from related party	(289)	(303)
Inventories	(629)	(1,469)
Prepaid expenses and other current assets	(182)	(695)
Other long-term assets	(96)	(8)
Accounts payable	(313)	683
Payable to related party	108	272
Accrued compensation	366	(867)
Accrued expenses	584	71
Accrued warranty	46	35
Deferred revenue	(417)	1,602
Operating lease liabilities	(251)	(239)
Other liabilities	(86)	(246)
Net cash used in operating activities	(2,843)	(3,253)
Investing activities:		
Acquisition of property and equipment	(43)	(26)
Net cash used in investing activities	(43)	(26)
Financing activities:		
Proceeds from stock option exercises	37	14
Taxes paid related to net share settlements of equity awards	—	(8)
Net cash provided by financing activities	37	6
Effect of foreign exchange rate changes	(25)	42
Net decrease in cash and cash equivalents	(2,874)	(3,231)
Cash and cash equivalents, beginning of period	13,922	23,852
Cash and cash equivalents, end of period	\$ 11,048	\$ 20,621
Supplemental disclosure of non-cash activities:		
Transfer of inventory to (from) property and equipment	\$ 4	\$ (20)

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 December 31, 2022, which was filed with the SEC on March 9, 2023. The results of operations for the three months ended April 1, 2023 and April 2, 2022 are not necessarily indicative of the results for the fiscal year ending December 30, 2023 or any future interim period. The three months ended April 1, 2023 and April 2, 2022 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 December 31, 2022, which was filed with the SEC on March 9, 2023.

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 condensed 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 the licensees’ net sales of products that utilize our technology. Our revenue is recognized in accordance with Accounting Standards Codification (“ASC”) Topic 606, “Revenue from Contracts with Customers.” 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.

The Company has the following revenue transaction types: (1) Product Sale Only, (2) Service Contracts, (3) System Repairs (outside of warranty), (4) Royalty Revenue and (5) 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 after shipment is made to these distributors.

The Company recognizes revenue from product sale at a point in time subject to the allocation of transaction price to additional performance obligations, if any.

- (2) **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 60 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.
- (3) **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.

- (4) **Royalty Revenue:** The Company has royalty agreements with four customers related to sale of the Company's intellectual property. Under the terms of these agreements, three customers are to remit a percentage of sales to the Company as the sales occur and one customer made an upfront prepayment for royalties.

The arrangements with three customers are for sales-based licenses of intellectual property, for which the guidance in paragraph ASC 606-10-55-65 applies. Therefore, the Company recognizes revenue at a point in time, 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. For the arrangement with one customer, the Company had concluded that there is one combined performance obligation to be satisfied. Therefore, the Company recognizes revenue related to this arrangement over time.

- (5) **Exclusive Distribution Rights:** On March 2, 2021, the Company and Topcon Corporation ("Topcon") entered into a distribution agreement ("Distribution Agreement"), 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 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 1.2 times 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 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 and returned to Topcon the arrangement fee allocated to Belarus (approximately \$0.2 million) because obtaining the necessary regulatory approvals and termination of existing distributor relationship was not feasible. For the three months ended April 1, 2023 and April 2, 2022, \$0.4 million and \$0.3 million in revenue related to the exclusive distribution rights was recorded, respectively.

Costs of Obtaining Revenue Contracts

The Company recognized assets from certain costs incurred to obtain revenue contracts. These costs relate to sales commissions arising from the sale of our products. The costs are considered incremental and recoverable of obtaining revenue contracts with customers. These deferred costs are amortized on a straight-line basis over the estimated period of benefit, which typically ranges

from 2 to 3 years. As of April 1, 2023, the Company recognized deferred costs incurred to obtain revenue contracts with customers, net of accumulated amortization, of \$149 thousand, and included these amounts in Prepaid expenses and other current assets and Other long-term assets in the Company's condensed consolidated balance sheets. Amortization expense was \$19 thousand and \$0 for the three months ended April 1, 2023 and April 2, 2022, respectively. There were no impairment expenses for both the three months ended April 1, 2023 and April 2, 2022, respectively.

Sales commissions that do not represent incremental and recoverable costs of obtaining a contract are expensed as incurred. As a practical expedient, the Company will not recognize such sales commission as a contract asset but rather recognize as expense when incurred if the amortization period of the asset that the Company would have otherwise recognized is one year or less.

Contract Fulfillment Costs

The Company recognized an asset from the costs incurred to fulfill a contract. These costs relate directly and must be incurred to satisfy performance obligations on certain specific contract with a customer. These costs are expected to be recovered over time and are amortized on a systematic basis that is consistent with the recognition of revenue to which it relates. As of April 1, 2023, the Company recognized deferred costs incurred to fulfill a contract with a customer, net of accumulated amortization, of \$743 thousand, and included these amounts in Prepaid expenses and other current assets and Other long-term assets in the Company's condensed consolidated balance sheets. Amortization expense was \$21 thousand and \$0 for the three months ended April 1, 2023 and April 2, 2022, respectively. There were no impairment expenses for both the three months ended April 1, 2023 and April 2, 2022, respectively.

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 1, 2023 and December 31, 2022, 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.

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 1, 2023 one customer, Topcon, accounted for more than 10% of total revenues, representing 32%. For the three months ended April 2, 2022, one customer, Topcon, accounted for more than 10% of total revenues, representing 30%. As of April 1, 2023, one customer, Topcon, accounted for over 10% of our accounts receivable, representing 35%. As of December 31, 2022, one customer, Topcon, accounted for more than 10% of our accounts receivable, representing 37%.

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 1, 2023 and April 2, 2022 is as follows:

	Three Months Ended	
	April 1, 2023	April 2, 2022
Balance, beginning of period	\$ 14,153	\$ 13,285
Additions to deferral	368	2,380
Revenue recognized	(785)	(778)
Balance, end of period	13,736	14,887
Non-current portion of deferred revenue	11,312	12,531
Current portion of deferred revenue	\$ 2,424	\$ 2,356

During the three months ended April 1, 2023 and April 2, 2022, approximately \$0.5 million and \$0.7 million were recognized pertaining to amounts deferred as of December 31, 2022 and January 1, 2022, respectively. As of April 1, 2023, approximately \$10.8 million of the non-current portion of deferred revenue and \$1.5 million of the current portion of deferred revenue pertain to exclusivity distribution rights 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 1, 2023 and April 2, 2022 is as follows:

	Three Months Ended	
	April 1, 2023	April 2, 2022
Balance, beginning of period	\$ 274	\$ 158
Accruals for product warranties	34	27
Cost of warranty claims	(89)	(56)
Adjustment to pre-existing warranties	101	64
Balance, end of period	\$ 320	\$ 193

Implementation Costs Incurred in a Cloud Computing Service Arrangement

The Company is currently implementing a new enterprise resource planning ("ERP") system. The new ERP system operates in a cloud-based environment. The Company concluded that this cloud computing arrangement does not include a license, and therefore, will account for this arrangement as one that is a service contract. As of April 1, 2023, the Company capitalized \$1.0 million in implementation costs, included in Prepaid expenses and other current assets and Other long-term assets in the Company's condensed consolidated balance sheets. The Company will amortize the capitalized implementation costs over five years on a straight-line basis once the ERP system is ready for use. There were no amortization expenses for both the three months ended April 1, 2023 and April 2, 2022.

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 June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13 "Measurement of Credit Losses on Financial Instruments," which amended the current approach to estimate credit losses on certain financial assets, including trade and other receivables, available-for-sale securities, and other financial instruments. Generally, this amendment requires entities to establish a valuation allowance for the expected lifetime losses of these certain financial assets. In November 2019, the FASB issued ASU No. 2019-10, "Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)," which amended the effective date for certain qualified entities to fiscal years beginning after December 15, 2022. On January 1, 2023, the Company adopted ASU No. 2016-13, using the modified retrospective approach by applying a cumulative effect adjustment of \$0.2 million to the opening balance of accumulated deficit.

3. Accounts Receivable and Allowance for Credit Losses

Trade Receivables

The Company has trade receivables with various individual customers such as private businesses, hospitals, universities, government and non-profit entities, and distributors. The Company has determined that geography is the similar risk characteristic to pool our trade receivables balances, and accordingly, groups such balances into either the domestic pool or the international pool. The domestic pool is primarily comprised of individual customers, and the international pool is primarily comprised of distributors.

The allowance for credit losses represents an estimate of the lifetime expected credit losses inherent in trade receivables as of the balance sheet date. We assess the adequacy of the allowance for credit losses on a quarterly basis based on historical information and current economic conditions and forecasts. Subsequent changes in the allowance for credit losses are recorded in current earnings and reversal of previous losses are permitted under the current guidance.

While we believe we have exercised prudent judgment and applied reasonable assumptions, there can be no assurance that in the future, changes in economic conditions or other factors would not cause changes in the financial health of our customers. If the financial health of our customers deteriorates, the timing and level of payments received could be impacted and therefore, could result in a change to our estimated losses.

The following table presents the activity in the allowance for credit losses for accounts receivable by pool type for three months ended April 1, 2023 (in thousands):

	Domestic	International	Total
Balance, beginning of period	\$ (235)	\$ (155)	\$ (390)
Impact of adoption of ASU 2016-13	141	103	244
Balance, end of period	<u>\$ (94)</u>	<u>\$ (52)</u>	<u>\$ (146)</u>

4. Related Party - Topcon

Topcon holds a 10.1% voting interest in the Company, which qualifies it to be a principal owner considered a related party, even though it currently does not have significant influence over the Company's operations.

Topcon resells certain of our products as our exclusive distributor in certain international regions. At the same time, the Company also purchases certain raw materials from Topcon. During the three months ended April 1, 2023, the Company's revenues related to Topcon amounted to approximately \$4.3 million, including \$0.4 million recognized exclusive distribution rights revenue. During the three months ended April 2, 2022, the Company's revenues related to Topcon amounted to approximately \$4.0 million, including \$0.3 million recognized exclusive distribution rights revenue. The Company's purchases from Topcon during the three months ended April 1, 2023 amounted to approximately \$0.1 million. As of April 1, 2023, the amounts receivable from and payable to Topcon were \$3.8 million and \$0.1 million, respectively. As of December 31, 2022, the amounts receivable from and payable to Topcon were \$3.5 million and \$15 thousand, respectively.

5. Inventories

The components of the Company's inventories as of April 1, 2023 and December 31, 2022 are as follows:

	April 1, 2023	December 31, 2022
Raw materials	\$ 6,481	\$ 5,820
Work in process	397	320
Finished goods	4,363	4,468
Total inventories	<u>\$ 11,241</u>	<u>\$ 10,608</u>

6. Goodwill and Intangible Assets

Goodwill

The carrying value of goodwill was \$1.0 million as of both April 1, 2023 and December 31, 2022.

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 2022 and determined that its goodwill was not impaired.

As of April 1, 2023, 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 of intangible assets carrying amounts (in thousands):

	April 1, 2023			Remaining Amortization Life	December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Customer relationships	\$ 340	\$ 238	\$ 102	4.00 Years	\$ 340	\$ 230	\$ 110
Developed technology	1,900	339	1,561	5.86 Years	1,900	272	1,628
Trade names	300	69	231	6.92 Years	300	61	239
Patents	600	600	-	None	600	600	-
	<u>\$ 3,140</u>	<u>\$ 1,246</u>	<u>\$ 1,894</u>		<u>\$ 3,140</u>	<u>\$ 1,163</u>	<u>\$ 1,977</u>

For the three months ended April 1, 2023 and April 2, 2022, amortization expense totaled \$83 thousand and \$48 thousand, respectively.

The amortization of developed technology was charged to research and development expense and the amortization of customer relations and trade names was charged to sales and marketing expense. Estimated future amortization expense for purchased intangible assets is as follows (in thousands):

Fiscal Year:	
Remainder of 2023 (nine months)	\$ 252
2024	335
2025	323
2026	319
2027	319
Thereafter	346
Total	<u>\$ 1,894</u>

7. 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 1, 2023 and December 31, 2022, approximate fair value because of the short maturity of these instruments.

As of April 1, 2023 and December 31, 2022, 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 1, 2023				As of December 31, 2022			
	Fair Value Measurements				Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	\$ 8,497	\$ —	\$ —	\$ 8,497	\$ 12,496	\$ —	\$ —	\$ 12,496

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.

8. Leases and Commitments and Contingencies

Operating Leases

Our operating leases consist of facility and office equipment leases. Operating lease expense was \$0.3 million for both the three months ended April 1, 2023 and April 2, 2022. The weighted average discount rate used in calculating the present value of lease payments was 4.9%. As of April 1, 2023, the weighted average remaining lease term for our operating leases was 1.5 years.

The following represents maturities of operating lease liabilities as of April 1, 2023 (in thousands):

Fiscal Year	Operating Lease Payments
Remainder of 2023 (nine months)	\$ 825
2024	723
2025	12
2026	10
Total lease payments	1,570
Less: Imputed interest	(52)
Total lease liabilities	\$ 1,518

Purchase Commitments

Our purchase commitments consist primarily of non-cancellable purchase commitments with vendors to manufacture certain components and ophthalmic instrumentation. As of April 1, 2023, our future minimum payments through fiscal year 2024 for our purchase commitments were approximately \$18.5 million, with \$16.8 million committed for the next 12 months.

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 stock option awards, restricted stock and restricted stock units ("RSUs") in accordance with FASB ASC Topic 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 1, 2023 were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022.

The following table shows stock-based compensation expense included in the condensed consolidated statements of operations for the three months ended April 1, 2023 and April 2, 2022 (in thousands):

	Three Months Ended	
	April 1, 2023	April 2, 2022
Cost of revenues	\$ 61	\$ 60
Research and development	52	29
Sales and marketing	121	122
General and administrative	239	173
	<u>\$ 473</u>	<u>\$ 384</u>

Stock-based compensation expense capitalized to inventory was immaterial for the three months ended April 1, 2023 and April 2, 2022.

As of April 1, 2023, there was \$1.9 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 1.57 years.

Summary of Stock Options

The following table summarizes stock options information during the three months ended April 1, 2023:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding as of December 31, 2022	2,232,967	\$ 4.27	
Granted	17,400	2.28	
Exercised	(17,499)	2.16	
Canceled or forfeited	(84,854)	4.06	
Outstanding as of April 1, 2023	<u>2,148,014</u>	\$ 4.28	\$ 1

The weighted average grant date fair value of the options granted was \$1.39 and \$2.85 per share for the three months ended April 1, 2023 and April 2, 2022, 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 1, 2023	April 2, 2022
Average risk free interest rate	3.83 %	2.43 %
Expected life (in years)	4.41	4.5
Dividend yield	— %	— %
Average volatility	76 %	76 %

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 1, 2023 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
Options outstanding	2,148,014	\$ 4.28	4.96	\$ 1
Options vested and expected to vest	2,086,540	\$ 4.30	4.92	\$ 1
Options exercisable	976,337	\$ 4.87	3.76	\$ 1

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of April 1, 2023, 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 1, 2023 and April 2, 2022 was approximately \$4 thousand and \$19 thousand, respectively.

Summary of RSUs

Information regarding RSUs activity for the three months ended April 1, 2023 is summarized below:

	Number of Shares
Outstanding as of December 31, 2022	473,029
RSUs forfeited	(30,960)
Outstanding as of April 1, 2023	442,069

10. Income Taxes

Provision for Income Tax

The Company calculates its interim tax provision in accordance with the provisions of ASC Topic 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 \$12 thousand and \$20 thousand for the three months ended April 1, 2023 and April 2, 2022, 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 2023, 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 December 31, 2022, the Company had \$1.4 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.

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 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 1, 2023 and April 2, 2022, potential shares from stock options and RSUs totaling 2,301,437 and 1,707,698 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 1, 2023	April 2, 2022
Numerator:		
Net loss	\$ (2,090)	\$ (2,391)
Denominator:		
Weighted average shares of common stock (basic)	16,001	15,881
Weighted average shares of common stock (diluted)	16,001	15,881
Per share data:		
Basic net loss per share	\$ (0.13)	\$ (0.15)
Diluted net loss per share	\$ (0.13)	\$ (0.15)

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 1, 2023	April 2, 2022
Cyclo G6	\$ 3,669	\$ 3,540
Retina	7,214	7,301
Other(1)	2,823	2,546
Total revenues	\$ 13,706	\$ 13,387

(1) Includes service contract revenues of \$383 thousand and \$362 thousand recognized during the three months ended April 1, 2023 and April 2, 2022, respectively. Includes \$364 thousand and \$277 thousand recognized revenue related to the exclusive

distribution rights during the three months ended April 1, 2023 and April 2, 2022, 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 1, 2023	April 2, 2022
United States	\$ 6,774	\$ 6,543
Europe, Middle East and Africa	4,177	3,431
Asia/Pacific Rim	2,143	2,853
Rest of Americas	612	560
Total revenues	<u>\$ 13,706</u>	<u>\$ 13,387</u>

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

Other than the United States, the Netherlands accounted for at least 10% of the Company's revenues during the three months ended April 1, 2023, representing 16%. Other than the United States, Japan and the Netherlands accounted for at least 10% of the Company's revenues during the three months ended April 2, 2022, representing 12% and 10%, respectively. The United States accounted for 49.4% and 48.9% of revenues for the three months ended April 1, 2023 and April 2, 2022, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management and should be read in conjunction with the section of this Quarterly Report on Form 10-Q entitled "Risk Factors." Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Risk Factors."

Overview

IRIDEX 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.

Our propriety MicroPulse[®] Technology and Endpoint Management[™] Technology are used for the treatment of glaucoma and retina disorders. Both technologies are offered as optional treatment modes in select laser consoles in addition to the standard continuous-wave ("CW") treatment mode. They allow low-energy, subvisible, tissue-sparing laser therapy by different means: MicroPulse technology uses short, microsecond-long laser pulses that allow tissue to cool between pulses giving physicians finer control of thermal elevation to minimize tissue damage. Endpoint Management technology uses a delivery algorithm to titrate the laser energy. CW laser photocoagulation can stabilize vision over the long term but can also result in varying degrees of vision loss. Both MicroPulse and Endpoint Management technologies have demonstrated clinical efficacy with a safer profile compared to standard high-energy CW laser for the treatment of both retinal diseases and glaucoma.

Our products consist of laser consoles, delivery devices and consumable probes.

Our laser consoles consist of the following product lines:

- **Glaucoma** – Our primary glaucoma console line is the Cyclo G6[®] laser system with MicroPulse technology. In addition, our medical retina consoles have features supporting glaucoma laser treatments.
- **Medical Retina** – Our medical-retina product line includes our portable IQ 532[®] and IQ 577[®] laser systems with MicroPulse technology; and the Pattern Scanning Laser ("PASCAL") System, an integrated workstation with Endpoint Management technology and MicroPulse technology. These systems are ideal for multispecialty practices because these lasers also can be used to treat glaucoma, i.e., single-spot laser trabeculoplasty using MicroPulse technology, iridotomy, and iridectomy using the IQ lasers; and pattern scanning laser trabeculoplasty ("PSLT") using the PASCAL laser system.
- **Surgical Retina** – Our surgical-retina product line includes our OcuLight[®] TX and OcuLight[®] SLx (with MicroPulse technology) 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, service 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 single-use delivery devices - MicroPulse P3[®], G-Probe[®], and G-Probe Illuminate[®].
- **Surgical Retina** – Probes used in our surgical-retina product line include our family of single-use EndoProbe[®] handpieces.

Ophthalmologists typically use our laser systems in hospital operating rooms and ambulatory surgical centers, as well as their offices and clinics. In operating rooms and ambulatory surgical centers, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a single-use consumable probe, including MicroPulse P3[®], G-Probe[®] and G-Probe Illuminate[®] delivery devices, and EndoProbe handpieces. In the offices and clinics, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a slit-lamp adapter.

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 currency fluctuations.

Cost of revenues consists primarily of our direct manufacturing costs which include 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 Macroeconomic Conditions to our Business

Current macroeconomic conditions, including any future resurgence of the COVID-19 pandemic and efforts to mitigate its impact, recessionary fears, inflation concerns, rising interest rates as a result of government actions to combat inflation, potential federal debt default and uncertainty in the global banking and financial services market, as well as other geopolitical developments, have impacted and may continue to impact business spending and the economy as a whole. As a result, we have seen customers opting for shorter deals and negative effects from foreign exchange fluctuations that have impacted and may continue to impact our operations.

The macroeconomic conditions on our business and operations remains highly uncertain, and it is not possible for us to predict the duration and extent to which they will affect our business, future results of operations, and financial condition.

For more information on risks associated with the current macroeconomic conditions, 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 1, 2023	April 2, 2022
Total revenues	100.0 %	100.0 %
Cost of revenues	56.7 %	55.4 %
Gross margin	43.3 %	44.6 %
Operating expenses:		
Research and development	12.8 %	15.8 %
Sales and marketing	31.2 %	32.1 %
General and administrative	16.3 %	13.8 %
Total operating expenses	60.3 %	61.7 %
Loss from operations	(17.0 %)	(17.1 %)
Other income (expense), net	1.9 %	(0.7 %)
Loss from operations before provision for income taxes	(15.1 %)	(17.8 %)
Provision for income taxes	0.10 %	0.1 %
Net loss	(15.2 %)	(17.9 %)

The following comparisons are between the three months ended April 1, 2023 and April 2, 2022 (in thousands):

Revenues

	Three Months Ended		Change in \$	Change in %
	April 1, 2023	April 2, 2022		
Cyclo G6	\$ 3,669	\$ 3,540	\$ 129	3.6 %
Retina	7,214	7,301	(87)	(1.2 %)
Other	2,823	2,546	277	10.9 %
Total revenues	\$ 13,706	\$ 13,387	\$ 319	2.4 %

Our total revenues increased by \$0.3 million, or 2.4%, from \$13.4 million to \$13.7 million. The increase was primarily driven by growth in Cyclo G6 probes and Legacy G probes.

While we believe that demand for our products remains and our outlook has improved, the overall capital expenditure landscape within hospitals, surgical centers and physician offices may be negatively impacted by any resurgence of the COVID-19 pandemic

and the spread of other variants. Until the COVID-19 pandemic subsides, we anticipate capital expenditures may continue to be deferred.

Gross Profit and Gross Margin

Gross profit remained relatively flat at \$5.9 million. Gross margin decreased by 1.3% from 44.6% to 43.3%. The decrease in gross margin was driven by higher manufacturing overhead.

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 decreased by \$0.4 million, or 17.3%, from \$2.1 million to \$1.7 million. Spending on investment in PASCAL product line and on new and expanded product portfolio decreased as we completed these new projects.

Sales and Marketing

Sales and marketing expenses remained relatively flat at \$4.3 million. Although additional headcount increased personnel and other related costs, there was an offset in marketing and advertising costs as we recently completed the release of a new system product.

General and Administrative

General and administrative expenses increased by \$0.5 million, or 22.4%, from \$1.8 million to \$2.3 million. The increase was attributable to increases in legal expenses for general corporate matters and higher personnel and other related costs due to higher headcount.

Other Income (Expense), Net

Other income, net was \$0.3 million for the three months ended April 1, 2023 compared to other expense, net, of \$0.1 million for the three months ended April 2, 2022. Other income (expense), net, consisted primarily of interest income or expense and foreign currency gain or loss.

Income Taxes

We recorded an income tax provision of \$12 thousand and \$20 thousand for the three months ended April 1, 2023 and April 2, 2022, 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 1, 2023, we had cash and cash equivalents of \$11.0 million and working capital of \$21.5 million compared to cash and cash equivalents of \$13.9 million and working capital of \$23.3 million as of December 31, 2022.

Net cash used in operating activities was \$2.8 million in the three months ended April 1, 2023 compared to net cash used in operating activities of \$3.3 million in the three months ended April 2, 2022. The decrease in net cash used by operating activities, expressed in direct cash flow terms, was primarily due to a decrease in vendor payments as we try to strategically manage our cash flows, offset by a decrease in cash receipts from customers.

For the three months ended April 1, 2023, net cash used in investing activities was \$43 thousand, which consisted of capital expenditures. For the three months ended April 2, 2022, net cash used in investing activities was \$26 thousand for capital expenditures.

For the three months ended April 1, 2023, net cash provided by financing activities was \$37 thousand, primarily from the net proceeds arising from the proceeds from stock option exercises. For the three months ended April 2, 2022, net cash provided by financing activities was \$6 thousand, primarily from proceeds from stock option exercises.

We have historically funded our operations primarily through sales of our products to customers, sales of our common stock and borrowing arrangements. As of April 1, 2023, our principal sources of liquidity consisted of cash and cash equivalents of \$11.0 million. We have incurred net losses over the last several years, and as of April 1, 2023, have an accumulated deficit of approximately \$71.6 million. We expect to continue to incur operating losses and negative cash flows from operations.

The Company has an existing Loan and Security Agreement (“Loan Agreement”) with Silicon Valley Bank (“SVB”) providing for up to \$8.0 million secured revolving loan facility (“Revolving Loan Facility”). In March 2022, the Fourth Amendment to the Loan Agreement was executed primarily to extend the term through May 31, 2022. In June 2022, the Fifth Amendment to the Loan

Agreement was executed primarily to extend the term through December 1, 2023. As of April 1, 2023 and December 31, 2022, there were no amounts outstanding under the Loan Agreement.

On March 10, 2023, SVB was placed into receivership by the Federal Deposit Insurance Corporation (“FDIC”). On March 13, 2023, the FDIC announced that it had transferred all insured and uninsured deposits and substantially all assets of SVB to a newly created, full-service FDIC-operated “bridge bank” called Silicon Valley Bridge Bank, N.A. (“SVBB”), where depositors would have full access to their money immediately. On March 27, 2023, First Citizens BancShares, Inc. (“First Citizens”) announced that it had entered into an agreement with the FDIC to purchase all of the assets and liabilities of SVBB. SVBB will operate as a division of First Citizens. We currently have full control of our cash and cash equivalents balance, and SVBB will continue to honor the terms of our existing Revolving Loan Facility.

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 1, 2023. 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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our condensed consolidated financial statements and related notes, before making a decision to invest in our common stock. Our business, financial condition, results of operations, or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material. If any of the risks actually occur, our business, financial condition, results of operations, and prospects could be adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

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

- general macroeconomic conditions, including inflationary pressures and rising interest rates, uncertainty in the global banking and financial services market, potential federal debt default, any future resurgence in the COVID-19 pandemic and responsive measures and the war between Russia and Ukraine.

Operational factors

- the success of our relationship with our strategic partner and main distributor Topcon;
- quality control and production issues;
- the complexity of our laser systems;
- defects in our laser systems;
- 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;
- costs, sales volumes, results of operations, and revenues;
- the loss of key personnel;
- meeting product demand;
- dependence on sole source and limited source suppliers;
- catastrophic loss;
- 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;
- adverse developments affecting financial institutions, including bank failures;
- recalls of our products; and
- managing growth effectively.

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, including changes to those laws; and
- environmental requirements.

Financing and transactional risks

- divestitures of our businesses or product lines;
- efforts to acquire additional companies 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 current macroeconomic conditions, including the effects of the COVID-19 pandemic and efforts to mitigate its impact have disrupted, and may continue to disrupt, our operations, including our ability to manufacture and supply products and perform research and development activities, and our customers' usage of our products as demand declined in elective surgeries in response to the COVID-19 pandemic, all of which have had and may 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 any future resurgence of the COVID-19 pandemic and related macroeconomic impacts may 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 were negatively impacted by the COVID-19 pandemic and related public health responses, such as travel restrictions in 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 interruptions in the supply of raw materials, components and sub-assemblies necessary to manufacture and assemble our products and reductions in the demand for our products as healthcare customers continue to divert medical resources and priorities towards the treatment of COVID-19. In addition, our customers may delay, cancel or redirect planned capital expenditures in order to focus resources on any future resurgence of COVID-19 or in response to macroeconomic disruption related to any future resurgence of the COVID-19 pandemic. 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 the near term COVID-19 pandemic may continue to negatively impact the use of our products and the number of ophthalmic treatments and procedures performed. If the volume of elective procedures continues to remain lower than normal, our results of operations and financial condition will continue to be adversely affected.

The COVID-19 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. In April 2023, President Biden signed legislation that will end the COVID-19 national emergency on May 11, 2023. The full impact of this termination of the national emergency and the wind-down of the public health emergency on FDA and other regulatory policies and operations are unclear.

The volatile macroeconomic environment, including 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 may likely continue to affect demand for our products and impact our results of operations. In addition, the failure of the U.S. federal government to manage its fiscal matters or to raise the debt ceiling, may result in a default on U.S. debt. Such a default may further negatively impact the economic environment, cause a drop in the stock market and our stock price, and curtail spending on health and health care related matters and adversely impact our results of operations as a result. 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 volatile macroeconomic conditions, including 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 may continue to be taken in response to any future resurgence of the COVID-19 pandemic (including restrictions on travel and transport and workforce pressures); the impact of the COVID-19 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 current volatile macroeconomic conditions, including the impact of the COVID-19 pandemic, subside. Although the magnitude of the impact of the COVID-19 pandemic on our business operations remains a highly dynamic situation, we have experienced and may continue to experience in subsequent periods, disruptions to our business that may adversely impact our business, financial condition and results of operations.

We may not be successful in our strategic partnership with Topcon 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, Topcon America Corporation (the "Investor") and Topcon Medical Laser Systems, Inc., a subsidiary of Topcon ("TMLS"), which included (i) an asset purchase agreement with TMLS, pursuant to which we acquired substantially all the assets (except for cash and cash equivalents) of TMLS, including rights to the PASCAL product (the "Asset Purchase Agreement"), (ii) 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"), and (iii) an investment agreement dated March 2, 2021 (the "Investment Agreement"), pursuant to which we sold the Investor 1,618,122 shares of 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 TMLS' 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 TMLS made certain customary representations and warranties and agreed to certain customary covenants. The Agreement provides that our company and TMLS 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 well as customary indemnification provisions.

As a result of the Distribution Agreement, we terminated our relationships with our prior distributors in certain geographies and we are using Topcon as our exclusive distributor. If Topcon is unable to generate as much revenue under the Distribution Agreement as we received from our prior 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, 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 may 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 (ourselves or through third parties) to manufacture or supply 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. 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 25 employees and two independent representatives, respectively, and our direct sales force in Germany consists of one employee. Our international independent distributors are managed by a team of eight people. We generally grant our distributors exclusive territories for the sale of our products in specified countries and regions. 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.

Growth in our sales and marketing organization may increase costs and 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 strain on our management, operating and financial systems and our sales, marketing, training and administrative resources. As a result, 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 2023, our international sales were \$6.9 million, or 50.6% 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 2023 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:

- macroeconomic conditions, including the impact of any future resurgence of the COVID-19 pandemic on the global economy and financial markets;
- fluctuations in foreign currency exchange rates;
- uncertainty in the global banking and financial services market;
- 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 was delayed due to the impact of the COVID-19 pandemic, and should the current macroeconomic conditions 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 macroeconomic fluctuations in the U.S. and worldwide economy including inflationary pressures that may cause the cost of manufacturing our products or servicing our products to increase. Concerns about consumer and investor confidence, volatile corporate profits and reduced capital spending, uncertainty in the global banking and financial services market, international conflicts, terrorist and military activity, civil unrest and pandemic-related illness could reduce customer orders or cause customer order cancellations. For example, any future resurgence of the COVID-19 pandemic may cause adverse impacts on global economic activity which could negatively impact our business. In addition, political and social turmoil related to international conflicts, such as that occurring in Russia and Ukraine, 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. Further, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the “debt ceiling.” Any U.S. government default on its debt could have broad macroeconomic effects including a drop in the stock market and our stock price. In addition, negative macroeconomic conditions in the United States (including elevated interest rates) have had, and may continue to have, an adverse impact on capital market conditions, which could limit our ability to obtain additional debt or equity financing on acceptable terms or at all.

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

We maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance.

We maintain cash deposits in financial institutions that may be higher than the \$250,000 limit insured by the FDIC or similar agencies. Bank failures, events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints. For example, on March 10, 2023, SVB failed and was taken into receivership by the FDIC. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or applicable foreign government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions, or by acquisition in the event of a failure or liquidity crisis.

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 macroeconomic conditions, including inflationary pressures and rising interest rates, uncertainty in the global banking and financial services market, potential federal debt default, any future resurgence of the COVID-19 pandemic and responsive measures and the war between Russia and Ukraine;
- 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 due to global constraints or other factors 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 any future resurgence of the 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, and our PASCAL product;
- 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 probe for the Cyclo G6 Laser 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 use our products and services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues associated therewith 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, Lumenis Ltd., Nidek Co. Ltd., Lumibird, and Norlase. 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 Holding 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.

Divestitures 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 have two main businesses: glaucoma and retina, domestic and international operations within each and many product lines within the two businesses. We periodically evaluate the performance and strategic fit 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 not realize the expected value from the divestiture of a business or product lines and may need to raise additional capital to replace the revenue generated from the business or product line that is divested. 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.

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 *California v. Texas* case). In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the Affordable Care Act, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the Affordable Care Act. 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 \$1.26 million per year for violations, depending on the circumstances and adjusted annually for inflation, 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 may be 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.

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 1, 2023, our patent portfolio includes 63 active United States patents and 83 active international patents on the technologies related to our products and processes. In addition, as of April 1, 2023, we have 11 patent applications pending in the United States and 22 international 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. Additionally, our common stock is currently trading at a price below the exercise price of many of our outstanding options. As a result, these “underwater” options are less useful as a motivation and retention tool for our existing employees. 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 highly competitive 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.

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 macroeconomic conditions, including any future resurgence of the COVID-19 pandemic and inflationary pressures 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 in a timely manner or at acceptable prices due to global supply chain constraints or other factors.

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 and those of our third-party service providers are potentially vulnerable to disruption, breakdown, damage, service interruption, system malfunction, power outage, natural disaster, malicious intrusion, ransomware, denial-of-service attacks, phishing attacks, social engineering, computer viruses, security breaches and other cyber-attacks. For example, companies have experienced an increase in phishing and spoofing attacks from third parties in connection with working remotely, either permanently or temporarily, due to the COVID-19 pandemic or due to political uncertainty and military actions associated with the significant military action against Ukraine launched by Russia. 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, 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 and those of our third-party service providers 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, we have experienced and may in the future experience spoofing attacks. In addition, our measures to secure our information technology systems 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, or perceived or reported to have been or be unable to, prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may be exposed to claims, demands, and litigation or governmental investigations and other proceedings and 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.

Furthermore, we may not have adequate insurance coverage to protect us from, or adequately mitigate, liabilities or damages resulting from cyber-attacks or security breaches. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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 surgical 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 or other processes such as the "de novo" 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 medical device products “CE” marked, an international symbol, affixed to all our medical device products demonstrating compliance with the European Medical Device Directives and/or Medical Device Regulations (“MDR”) and all applicable standards. While currently all our released medical device products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their periodic audits. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. There are several major regulatory changes occurring in the regulation of medical devices in the EU. The revision of the quality system regulation (ISO 13485:2016) has been released that substantially increased the requirements for a medical device quality system. The MDR has replaced the 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. Similarly, Switzerland has changed its relationship with the EU and in May 2022, will require medical device manufacturers, including us, to contract with a Swiss Authorized Representative. Additionally, the new revision 4 of the clinical evaluation report guidance document (MEDDEV 2.7.1) and the Medical Device Coordination Group (MDCG) guidance regarding clinical evidence (MDCG 2020-6) severely restricts the use of substantial equivalence for new products, resulting in the need for formal clinical trial data for many products. These and future changes will increase the cost for compliance and for product development, and they lengthen product introduction cycles. Failure to comply with these changes and any future 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.

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.

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 United States, 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. We submitted a follow up request for termination on September 29, 2021. 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, 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.

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.

Significant developments resulting from recent and potential changes in U.S. 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 United States 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, consolidated 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.

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.

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, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine. During the first quarter of fiscal year 2023, the trading price of our common stock fluctuated from a low of \$2.00 per share to a high of \$2.46 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

Exhibit No.	Exhibit Title
31.1	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
31.2	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.CAL	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.

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

Date: May 11, 2023

By: /s/ DAVID I. BRUCE

Name: David I. Bruce

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

Date: May 11, 2023

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 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 11, 2023

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 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, Fuad Ahmad, 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 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 11, 2023

By: /s/ FUAD AHMAD
Name: Fuad Ahmad
Title: Interim Chief Financial Officer
(Principal Financial 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 1, 2023 (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 11, 2023

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 1, 2023 (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 11, 2023

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