

**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 September 29, 2018

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**

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 checked="" type="checkbox"/>
Non-accelerated filer	<input 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 October 25, 2018 was 13,594,140.

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**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)

	<u>September 29, 2018</u>	<u>December 30, 2017 (1)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 23,725	\$ 21,707
Accounts receivable, net of allowance for doubtful accounts of \$213 as of September 29, 2018 and \$226 as of December 30, 2017	8,430	7,863
Inventories	8,725	9,381
Prepaid expenses and other current assets	492	500
Total current assets	<u>41,372</u>	<u>39,451</u>
Property and equipment, net	1,312	1,403
Intangible assets, net	104	116
Goodwill	533	533
Other long-term assets	216	143
Total assets	<u>\$ 43,537</u>	<u>\$ 41,646</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,552	\$ 1,724
Accrued compensation	2,284	2,459
Accrued expenses	2,643	2,153
Accrued warranty	694	1,536
Deferred revenue	2,217	2,520
Total current liabilities	<u>10,390</u>	<u>10,392</u>
Long-term liabilities:		
Accrued warranty	138	199
Other long-term liabilities	400	533
Total liabilities	<u>10,928</u>	<u>11,124</u>
Commitments and contingencies (Note 6)		
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 13,594,799 and 11,596,274 shares as of September 29, 2018 and December 30, 2017, respectively	145	126
Additional paid-in capital	71,283	59,385
Accumulated other comprehensive income	127	—
Accumulated deficit	(38,946)	(28,989)
Total stockholders' equity	<u>32,609</u>	<u>30,522</u>
Total liabilities and stockholders' equity	<u>\$ 43,537</u>	<u>\$ 41,646</u>

(1) Derived from the audited consolidated financial statements included in the Annual Report on Form 10-K filed with the SEC for the year ended December 30, 2017.

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		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Total revenues	\$ 11,320	\$ 10,865	\$ 31,133	\$ 31,350
Cost of revenues	6,744	6,492	18,367	18,017
Gross profit	<u>4,576</u>	<u>4,373</u>	<u>12,766</u>	<u>13,333</u>
Operating expenses:				
Research and development	1,149	1,320	3,154	4,028
Sales and marketing	4,144	3,769	12,362	10,346
General and administrative	2,343	2,530	7,209	6,804
Gain on sale of intellectual property	-	(175)	-	(175)
Total operating expenses	<u>7,636</u>	<u>7,444</u>	<u>22,725</u>	<u>21,003</u>
Loss from operations	(3,060)	(3,071)	(9,959)	(7,670)
Other (expense) income, net	(8)	(16)	16	(19)
Loss from operations before provision for income taxes	(3,068)	(3,087)	(9,943)	(7,689)
Provision for income taxes	6	9	14	23
Net loss	<u>\$ (3,074)</u>	<u>\$ (3,096)</u>	<u>\$ (9,957)</u>	<u>\$ (7,712)</u>
Net loss per share:				
Basic	<u>\$ (0.26)</u>	<u>\$ (0.27)</u>	<u>\$ (0.85)</u>	<u>\$ (0.67)</u>
Diluted	<u>\$ (0.26)</u>	<u>\$ (0.27)</u>	<u>\$ (0.85)</u>	<u>\$ (0.67)</u>
Weighted average shares used in computing net loss per common share:				
Basic	<u>11,925</u>	<u>11,569</u>	<u>11,732</u>	<u>11,544</u>
Diluted	<u>11,925</u>	<u>11,569</u>	<u>11,732</u>	<u>11,544</u>

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

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

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 29, 2018</u>	<u>September 30, 2017</u>	<u>September 29, 2018</u>	<u>September 30, 2017</u>
Net loss	\$ (3,074)	\$ (3,096)	\$ (9,957)	\$ (7,712)
Foreign currency translation adjustments	86	—	127	—
Comprehensive loss	<u>\$ (2,988)</u>	<u>\$ (3,096)</u>	<u>\$ (9,830)</u>	<u>\$ (7,712)</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)

	Nine Months Ended	
	September 29, 2018	September 30, 2017
<b>Operating activities:</b>		
Net loss	\$ (9,957)	\$ (7,712)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Gain on sale of intellectual property	—	(175)
Depreciation and amortization	617	660
Change in fair value of earn-out liability	94	122
Stock-based compensation	1,516	1,357
Provision for doubtful accounts	—	(4)
Changes in operating assets and liabilities:		
Accounts receivable	(567)	2,639
Inventories	533	974
Prepaid expenses and other current assets	8	(221)
Other long-term assets	(73)	32
Accounts payable	828	(130)
Accrued compensation	(175)	(8)
Accrued expenses	335	(347)
Accrued warranty	(903)	79
Deferred revenue	(303)	20
Other long-term liabilities	73	80
Net cash used in operating activities	<u>(7,974)</u>	<u>(2,634)</u>
<b>Investing activities:</b>		
Acquisition of property and equipment	(391)	(542)
Proceeds from sale of intellectual property	—	175
Payment on earn-out liability	(302)	(292)
Net cash used in investing activities	<u>(693)</u>	<u>(659)</u>
<b>Financing activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	10,637	2,263
Proceeds from stock option exercises	97	328
Taxes paid related to net share settlements of equity awards	(176)	(294)
Net cash provided by financing activities	<u>10,558</u>	<u>2,297</u>
Effect of foreign exchange rate changes	127	-
Net increase (decrease) in cash and cash equivalents	2,018	(996)
Cash and cash equivalents, beginning of period	21,707	23,747
Cash and cash equivalents, end of period	<u>\$ 23,725</u>	<u>\$ 22,751</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for:		
Income taxes	\$ 9	\$ 19
<b>Supplemental disclosure of non-cash activities:</b>		
Transfer of inventory to property and equipment	\$ 123	\$ —

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 30, 2017, which was filed with the Securities and Exchange Commission (“SEC”) on March 14, 2018. The results of operations for the three and nine months ended September 29, 2018 and September 30, 2017 are not necessarily indicative of the results for the fiscal year ending December 29, 2018 or any future interim period. The three and nine months ended September 29, 2018 and September 30, 2017, each had 13 weeks and 39 weeks, respectively. 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 30, 2017, which was filed with the SEC on March 14, 2018.

*Financial Statement Presentation.*

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

*Use of Estimates.*

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

*Revenue Recognition.*

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

The Company has the following revenue transaction types: (1) Product Sale Only, (2) LAP Programs, (3) Extended Warranty, (4) System Repairs (outside of warranty) and (5) Royalty Revenue.

- (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 eye disease in the retina and glaucoma eye diseases. Inside the United States and Germany the products are sold directly to the end users. In other countries outside of the United States, the Company utilizes independent, third-party distributors to market and sell the Company’s products. There is no continuing obligation subsequent to the shipment to the distributors.

Under the new guidance, there is no change in our revenue recognition for product-sale-only transactions, as compared to revenue recognition for these transactions under the prior revenue recognition standards. For a description of our prior revenue recognition standards, see Note 2 to the consolidated financial statements included as part of our Annual Report on Form 10-K for the period ended December 30, 2017. The Company recognizes revenue from product sale at a point in

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

- (2) **VIP/LAP Programs:** The Company sometimes enters into VIP or Laser Advantage Program (LAP) contracts with customers. For the VIP program, under the terms of such contracts, the customer is not charged for the system upon the initial agreement, but rather is obligated to purchase a quarterly minimum quantity of Endoprobes (classified as disposables) at a premium during the contract period, such that at the end of the contract period the system has been paid in full. The Company decided to replace its previously utilized VIP program (contract length of two years) with an LAP program (contract length of 12 months or less) beginning in fourth quarter of 2016. Under the LAP program, the system is given away free of charge and title is transferred after the customer purchases the minimum required number of boxes of probes (classified as disposables). Customers with older machines have the ability to trade in their old machines for the most current laser equipment offered in the program (G6 Laser) and receive a discount on the program's minimum purchase requirements. Under ASC 606, this non-cash consideration must be included in the transaction price. However, the Company has determined that there is no value associated with the old machine and the trade in is essentially offered to encourage customers to purchase more consumables under the program.

Under the new guidance, there is no change in our revenue recognition for product sales under VIP/LAP programs as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from product sales under VIP/LAP programs at a point in time. For both programs, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

- (3) **Extended Warranty:** The Company offers a standard 2 year warranty on all system sales (5 years on the laser heads for its IQ 532/577 laser consoles). The Company also offers an extended warranty which is sold to customers in incremental, one-year warranty periods which begin subsequent to the expiration of the standard 2 year warranty. The customer can opt to purchase the extended warranty at the time of the system sale or after the initial system sale.

Under the new guidance, there is no change in our revenue recognition for extended warranty as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from extended warranty ratably over the warranty period. Revenue recognition for the sale of an extended warranty is largely dependent on the timing of the sale as follows:

- a. **Extended Warranty Sale in Conjunction with System Sale:** If the customer opts to purchase an extended warranty 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. **Extended Warranty Sale Subsequent to System Sale:** If the customer opts to purchase an extended warranty after the initial system sale, the Company determines the amount of time that has elapsed since the initial system sale. If the extended warranty 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 extended warranty is purchased subsequent to sixty days after the initial sale, the sale of the extended warranty is deemed a separate contract and is deferred at the selling price and recognized ratably over the extended warranty period as the performance obligation is satisfied.
- (4) **System Repairs (outside of warranty):** Customers will sometime request repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contract.

Under the new guidance, there is no change in our revenue recognition for system repairs (outside warranty) as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from system repairs (outside of warranty) at a point in time. When the customer request repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contracts, these repair contracts are considered separate from the initial sale, and as such, revenue is recognized as the repair services are rendered and the performance obligation satisfied.

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



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

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

*Concentration of Credit Risk.*

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

We market our products to distributors and end-users throughout the world. Sales to international distributors are generally made on open credit terms and letters of credit. Management performs ongoing credit evaluations of our customers and maintains an allowance for potential credit losses. Historically, we have not experienced any significant losses related to individual customers or a group of customers in any particular geographic area. For the three months ended September 29, 2018 one customer accounted for more than 10% of total revenues, representing 11%. For the nine months ended September 29, 2018, no single customer accounted for more than 10% of total revenues. During the three and nine months ended September 30, 2017, no single customer accounted for more than 10% of total revenues. As of September 29, 2018, one customer accounted for over 10% of our accounts receivable, representing 18%. As of December 30, 2017, no customer accounted for more than 10% of our accounts receivable.

*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. Revenue related to extended 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. The deferred revenue balance is expected to be recognized over the next 12 months.

A reconciliation of the changes in the Company's deferred revenue balance for the nine months ended September 29, 2018 and September 30, 2017 is as follows:

	Nine Months Ended	
	September 29, 2018	September 30, 2017
Balance, beginning of period	\$ 2,520	\$ 1,383
Additions to deferral	1,426	981
Revenue recognized	(1,729)	(961)
Balance, end of period	<u>\$ 2,217</u>	<u>\$ 1,403</u>

*Warranty.*

The Company currently provides a two year full warranty on its products. In addition, in March 2017, the Company began to offer a five year warranty on the laser heads for its IQ 532/577 laser consoles. The associated costs of these warranties are accrued for upon shipment of the products. The Company had previously provided a one to two year warranty on its product. Actual warranty costs incurred have not materially differed from those accrued. In March 2018, we have reversed the warranty expense associated with products shipped outside of the United States that were accrued in December 2017 as these reserves are no longer deemed required. 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 statement of operations as cost of revenues.

A reconciliation of the changes in the Company's warranty liability for the nine months ended September 29, 2018 and September 30, 2017 is as follows:

	Nine Months Ended	
	September 29, 2018	September 30, 2017
Balance, beginning of period	\$ 1,735	\$ 603
Accruals for product warranties	298	319
Cost of warranty claims	(1,201)	(240)
Balance, end of period	<u>\$ 832</u>	<u>\$ 682</u>

*Reclassifications.*

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

*Recently Adopted Accounting Standards.*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 Revenue from Contracts with Customers (Topic 606) ("ASC 606"), which, along with amendments issued in 2015, 2016 and 2017, replaces nearly all current U.S. GAAP guidance on this topic with a comprehensive revenue measurement and recognition standard and expanded disclosure requirements. This new guidance provides a five-step analysis in determining when and how revenue is recognized. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In addition, the new guidance requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

As part of our assessment and implementation plan, we evaluated our policies, procedures and internal controls. In preparation for adoption of the standard, the Company has implemented internal controls to enable the preparation of financial information, including the assessment of the impact of the standard. The Company has adopted this guidance using the modified retrospective method in the first quarter of fiscal 2018. Under the modified retrospective method, the new standards apply to all new contracts initiated on or after the effective date, and for contracts which have remaining obligations as of the effective date, an adjustment to the opening balance of retained earnings is required. Based on the results of the procedures taken in adopting this standard, we determined that our accounting for revenues under the then prescribed standard (ASC 605) was not different from the new ASC 606 standard. As such, we did not have any adjustments to our opening balance of our retained earnings.

In August 2016, the FASB issued ASU 2016-15 "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." The amendment gives guidance and reduces diversity in practice with respect to certain types of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The adoption of this standard in fiscal year 2018 did not have a material impact on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, to ASC 740 "Income Taxes," which simplifies the recording of an inter-entity transfer of assets other than inventory. The new guidance requires that a company recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The new guidance becomes effective for annual reporting periods beginning after December 15, 2017 and must be applied using a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the adoption period. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting." The amendments in ASU 2017-09 include guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. These amendments require the entity to account for the effects of a modification unless all of the following conditions are met: the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or value using an alternative measurement method) of the original award immediately before the original award is modified; the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company's consolidated financial statements.

In March 2018, the FASB issued ASU 2018-05, “Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118.” ASU 2018-05 formally amended ASC Topic 740, Income Taxes (“ASC 740”) for the guidance previously provided by SEC Staff Accounting Bulletin No. 118 (“SAB 118”), which provides guidance for the application of ASC 740 in the reporting period in which the U.S. Tax Cuts and Jobs Act (the “Tax Reform Act”) was signed into law. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company’s consolidated financial statements.

*Recent Accounting Standards Not Yet Adopted.*

In February 2016, the FASB issued ASU 2016-02, “Leases,” which, along with amendments issued in 2018, modified lessee accounting guidance under Topic 840. This ASU requires the Company to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leases with terms of more than twelve months. This ASU also requires disclosures enabling the users of financial statements to understand the amount, timing and uncertainty of cash flows arising from leases. This new standard will become effective for annual periods beginning after December 15, 2018 (including interim reporting periods within those periods). Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In July 2018, the FASB issued ASU 2018-09, “Codification Improvements,” which clarifies and makes minor improvements to the Codification. The amendments impacts various areas, such as Subtopic 220-10, Income Statement-Reporting Comprehensive Income-Overall; Subtopic 718-740, Compensation-Stock Compensation-Income Taxes; and Subtopic 820-10, Fair Value Measurement-Overall. The guidance is effective for annual periods beginning after December 15, 2018. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,” which removes, modifies and adds certain disclosure requirements on fair value measurements. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

**3. Inventories**

The components of the Company’s inventories as of September 29, 2018 and December 30, 2017 are as follows:

	<u>September 29, 2018</u>	<u>December 30, 2017</u>
Raw materials	\$ 3,229	\$ 4,147
Work in process	824	1,567
Finished goods	4,672	3,667
Total inventories	<u>\$ 8,725</u>	<u>\$ 9,381</u>

**4. Goodwill and Intangible Assets**

*Goodwill.*

The carrying value of goodwill was \$0.5 million as of September 29, 2018 and December 30, 2017.

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 2018 and determined that its goodwill was not impaired. As of September 29, 2018, the Company had not identified any factors that indicated there was an impairment of its goodwill and determined that no additional impairment analysis was then required.

## Intangible Assets.

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

	September 29, 2018			Remaining Amortization Life	December 30, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Customer relations	240	136	104	6.50 Years	240	124	116

For the nine months ended September 29, 2018 and September 30, 2017, amortization expense totaled \$12 thousand for each period.

The amortization of customer relations was charged to sales and marketing expense and the amortization of patents was charged to cost of revenues. Future estimated amortization expense (in thousands):

Fiscal Year:	
2018 (three months)	\$ 4
2019	16
2020	16
2021	16
2022	16
Thereafter	36
Total	<u>\$ 104</u>

## 5. 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, as well as 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 September 29, 2018 and December 30, 2017, approximate fair value because of the short maturity of these instruments.

As of September 29, 2018 and December 30, 2017, financial assets and liabilities 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 September 29, 2018				As of December 30, 2017			
	Fair Value Measurements				Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Money market funds	\$ 22,844	\$ —	\$ —	\$ 22,844	\$ 20,950	\$ —	\$ —	\$ 20,950
<b>Liabilities:</b>								
Earn-out liability	\$ —	\$ —	\$ 364	\$ 364	\$ —	\$ —	\$ 572	\$ 572

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 financial assets or liabilities. The fair value of the earn-out liability arising from the acquisition of RetinaLabs, Inc. is classified within Level 3 of the fair value hierarchy since it is based on significant unobservable inputs. The significant unobservable inputs include projected royalties and discount rates to present value the payments. A significant increase (decrease) in the projected royalty payments in isolation could result in a significantly higher (lower) fair value measurement and a significant increase (decrease) in the discount rate in isolation could result in a significantly lower (higher) fair value measurement. The fair value of the earn-out liability is calculated on a quarterly basis by the Company based on a collaborative effort of the Company's operations, finance and accounting groups as additional information becomes available. Any change in the fair value adjustment is recorded in the statement of operations of that period.

The following tables present quantitative information about the inputs and valuation methodologies used for our fair value measurements classified in Level 3 of the fair value hierarchy as of September 29, 2018 and December 30, 2017.

As of September 29, 2018	Fair Value (in thousands)	Valuation Technique	Significant Unobservable Input	Weighted Average (range)
Earn-out liability	\$ 364	Discounted cash flow	Projected royalties (in thousands)	\$1,314
			Discount rate	10.35% (10.20% - 27.00%)
As of December 30, 2017	Fair Value (in thousands)	Valuation Technique	Significant Unobservable Input	Weighted Average (range)
Earn-out liability	\$ 572	Discounted cash flow	Projected royalties (in thousands)	\$1,622
			Discount rate	10.90% (10.90% - 27.00%)

A reconciliation of the changes in the Company's earn-out liability (Level 3 liability) for the nine months ended September 29, 2018 and September 30, 2017 is as follows:

(in thousands)	Nine Months Ended	
	September 29, 2018	September 30, 2017
Balance as of beginning of the period	\$ 572	\$ 694
Payments against earn-out	(302)	(292)
Change in fair value of earn-out liability	94	122
Balance as of the end of the period	\$ 364	\$ 524

The earn-out liability is included in accrued expenses and other long-term liabilities in the condensed consolidated balance sheets. Any change in the fair value adjustment is recorded to other expense in the condensed consolidated statements of operations.

## 6. Commitments and Contingencies

### *Operating Lease Commitments.*

Our operating lease commitments consist primarily of our facility lease and various office and computer equipment leases. As of September 29, 2018, our total future minimum lease payments through fiscal year 2022 under current operating leases was approximately \$4.9 million.

### *Purchase Commitments.*

Our purchase commitments consist primarily of non-cancellable purchase commitments with vendors to manufacture certain components and ophthalmic instrumentation. As of September 29, 2018, our future minimum payments through fiscal year 2019 for our purchase commitments was approximately \$13.4 million.

### *Indemnities.*

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties (generally our business partners or customers) in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to our products. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the 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.*

In January 2018, we filed a lawsuit against Quantel Medical, S.A., Quantel USA, Inc., and Quantel, S.A. (collectively, "Quantel") in the U.S. District Court for the Northern District of California. The lawsuit alleges that Quantel products infringe U.S. Patent No. 7,771,417, that Quantel breached an earlier agreement between Quantel and the Company, and that Quantel has infringed upon the Company's MicroPulse® trademark, Registration No. 4550188 on the principal register. Quantel previously had a limited license to the asserted Company patent and trademark. Our complaint filed in connection with this matter asserts that the license was terminated in early 2017 for material breach, but that Quantel continued to use our intellectual property without authorization.

On March 8, 2017, OD-OS GmbH noticed an opposition to the Company's European Patent No. currently EP 1 856 774 at the European Patent Office ("EPO"). On June 8, 2018, Quantel intervened in the Opposition. Oral proceedings on the opposition took place on July 13, 2018. At the conclusion of those proceedings, the EPO's Opposition Division communicated that it would move to revoke the patent. The formal written decision from the Opposition Division was issued on October 1, 2018. The Company filed its notice of appeal on October 10, 2018.

In late May of 2018, Quantel applied to the Paris District Court in Paris, France for a ruling that its products do not infringe the French Part of Iridex's European Patent at issue in the opposition, EP 1 856 774. A scheduling conference is set for November 6, 2018.

In addition, 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.

## 7. Stockholders' Equity and Stock-Based Compensation

### Common Stock

In September 2018, the Company completed its registered underwritten public offering of 1,916,667 shares of the Company's common stock at a public offering price of \$6.00 per share, pursuant to an underwriting agreement with Stifel, Nicolaus & Company, Incorporated, as representative of the underwriters named therein. The resulting aggregate net proceeds to the Company from the common stock offering was approximately \$10.6 million, after deducting underwriting discount and offering expenses.

### Stock-Based Compensation

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

The Company values options using the Black-Scholes option pricing model. Restricted stock and time-based restricted stock units are valued at the grant date fair value of the underlying common shares. Performance-based restricted stock units 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.

For the nine months ended September 29, 2018, the only active stock-based compensation plan was the 2008 Equity Incentive Plan, or Incentive Plan. The terms of awards granted during the nine months ended September 29, 2018 were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 30, 2017.

The following table shows stock-based compensation expenses included in the condensed consolidated statements of operations for the three and nine months ended September 29, 2018 and September 30, 2017:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Cost of revenues	\$ 23	\$ 39	\$ 68	\$ 131
Research and development	94	104	214	215
Sales and marketing	169	59	348	238
General and administrative	387	319	886	773
	<u>\$ 673</u>	<u>\$ 521</u>	<u>\$ 1,516</u>	<u>\$ 1,357</u>

Stock-based compensation expense capitalized to inventory was immaterial for the nine months ended September 29, 2018 and September 30, 2017.

Occasionally, the Company will grant stock-based instruments to non-employees. During the nine months ended September 29, 2018 and September 30, 2017, the amount of stock-based compensation related to non-employee options was not material.

#### Summary of Stock Options.

The following table summarizes information regarding activity under the Incentive Plan during the nine months ended September 29, 2018:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding as of December 30, 2017	857,311	\$ 9.49	
Granted	136,435	\$ 6.22	
Exercised	(23,750)	\$ 4.10	
Canceled or forfeited	(62,286)	\$ 10.48	
Outstanding as of September 29, 2018	<u>907,710</u>	\$ 9.07	\$ 132

The weighted average grant date fair value of the options granted under the Incentive Plan as calculated using the Black-Scholes option-pricing model was \$2.47 and \$3.55 per share for the three months ended September 29, 2018 and September 30, 2017, respectively. The weighted average grant date fair value of the options granted under the Incentive Plan as calculated using the Black-Scholes option-pricing model was \$2.34 and \$3.75 per share for the nine months ended September 29, 2018 and September 30, 2017, respectively.

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

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Average risk free interest rate	2.95%	1.80%	2.71%	1.79%
Expected life (in years)	4.55 years	4.55 years	4.55 years	4.55 years
Dividend yield	—%	—%	—%	—%
Average volatility	41%	42%	41%	42%

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 September 29, 2018 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
Options outstanding	907,710	\$ 9.07	5.06	\$ 132
Options vested and expected to vest	848,436	\$ 9.09	5.00	\$ 126
Options exercisable	384,468	\$ 9.07	3.87	\$ 87

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of September 29, 2018, 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 nine months ended September 29, 2018 and September 30, 2017 was approximately \$71 thousand and \$328 thousand, respectively.

As of September 29, 2018, there was \$5.9 million of total unrecognized compensation cost, net of expected forfeitures, related to non-vested stock-based compensation arrangements under the Incentive Plan. The cost is expected to be recognized over a weighted average period of 2.91 years.



## Summary of Restricted Stock Units and Awards

Information regarding the restricted stock units (“RSUs”) activity for the nine months ended September 29, 2018 is summarized below:

	Number of Shares
Outstanding as of December 30, 2017	361,148
Restricted stock units granted	408,750
Restricted stock units released	(76,399)
Restricted stock units forfeited	(6,750)
Outstanding as of September 29, 2018	686,749

During the nine months ended September 29, 2018, the Company awarded 408,750 restricted stock units at a weighted-average grant date fair value of \$7.86 per share.

RSUs granted with market conditions are valued using a Monte Carlo simulation model and compensation expense is recognized ratably during the service period even if the market condition is not satisfied. To the extent that the market condition is not met, the RSUs will not vest and will be cancelled. 72,870 RSUs with market conditions were granted during the nine months ended September 29, 2018.

RSUs granted with performance conditions are valued at the grant date fair value of the underlying common shares. The Company makes a determination regarding the probability of the performance criteria being achieved and compensation expense is recognized ratably over the vesting period, if it is expected that the performance criteria will be met. During the nine months ended September 29, 2018, the Company awarded 165,330 RSUs granted with performance conditions.

Information regarding the restricted stock awards activity during the nine months ended September 29, 2018 is summarized below:

	Number of Shares
Outstanding as of December 30, 2017	4,301
Restricted stock awards granted	—
Restricted stock awards released	(4,301)
Outstanding as of September 29, 2018	—

## 8. Income Taxes

### Provision for Income Tax.

The Company calculates its interim tax provision in accordance with the provisions of ASC 740-270, *Income Taxes; Interim Reporting*. For interim periods, the Company estimates its annual effective income tax rate and applies the estimated rate to the year-to-date income or loss before income taxes. The Company also computes the tax provision or benefit related to items reported separately and recognizes the items net of their related tax effect in the interim periods in which they occur. The Company also recognizes the effect of changes in enacted tax laws or rates in the interim periods in which the changes occur. The Company recorded a provision for income tax of \$14 thousand and \$23 thousand for the nine months ended September 29, 2018 and September 30, 2017, respectively.

In December 2017, the Securities and Exchange Commission staff issued Staff Accounting Bulletin No.118 (SAB 118) to provide guidance on the application of the Tax Reform Act when a company does not have necessary information available, prepared, or analyzed to reflect the effects of the Tax Reform Act. SAB 118 provides guidance for companies under three scenarios (1) measurement of certain income tax effects is complete, (2) measurement of certain income tax effect can be reasonably estimated, and (3) measurement of certain income tax effects cannot be reasonably estimated. Companies are to complete the accounting under ASC 740 in regards to the Tax Reform Act within a measurement period that does not extend one year from the date of enactment (i.e., December 22, 2018). The Company is still within the measurement period as of the end of the third quarter of 2018 and the Company is continuing to review the impact of the adoption of the Tax Reform Act on the Company.

### 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 fourth quarter of fiscal year 2017, based on the Company’s recent history of earnings and its forecasted losses, management believes on the more likely than not basis that a full valuation allowance is required. Accordingly, in the fourth quarter of fiscal year 2017, the company provided 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 30, 2017, the Company had \$1.0 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.

## 9. Computation of Basic and Diluted Net Loss Per Common Share

Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding during the period. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options, and the release (vesting) of restricted stock units and awards and are calculated under the treasury stock method. Common stock equivalent shares from unexercised stock options, and unvested restricted stock units 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 September 29, 2018 and September 30, 2017, potential shares from stock options, RSUs and Restricted Stock Awards (“RSAs”) totaling 1,436,320 and 842,775 shares, respectively, were excluded from the computation of diluted weighted average shares outstanding. For the nine months ended September 29, 2018 and September 30, 2017, potential shares from stock options, RSUs and RSAs totaling 1,253,843 and 868,198 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		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
<b>Numerator:</b>				
Net loss	\$ (3,074)	\$ (3,096)	\$ (9,957)	\$ (7,712)
<b>Denominator:</b>				
Weighted average shares of common stock (basic)	11,925	11,569	11,732	11,544
Weighted average shares of common stock (diluted)	11,925	11,569	11,732	11,544
<b>Per share data:</b>				
Basic net loss per share	\$ (0.26)	\$ (0.27)	\$ (0.85)	\$ (0.67)
Diluted net loss per share	\$ (0.26)	\$ (0.27)	\$ (0.85)	\$ (0.67)

## 10. 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 geographic region, based on the sales destination, is as follows:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
United States	\$ 6,182	\$ 6,294	\$ 16,156	\$ 17,880
Europe	2,020	1,727	6,680	5,502
Rest of Americas	554	689	1,862	1,853
Asia/Pacific Rim	2,564	2,155	6,435	6,115
	<u>\$ 11,320</u>	<u>\$ 10,865</u>	<u>\$ 31,133</u>	<u>\$ 31,350</u>

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

Other than the United States, China accounted for more than 10% of the Company's revenues during the three months ended September 29, 2018, representing 11%. No individual country accounted for more than 10% of the Company's revenues, other than the United States, during the nine months ended September 29, 2018 and during the three and nine months ended September 30, 2017. The United States accounted for 54.6% and 57.9% of revenues for the three months ended September 29, 2018 and September 30, 2017, respectively. For the nine months ended September 29, 2018 and September 30, 2017, the United States accounted for 51.9% and 57.0% of sales, respectively. International sales accounted for 45.4% and 42.1% of revenues for the three months ended September 29, 2018 and September 30, 2017, respectively. For the nine months ended September 29, 2018 and September 30, 2017, International sales accounted for 48.1% and 43.0% of sales, respectively.

## 11. Subsequent Events

The Company has evaluated subsequent events and has concluded that no subsequent events that require disclosure in the financial statements have occurred since the quarter ended September 29, 2018.

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

This Quarterly Report on Form 10-Q contains certain 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. These statements are based on management’s beliefs and assumptions and on information currently available to management. These statements include statements concerning future demand and order levels for the Company’s products, future operating expenses, changes in personnel, product development and intellectual property related matters, the adoption and effect of Company products on its results, the markets in which the Company operates, usage and efficacy of the Company’s products, the Company’s future financial results, the impact of the Company’s adoption of new or revised accounting standards, and the Company’s strategic plans and objectives. In some cases, forward-looking statements can be identified by terminology, such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “intends,” “potential,” “continue,” or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. The reader is strongly urged to read the information contained under Item 1A of Part II of this Quarterly Report on Form 10-Q for a more detailed description of these significant risks and uncertainties. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management’s analysis only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update such forward-looking statements to reflect events or circumstances occurring after the date of this report.

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.

### Overview

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

Our laser consoles consist of the following product lines:

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

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

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

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

Our products are sold in the United States predominantly through a direct sales force and internationally primarily through independent distributors. We established direct sales capabilities in Germany in 2017.

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 will be denominated in Euros and will be subject to risks associated with the currency fluctuations.

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

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

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

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

## Results of Operations

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

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Revenues	100.0%	100.0%	100.0%	100.0%
Cost of revenues	59.6%	59.8%	59.0%	57.5%
Gross margin	40.4%	40.2%	41.0%	42.5%
Operating expenses:				
Research and development	10.2%	12.1%	10.1%	12.8%
Sales and marketing	36.6%	34.7%	39.7%	33.0%
General and administrative	20.7%	23.3%	23.2%	21.7%
Gain on sale of intangible assets	---	(1.6%)	---	(0.6%)
Total operating expenses	67.5%	68.5%	73.0%	66.9%
Loss from operations	(27.1%)	(28.3%)	(32.0%)	(24.4%)
Other income (expense), net	---	(0.1%)	---	(0.1%)
Loss from operations before provision for income taxes	(27.1%)	(28.4%)	(32.0%)	(24.5%)
Provision for income taxes	0.1%	0.1%	---	0.1%
Net loss	(27.2%)	(28.5%)	(32.0%)	(24.6%)

The following comparisons are between the three months ended September 29, 2018 and September 30, 2017:

Revenues.

(in thousands)	Three Months Ended	Three Months Ended	Change in \$	Change in %
	September 29, 2018	September 30, 2017		
Systems – domestic	\$ 2,541	\$ 2,497	\$ 44	1.8%
Systems – international	3,319	2,986	333	11.2%
Recurring revenues	5,460	5,382	78	1.4%
Total revenues	\$ 11,320	\$ 10,865	\$ 455	4.2%

Our total revenues increased by \$0.5 million, or 4.2%, from \$10.9 million to \$11.3 million for the third quarter of fiscal year 2018. The increase is primarily due to an increase in international systems sales of \$0.3 million. Our recurring revenues increased by \$0.1 million due to an increase in G6 related probes, partially offset by a decrease in legacy probe sales.

### *Gross Profit and Gross Margin.*

Gross profit was \$4.6 million compared with \$4.4 million, an increase of \$0.2 million. Gross margin was 40.4% compared with 40.2%, an increase of 0.2 percentage points. The increase in gross margin was attributable to a favorable shift in product mix and a decrease in manufacturing variances and manufacturing overhead spending, partially offset by an unfavorable geographic mix.

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

### *Research and Development.*

Research and development (“R&D”) expenses decreased by \$0.2 million, or 13.0%, from \$1.3 million to \$1.1 million. The decrease in spending was primarily attributable to a decrease in salaries and related costs due to a decrease in headcount.

### *Sales and Marketing.*

Sales and marketing expenses increased by \$0.3 million, or 9.9%, from \$3.8 million to \$4.1 million. The increase in spending was attributable to an increase in salaries and related costs due to an increase in headcount, commission expense, and other general selling and marketing expenses.

### *General and Administrative.*

General and administrative expenses decreased by \$0.2 million, or 7.4%, from \$2.5 million to \$2.3 million. The decrease in spending was primarily attributable to a decrease in severance costs, partially offset by an increase in our German operations.

### *Other Income (Expense), Net.*

Other expense, net amounted to \$8 thousand, compared to other expense, net of \$16 thousand. Other income (expense), net, consisted primarily of the change in expense associated with the re-measurement of contingent liabilities, partially offset by interest income.

### *Income Taxes.*

We recorded an income tax provision of \$6 thousand and \$9 thousand, respectively.

### **The following comparisons are between the nine months ended September 29, 2018 and September 30, 2017:**

#### *Revenues.*

(in thousands)	Nine Months Ended	Nine Months Ended	Change in \$	Change in %
	September 29, 2018	September 30, 2017		
Systems – domestic	\$ 5,099	\$ 6,463	\$ (1,364)	(21.1%)
Systems – international	9,218	8,422	796	9.5%
Recurring revenues	16,816	16,465	351	2.1%
Total revenues	<u>\$ 31,133</u>	<u>\$ 31,350</u>	<u>\$ (217)</u>	(0.7%)

Our total revenues decreased \$0.2 million, or 0.7%, from \$31.3 million to \$31.1 million for the first nine months of fiscal year 2018. The decrease is due mainly to a decrease in domestic systems sales of \$1.4 million, partially offset by an increase in international system sales of \$0.8 million. Domestic system sales were impacted by a decrease in retina system sales primarily due to the impact of our voluntary recall. Our recurring revenues increased by \$0.4 million due to an increase in G6 related probes, partially offset by a decrease in legacy probe sales.

### *Gross Profit and Gross Margin.*

Gross profit was \$12.8 million compared with \$13.3 million, a decrease of \$0.5 million. Gross margin was 41.0% compared with 42.5%, a decrease of 1.5 percentage points. Gross margin was primarily impacted by unfavorable geographic mix and an increase in manufacturing overhead spending, partially offset by a decrease in manufacturing variances.

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 \$0.8 million, or 21.7%, from \$4.0 million to \$3.2 million. The decrease in spending was primarily attributable to a decrease in salaries and related costs as a result of a decrease in headcount.

#### *Sales and Marketing.*

Sales and marketing expenses increased \$2.1 million, or 19.5%, from \$10.3 million to \$12.4 million. The increase in spending was attributable to an increase in salaries and related costs due to an increase in headcount, increase in our German operations, and other general selling and marketing expenses.

#### *General and Administrative.*

General and administrative expenses increased \$0.4 million, or 6.0%, from \$6.8 million to \$7.2 million. The increase in spending was attributable to an increase in our German operations, legal expenses, and an increase in salaries and related costs due to an increase in headcount.

#### *Other Income (Expense), Net.*

Other income, net amounted to \$16 thousand, compared with other expense, net of \$19 thousand. Other income (expense), net, consisted primarily of the change in expense associated with the re-measurement of contingent liabilities, partially offset by interest income.

#### *Income Taxes.*

We recorded an income tax provision of \$14 thousand and \$23 thousand, respectively.

#### *Liquidity and Capital Resources.*

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

As of September 29, 2018, we had cash and cash equivalents of \$23.7 million and working capital of \$31.0 million compared to cash and cash equivalents of \$21.7 million and working capital of \$29.1 million as of December 30, 2017.

Net cash used in operating activities was \$8.0 million in the nine months ended September 29, 2018 compared to \$2.6 million in the nine months ended September 30, 2017. The increase in net cash used in operating activities was primarily due to changes in working capital, driven by lower cash collections and timing of vendor payments.

For the nine months ended September 29, 2018, net cash used in investing activities was \$0.7 million, which consisted of \$0.4 million on capital expenditures and \$0.3 million for payment of the contingent earn-out liability. Net cash used in investing activities for the nine months ended September 30, 2017 was \$0.7 million, which consisted of \$0.5 million on capital expenditures and \$0.3 million for payment of the contingent earn-out liability, partially offset by \$0.2 million proceeds from sale of intellectual property.

For the nine months ended September 29, 2018, net cash provided by financing activities was \$10.6 million, which consisted of \$10.6 million net proceeds arising from the issuance of common stock and \$0.1 million proceeds from stock option exercises, partially offset by payroll taxes related to net share settlement of equity awards. Net cash provided by financing activities for the nine months ended September 30, 2017 was \$2.3 million, which consisted of \$2.3 million net proceeds arising from issuance of common stock and \$0.3 million proceeds from stock option exercises, partially offset by \$0.3 million payroll taxes related to net share settlement of equity awards.

We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs over the next 12 months.

### *Contractual Obligations and Commitments.*

Our contractual obligations and commitments as of September 29, 2018 are as follows:

<i>(in thousands)</i>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>
Operating leases payments	\$ 4,851	\$ 1,277	\$ 3,574	\$ —	\$ —
Purchase commitments	13,368	8,470	4,898	—	—
Total obligations	<u>\$ 18,219</u>	<u>\$ 9,747</u>	<u>\$ 8,472</u>	<u>\$ —</u>	<u>\$ —</u>

Our operating lease commitments consist primarily of our facility leases.

Our purchase commitments consist primarily of non-cancellable purchase commitments with vendors to manufacture certain components and ophthalmic instrumentation.

### *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.

### **Other Information**

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In November 1995, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at [www.IRIDEX.com](http://www.IRIDEX.com). Investors and others should note that we announce material financial information to our investors using SEC filings, press releases, our investor relations website, public conference calls and webcasts. We use these channels as well as social media to communicate with investors, customers and the public about our company, our products and other issues. It is possible that the information we post on social media channels could be deemed to be material information. We encourage investors, our customers, and others interested in our company to review the information we post on our Facebook page ([www.facebook.com/IRIDEX](http://www.facebook.com/IRIDEX)) and Twitter feed (<https://twitter.com/IRIDEX>). Any information on, or that can be accessed through, our website and social media channels is not part of this report.

### **Item 3. Quantitative and Qualitative Disclosure about Market Risk**

Market risk represents the risk of loss that may impact the financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. Our international revenues and costs for the nine months ended September 29, 2018 were primarily denominated in U.S. dollars and therefore changes in foreign currency rates will not have an impact on our income statement or cash flows. 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. As we continue to expand our international sales, our non-U.S. dollar denominated revenue and our exposure to gains and losses on international currency transactions may increase. Sales to direct end users transacted through our German office are denominated in Euros and will be subject to risks associated with the currency fluctuations. We currently do not engage in transactions to hedge against the risk of the currency fluctuation, but we may do so in the future.

#### *Interest Rate Risk.*

Our exposure to interest rate risk as of September 29, 2018 is related to our cash equivalent holdings, which is not material given the nature of our cash equivalent holdings. Since we have no fixed or variable interest rate debt outstanding, our interest expense is not affected by changes in interest rates. In the event we issue any new variable-rate debt in the future, increases in interest rates would increase the interest expense associated with the debt.

### **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 Chief Executive Officer and our Chief 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 Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 29, 2018. Based on the foregoing, our Chief Executive Officer and our Chief 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**

In January 2018, we filed a lawsuit against Quantel Medical, S.A., Quantel USA, Inc., and Quantel, S.A. (collectively, “Quantel”) in the U.S. District Court for the Northern District of California. The lawsuit alleges that Quantel products infringe U.S. Patent No. 7,771,417, that Quantel breached an earlier agreement between Quantel and the Company, and that Quantel has infringed upon the Company’s MicroPulse® trademark, Registration No. 4550188 on the principal register. Quantel previously had a limited license to the asserted Company patent and trademark. Our complaint filed in connection with this matter asserts that the license was terminated in early 2017 for material breach, but that Quantel continued to use our intellectual property without authorization.

On March 8, 2017, OD-OS GmbH noticed an opposition to the Company’s European Patent No. currently EP 1 856 774 at the European Patent Office (“EPO”). On June 8, 2018, Quantel intervened in the Opposition. Oral proceedings on the opposition took place on July 13, 2018. At the conclusion of those proceedings, the EPO’s Opposition Division communicated that it would move to revoke the patent. The formal written decision from the Opposition Division was issued on October 1, 2018. The Company filed its notice of appeal on October 10, 2018.

In late May of 2018, Quantel applied to the Paris District Court in Paris, France for a ruling that its products do not infringe the French Part of Iridex’s European Patent at issue in the opposition, EP 1 856 774. A scheduling conference is set for November 6, 2018.

In addition, 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**

#### **Factors That May Affect Future Results**

In addition to the other information contained in this Quarterly Report 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.

*If applicable, we have marked with an asterisk (\*) those risk factors below that reflect substantive changes to the text of the risk factors included in our Annual Report on Form 10-K for the year ended December 30, 2017, which was filed with the SEC on March 14, 2018.*

## Risks Relating to our Business

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

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

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

In the past several years, we have experienced supply chain, production and training issues as we have expanded our product lines and sales volumes, and may experience similar issues in the future as we continue to grow our business. 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 network of international distributors to sell our products and any failure to maintain our sales force and distributor relationships 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, relationships with independent distributors outside the United States, and the establishment of our direct sales capabilities in Germany. Currently our direct and independent sales forces within the United States consist of approximately 21 employees and one independent representative, respectively. Our international independent distributors are managed by a team of seven people. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are largely dependent on the efforts of these third parties. If any distributor breaches the terms of its distribution agreement with us or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would 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 and distributor agreements are generally terminable at will by either party and independents and distributors may terminate their relationships with us, which would affect our sales and results of operations. As we establish our direct sales capabilities in Germany, we may be unable to recruit and retain qualified personnel in this region. 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 create operational challenges without immediately offsetting benefits.***

We have increased and continue to increase our internal sales and marketing functions. This growth may place a significant strain on our management, operating and financial systems and our sales, marketing, training and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. For example, if we are unable to provide adequate training for our expanding sales force, our ability to fully utilize new sales and marketing resources may be adversely impacted, we could suffer reputational harm and our ability to maintain our installed base of customers may be negatively impacted. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

It can take six months or longer before our internal sales representatives are fully trained and productive in selling our solution to prospective clients. This ramp 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 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 will 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 third quarter of fiscal 2018, our international sales were \$5.1 million, or 45.4% 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 quarter ended September 29, 2018 have been denominated in U.S. dollars except for a sale 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 our 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:

- fluctuations in foreign currency exchange rates;
- product and production issues;
- performance of our international channel of distributors;
- longer accounts receivable collection periods;
- impact of recessions in global economies and availability of credit;
- political and economic instability;
- 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;
- 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, 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.

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 Food and Drug Administration (“FDA”) and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

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

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

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

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

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

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

- changes in the prices at which we can sell our products, including the impact of changes in exchange rates;
- general economic uncertainties and political concerns;
- introduction of new products, product enhancements and new applications by our competitors, including new drugs, entry of new competitors into our markets, pricing pressures and other competitive factors;
- any delays or reductions in product shipments, or product recalls, resulting from manufacturing, distribution or other operational issues;
- the timing of the introduction and market acceptance of new products, product enhancements and new applications;
- changes in demand for our existing line of ophthalmology products;
- the cost and availability of components and subassemblies, including the willingness and ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;
- our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- fluctuations in our product mix within ophthalmology products and foreign and domestic sales;
- the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- our long and highly variable sales cycle;
- changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products;
- variances in shipment volumes as a result of product, supply chain and training issues; and
- increased product innovation costs.

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

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

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

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

- acceptance of product performance, features, ease of use, scalability and durability, including with respect to our MicroPulse laser photocoagulation systems;
- recommendations and opinions by ophthalmologists, other clinicians, and their associated opinion leaders;
- marketing and clinical study outcomes;
- price of our products and prices of competing products and technologies, particularly in light of the current macro-economic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;

- availability of competing products, technologies and alternative treatments; and
- level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation, including our MP3 and EndoProbe devices. Our ability to increase recurring revenues from the sale of consumable products will depend primarily upon the features of our current products and product innovation, the quality of, ease of use and prices of our products, including the relationship to prices of competing products. The level of our service revenues will depend on the quality of service we provide and the responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices, consumables or services may have a material adverse effect on our business, results of operations and financial condition.

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

Competition in the market for laser systems and delivery devices used for ophthalmic treatment procedures is intense and is expected to increase. This market is also characterized by technological innovation and change. We compete by providing features and services that are valued by our customers such as: enhanced product performance, 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 and Lomb (Valeant), Carl Zeiss Meditec AG, Ellex Medical Lasers, Ltd., Lumenis Ltd., Nidek Co. Ltd., Quantel Medical SA, and Topcon Corporation. We also compete with alternative glaucoma surgical device companies such as Alcon, Allergan, and Glaukos. Pharmaceuticals represent alternative treatments to our laser procedures. Some of our principal pharmaceutical competitors are Alcon, Allergan, OSI Pharmaceuticals (Astellas), Pfizer, Regeneron, Roche (Genentech) and Valeant Pharmaceuticals. Some of our competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical device companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the conditions targeted by us, or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

***Our 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. 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. 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. Open Payments, commonly known as the Sunshine Act, is a relatively new law, and compliance with this law has presented a number of challenges to companies such as ours, in terms of interpretation of the law and its implementation. Under the Sunshine Act, Centers for Medicare & Medicaid Services (“CMS”) has the potential to impose penalties of up to \$1.15 million per year for violations, depending on the circumstances, although enforcement has been negligible to date. Payments reported under the Sunshine Act also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute and other healthcare laws. The risk that we are our being found in violation of these laws may be increased by the fact that we do not have a formal healthcare compliance program in place. Further, while safe harbors may in some instances be available and utilized by companies to reduce risks associated with the Anti-Kickback Statute and certain other healthcare laws, we have not necessarily utilized such safe harbors nor fully followed all elements required to claim the benefit of such safe harbors in all possible instances. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

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

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

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

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

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

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

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

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

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

Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. Our patent portfolio includes 20 active United States patents and 13 active foreign patents on the technologies related to our products and processes. In addition, we have 6 patent applications pending in the United States and 12 foreign patent applications pending. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Patents have a limited lifetime and once a patent expires competition may increase.

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

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

Numerous patents are held by others, including academic institutions and our competitors. Patent applications filed in the United States after November 2000 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 to you 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.

In January 2018, we filed a lawsuit against Quantel Medical, S.A., Quantel USA, Inc., and Quantel, S.A. (collectively, "Quantel") in the U.S. District Court for the Northern District of California. The lawsuit alleges that Quantel products infringe U.S. Patent No. 7,771,417, that Quantel breached an earlier agreement between Quantel and the Company, and that Quantel has infringed



upon the Company's MicroPulse® trademark, Registration No. 4550188 on the principal register. Quantel previously had a limited license to the asserted Company patent and trademark. Our complaint filed in connection with this matter asserts that the license was terminated in early 2017 for material breach, but that Quantel continued to use our intellectual property without authorization. If we are unsuccessful in prosecuting our claims against Quantel, this could have a material adverse effect on our business, results of operations and financial condition.

On March 8, 2017, OD-OS GmbH noticed an opposition to the Company's European Patent No. currently EP 1 856 774 at the European Patent Office ("EPO"). On June 8, 2018, Quantel intervened in the Opposition. Oral proceedings on the opposition took place on July 13, 2018. At the conclusion of those proceedings, the EPO's Opposition Division communicated that it would move to revoke the patent. The formal written decision from the Opposition Division was issued on October 1, 2018. The Company filed its notice of appeal on October 10, 2018. If our appeal of this decision is unsuccessful, it could have a material adverse effect on our business, results of operations and financial condition.

In late May of 2018, Quantel applied to the Paris District Court in Paris, France for a ruling that its products do not infringe the French Part of Iridex's European Patent at issue in the opposition, EP 1 856 774. A scheduling conference is set for November 6, 2018. If we are unsuccessful in this litigation it could 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 assurances to you that we will be able to retain them. Key personnel have left our company in the past, and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

***\*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.

Sales or issuances of a substantial amount of securities, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock. As of September 29, 2018, we had 13,594,799 shares of common stock outstanding, all of which shares were, and continue to be, eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. Future resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of September 29, 2018, holders of an aggregate of 982,742 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. In addition, the shares of common stock subject to outstanding options and Restricted Stock Units under our 2008 Equity Incentive Plan and the shares reserved for future issuance under the Incentive Plan may become eligible for sale in the public markets in the future, subject to certain legal and control limitations.

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 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 sources. 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:

- unavailability of shortages or limitations on the ability to obtain supplies of components and products in the quantities that we require;
- delays in delivery or failure of suppliers to deliver critical components and products on the dates we require;
- failure of suppliers to manufacture and assemble components and products to our specifications, and potentially reduced quality; and
- inability to obtain components and products at acceptable prices.

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

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

Our facilities could be subject to catastrophic loss such as fire, flood 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. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

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

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

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

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

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

We market our products to numerous health care providers, including physicians, hospitals, ASCs, 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 Federal Food, Drug and Cosmetic Act (“FDCA”) 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 FDCA and implemented by the FDA. Unless otherwise exempt, a device manufacturer must obtain marketing “clearance” through the 510(k) premarket notification process, or “approval” through the lengthier premarket approval application (“PMA”) process. Not all devices are eligible for the 510(k) clearance process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory clearance or approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes a broad range of additional requirements on medical device companies. Our products must be produced in compliance with the Quality System Regulation (“QSR”) and our manufacturing facilities are subject to establishment registration and device listing requirements from the FDA, and similar requirements from certain state authorities, and ongoing periodic inspections by the FDA, including unannounced inspections for compliance with applicable requirements. We are subject to monitoring,

recordkeeping, and reporting obligations for medical device adverse events and malfunctions; notification of our products' defects or failure to comply with the FDA's laser regulations; and reporting of recalls, corrections, or removals of our products. The FDA also imposes requirements for the labeling of our products, and places limitations on claims we are permitted to make about our products in promotional labeling. The Federal Trade Commission has jurisdiction over the advertising of all of our products, which are non-restricted devices, and exercises oversight in coordination with the FDA.

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

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products "CE" marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directive and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. There are a number of major regulatory changes occurring in the regulation of medical devices in the EU. A new revision of the quality system regulation (ISO 13485:2016) has been released that substantially increases the requirements for a medical device quality system. The Medical Device Regulation (MDR) will replace the current medical device directive (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. Additionally, the new revision 4 of the clinical evaluation report guidance document (MEDDEV 2.7.1) severely restricts the use of substantial equivalence for new products, resulting in the need for formal clinical trial data for most new products. These changes will increase the cost for compliance and for product development, and they lengthen product introduction cycles. Failure to comply with these changes can have an adverse effect on our ability to release new products in a timely manner.

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

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

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

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

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

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products

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

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

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

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

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

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

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

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

For example, on February 23, 2018, we initiated a worldwide voluntary recall of a specific laser accessory called the TruFocus LIO Premiere™ ("LIO"). The LIO is a head-mounted indirect ophthalmoscope that connects to our laser console and is used to view and perform laser treatment on a patient's retina. This recall was prompted after we received reports of three adverse events from one physician in the U.S., resulting in focal cataracts and iris burns occurring during procedures in which the TruFocus LIO Premiere was used. We identified several potential root causes for the adverse events, including use error. The recall is still in progress and expected to be completed by year-end.

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

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

We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue. We believe we maintain adequate levels of product liability insurance. 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.

***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.***

Since 1989, we have completed six acquisitions. 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 the EPS, 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.

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

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

***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.

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

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act makes broad and complex changes to the U.S. federal tax code that affected 2017, the current year and onwards, including, but not limited to, a reduction of the U.S. federal corporate tax rate from approximately 35% to 21%, a general elimination of U.S. federal income taxes on dividends from foreign subsidiaries, limitations on the use of net operating loss deduction, and disallowance of most entertainment expenses.

In addition 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. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740, Income taxes for the year ended December 31, 2017. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 is complete. The Company is still within the measurement period as of third quarter of 2018 and no further conclusions have been made, as the Company reviews the law change and the impact to the Company.

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

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

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

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

***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 European Union (“EU”) Directive 2011/65/EU relating to Restrictions on the Use of Certain Hazardous Substances “RoHS Directive, 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. For the third quarter of 2018, the trading price of our common stock fluctuated from \$6.00 per share to a high of \$9.15 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. In addition, our loan facility with Silicon Valley Bank restricts us from paying any dividends or making any other distribution or payment on account of our common stock. 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 as of September 29, 2018. 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 persist. We are an accelerated filer and our independent registered public accounting firm is required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 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 or by a committee of our board of directors, 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.

**Use of Proceeds**

On September 18, 2018, we sold 1,916,667 shares of the Company's common stock (including 250,000 shares of common stock from the exercise of the overallotment option of shares granted to the underwriters) at a price of \$6.00 per share. The offer and sale of all of the shares in the public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333- 213094). We entered into an underwriting agreement with underwriters for whom Stifel, Nicolaus & Company, Incorporated acted as representative. The net proceeds to the Company after deducting estimated underwriting discounts and commissions, fees and expenses of approximately \$0.9 million was approximately \$10.6 million. There has been no material change in the planned use of proceeds as described in our final prospectus filed with the SEC on September 14, 2018 pursuant to Rule 424(b) of the Securities Act. We invested the funds received in registered money market funds.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

## Item 6. Exhibits

<b>Exhibit No.</b>	<b>Exhibit Title</b>
3.1 (1) (P)	Amended and Restated Certificate of Incorporation of Registrant.
3.2 (2)	<a href="#">Amended and Restated Bylaws of Registrant.</a>
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).</a>
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).</a>
32.1*	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.CAL	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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

- (1) Incorporated by reference to the Exhibits filed with the Registration Statement on Form SB-2 (No. 333-00320-LA) which was declared effective on February 15, 1996.
  - (2) Incorporated by reference to the Exhibits filed with the Registrant’s Report on Form 8-K on November 21, 2007.
- (P) Print filing.

### Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, MicroPulse, OcuLight, SmartKey, and EndoProbe, are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, IQ 577, IQ 532, Cyclo G6, TxCell, OtoProbe, Symphony, EasyFit, Endoview, MoistAir and GreenTip product names are our trademarks. All other trademarks or trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

## SIGNATURES

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

IRIDEX Corporation (Registrant)

Date: November 6, 2018

By: /s/ WILLIAM M. MOORE

Name: William M. Moore

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

Date: November 6, 2018

By: /s/ ATABAK MOKARI

Name: Atabak Mokari

Title: Chief Financial Officer and Vice President of  
Corporate Development  
(Principal Financial Officer)

Date: November 6, 2018

By: /s/ ROMEO R. DIZON

Name: Romeo R. Dizon

Title: Vice President and Controller  
(Principal Accounting 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, William M. Moore, certify that:

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

Date: November 6, 2018

By: /s/ WILLIAM M. MOORE  
Name: William M. Moore  
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, Atabak Mokari, certify that:

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

Date: November 6, 2018

By:           /s/ ATABAK MOKARI            
Name: Atabak Mokari  
Title: Chief Financial Officer and Vice President of  
Corporate Development  
(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, William M. Moore, 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 September 29, 2018 (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: November 6, 2018

By: /s/ WILLIAM M. MOORE  
Name: William M. Moore  
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, Atabak Mokari, 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 September 29, 2018 (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: November 6, 2018

By: /s/ ATABAK MOKARI  
Name: Atabak Mokari  
Title: Chief Financial Officer and Vice President of Corporate Development  
(Principal Financial Officer)