

IRIDEX CORP  
Form 10-Q  
November 04, 2011  
[Table of Contents](#)

# 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 October 1, 2011

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)

Edgar Filing: IRIDEX CORP - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

**1212 Terra Bella Avenue**

**Mountain View, California**  
(Address of principal executive offices)

**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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
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, \$.01 par value, issued and outstanding as of October 28, 2011 was 8,951,833.

**Table of Contents**

**TABLE OF CONTENTS**

<b>Items</b>	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Condensed Consolidated Financial Statements</u>	3
<u>Unaudited Condensed Consolidated Balance Sheet as of October 1, 2011 and January 1, 2011</u>	3
<u>Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended October 1, 2011 and October 2, 2010</u>	4
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended October 1, 2011 and October 2, 2010</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	17
<u>Item 4. Controls and Procedures</u>	17
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	18
<u>Item 1A. Risk Factors</u>	18
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
<u>Item 3. Defaults Upon Senior Securities</u>	25
<u>Item 4. Removed and Reserved</u>	25
<u>Item 5. Other Information</u>	25
<u>Item 6. Exhibits</u>	26
<u>Signature</u>	27
<u>Exhibit Index</u>	28

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (unaudited)  
IRIDEX Corporation****Condensed Consolidated Balance Sheets****(Unaudited, in thousands except for share data)**

	October 1, 2011	January 1, 2011 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,535	\$ 9,014
Accounts receivable, net of allowance for doubtful accounts of \$326 at Oct. 1, 2011 and \$369 at Jan. 1, 2011	7,738	7,526
Inventories, net	10,176	9,212
Prepaid expenses and other current assets	571	620
<b>Total current assets</b>	<b>28,020</b>	<b>26,372</b>
Property and equipment, net	316	360
Other intangible assets, net	1,772	1,797
Goodwill	533	473
Other long term assets	225	218
<b>Total assets</b>	<b>\$ 30,866</b>	<b>\$ 29,220</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,222	\$ 1,981
Accrued compensation	1,694	2,304
Accrued expenses	1,657	1,822
Accrued warranty	802	956
Deferred revenue	2,132	2,134
<b>Total current liabilities</b>	<b>8,507</b>	<b>9,197</b>
Long-term liabilities	776	596
<b>Total liabilities</b>	<b>9,283</b>	<b>9,793</b>
Stockholders equity:		
Convertible preferred stock, \$0.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: 500,000 shares at Oct. 1, 2011 and at Jan. 1, 2011	5	5
Common stock		
Authorized: 30,000,000 shares;		
Issued and outstanding: 8,951,833 and 8,986,418 shares at Oct. 1, 2011 and Jan. 1, 2011, respectively	92	89
Additional paid-in capital	41,861	41,168
Accumulated other comprehensive loss	(48)	(205)
Treasury stock, at cost	(951)	(430)
Accumulated deficit	(19,376)	(21,200)

Edgar Filing: IRIDEX CORP - Form 10-Q

Total stockholders' equity	21,583	19,427
Total liabilities and stockholders' equity	\$ 30,866	\$ 29,220

- (1) Derived from the consolidated audited financial statements included in our annual report filed on Form 10-K with the SEC for the year ended January 1, 2011.

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

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October</b>	<b>October</b>	<b>October</b>	<b>October</b>
	<b>1, 2011</b>	<b>2, 2010</b>	<b>1, 2011</b>	<b>2, 2010</b>
<b>Revenues:</b>				
Product revenues	\$ 8,836	\$ 8,740	\$ 26,791	\$ 25,093
Service revenues	1,957	2,078	6,012	6,373
<b>Total revenues</b>	<b>10,793</b>	<b>10,818</b>	<b>32,803</b>	<b>31,466</b>
Cost of revenues	5,892	5,569	17,787	16,456
<b>Gross profit</b>	<b>4,901</b>	<b>5,249</b>	<b>15,016</b>	<b>15,010</b>
<b>Operating expenses:</b>				
Research and development	894	920	2,768	2,913
Sales and marketing	2,222	2,319	7,058	6,984
General and administrative	1,269	1,125	3,627	3,490
<b>Total operating expenses</b>	<b>4,385</b>	<b>4,364</b>	<b>13,453</b>	<b>13,387</b>
Income from operations	516	885	1,563	1,623
Legal settlement	0	0	800	800
Interest and other income (expense), net	(131)	63	(232)	(49)
<b>Income before income taxes</b>	<b>385</b>	<b>948</b>	<b>2,131</b>	<b>2,374</b>
Provision for income taxes	36	38	307	165
<b>Net income</b>	<b>\$ 349</b>	<b>\$ 910</b>	<b>\$ 1,824</b>	<b>\$ 2,209</b>
Net income per share-basic	\$ 0.04	\$ 0.10	\$ 0.20	\$ 0.25
Net income per share-diluted	\$ 0.03	\$ 0.09	\$ 0.18	\$ 0.22
Shares used in computing net income per share-basic	8,965	8,974	8,963	8,930
Shares used in computing net income per share-diluted	10,253	10,148	10,233	10,112

**Condensed Consolidated Statements of Comprehensive Income****(Unaudited, in thousands)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October</b>	<b>October</b>	<b>October</b>	<b>October</b>
	<b>1, 2011</b>	<b>2, 2010</b>	<b>1, 2011</b>	<b>2, 2010</b>
Net income	\$ 349	\$ 910	\$ 1,824	\$ 2,209

Edgar Filing: IRIDEX CORP - Form 10-Q

Foreign currency translation adjustments	20	(7)	(13)	0
Recognition of accumulated foreign currency translation loss	0	0	170	0
Comprehensive income	\$ 369	\$ 903	\$ 1,981	\$ 2,209

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

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

	<b>Nine Months Ended</b>	
	<b>October 1, 2011</b>	<b>October 2, 2010</b>
<b>Operating activities:</b>		
Net income	\$ 1,824	\$ 2,209
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	307	406
Loss on liquidation of foreign subsidiary	170	0
Change in fair value of earn-out liability	55	0
Stock compensation recognized	374	415
Provision for doubtful accounts	(12)	0
Provision for inventory reserves	31	171
Changes in operating assets and liabilities:		
Accounts receivable	(200)	(472)
Inventories	(995)	(954)
Other current assets and other long term assets	42	135
Accounts payable	241	509
Accrued compensation and expenses	(755)	(566)
Accrued warranty and deferred revenue	(156)	(288)
<b>Net cash provided by operating activities</b>	<b>926</b>	<b>1,565</b>
<b>Investing activities:</b>		
Purchases of property and equipment	(118)	(168)
Cash paid in business combinations	(75)	(225)
<b>Net cash used in investing activities</b>	<b>(193)</b>	<b>(393)</b>
<b>Financing activities:</b>		
Proceeds from stock option exercises	322	62
Repurchase of common stock	(521)	0
Proceeds from borrowings	0	5,876
Repayment of borrowings	0	(9,396)
<b>Net cash used in financing activities</b>	<b>(199)</b>	<b>(3,458)</b>
Effect of foreign exchange rate changes	(13)	0
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>521</b>	<b>(2,286)</b>
Cash and cash equivalents at beginning of period	9,014	9,378
<b>Cash and cash equivalents at end of period</b>	<b>\$ 9,535</b>	<b>\$ 7,092</b>
<b>Supplemental non-cash activities:</b>		
Shares issued at acquisition	\$ 0	\$ 444
Earn-out - net present value of additional shares	\$ 0	\$ 264
Earn-out - net present value of additional cash liability	\$ 105	\$ 380

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





---

**Table of Contents**

**IRIDEX Corporation**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of IRIDEX Corporation (the Company) have been prepared in accordance with generally accepted accounting principles in the United States 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 accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto, together with management's discussion and analysis of the Company's financial condition and results of operations, contained in our Annual Report on Form 10-K for the fiscal year ended January 1, 2011, which was filed with the Securities and Exchange Commission (SEC) on March 25, 2011. The results of operations for the three and nine month periods ended October 1, 2011 are not necessarily indicative of the results for the year ending December 31, 2011 or any future interim period.

*Recently Issued and Adopted Accounting Standards*

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-08, Intangibles-Goodwill and Other (Topic 350): Testing Goodwill for Impairment. This standard is intended to simplify how entities test goodwill for impairment. ASU 2011-08 permits an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350, Intangibles-Goodwill and Other. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill impairment tests performed as of a date before September 15, 2011, if an entity's financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The Company will adopt this standard in the first quarter of fiscal year 2012 and does not expect its adoption to have a material effect on its financial position, results of operations, or cash flows.

In June 2011, FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. ASU 2011-05 allows an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. It does not, however, change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU 2011-05 should be applied retrospectively. ASU 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption is permitted. We do not expect adoption of this standard to have a material impact on our financial position, results of operations, or cash flows.

In December 2010, the FASB issued ASU 2010-29, Business Combinations (Topic 805): Disclosure of Supplementary Pro Forma Information for Business Combinations. ASU 2010-29 specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The amendments in this update also expand the supplemental pro forma disclosures under Topic 805 to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. ASU 2010-29 is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The adoption of this standard did not have a material impact on our financial position, results of operations, or cash flows. Unless the Company has a significant business combination, this standard is not expected to have a material impact on our future financial position, results of operations, or cash flows.

In December 2010, the FASB issued ASU 2010-28, Intangibles-Goodwill and Other (Topic 350): When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts. ASU 2010-28 modifies Step 1 of the goodwill impairment test

## Edgar Filing: IRIDEX CORP - Form 10-Q

so that for reporting units with zero or negative carrying amounts, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not based on an assessment of qualitative indicators that goodwill impairment exists. In determining whether it is more likely than not that goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that impairment may exist. ASU 2010-28 was effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. The adoption of this standard did not have a material impact on our financial position, results of operations, or cash flows.

In January 2010, the FASB issued ASU 2010-6, Improving Disclosures about Fair Value Measurements, which updates fair value measurement and disclosures, adding new requirements for disclosures for levels 1 and 2, separate disclosures and purchases, sales, issuances, and settlements relating to Level 3 measurements and clarification of existing fair value disclosures. This update was effective for interim and annual periods beginning after December 15, 2009, except for the requirement to provide Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which was effective for fiscal years beginning after December 15, 2010. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on our financial position, results of operations, or cash flows.

In October 2009, the FASB issued ASU 2009-13, Multiple-Deliverable Revenue Arrangements-a consensus of the FASB Emerging Issues Task Force. ASU 2009-13 addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services ( deliverables ) separately rather than as a combined unit. Specifically, this guidance amends the criteria in the Revenue Recognition-Multiple-Element Arrangements subtopic of the Codification for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence ( VSOE ); (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor s multiple-deliverable revenue arrangements. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with the option to provide retrospective presentation for prior years. The adoption of this standard did not have a material impact on our financial position, results of operations, or cash flows because we had VSOE of fair value established on most elements.

### **2. Summary of Significant Accounting Policies**

The Company s significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended January 1, 2011, which was filed with the SEC on March 25, 2011.

**Table of Contents***Revenue Recognition*

Our revenues arise from the sale of laser consoles, delivery devices, consumables and service and support activities. Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided that no significant obligations remain and collection of the receivables is reasonably assured. Shipments are generally made with Free-On-Board (FOB) shipping point terms, whereby title passes upon shipment from our dock. Any shipments with FOB receiving point terms are recorded as revenue when the shipment arrives at the receiving point. Cost is recognized as product sales revenue is recognized.

The Company's sales may include post-sales obligations for training and or other deliverables. For revenue arrangements with multiple deliverables such as these, effective for new or modified arrangements entered into beginning on January 2, 2011, the date we adopted the new revenue recognition guidance for arrangements with multiple deliverables on a prospective basis, we allocate arrangement consideration at the inception of the arrangement to all deliverables using the relative selling price method. This method requires us to determine the selling price at which each deliverable could be sold if it were sold regularly on a standalone basis. When available, VSOE of fair value as the selling price. VSOE represents the price charged for a deliverable when it is sold separately or for a deliverable not yet being sold separately, the price established by management with the relevant authority. We have established VSOE of fair value for our post-installation technical support services. When VSOE of fair value is not available, third-party evidence ( TPE ) of fair value for similar products and services is acceptable; however, our offerings and market strategy differ from those of our competitors, such that we cannot obtain sufficient comparable information about third parties' prices. If neither VSOE nor TPE are available, we use our best estimates of selling prices ( BESP ). We determine BESP considering factors such as market conditions, sales channels, internal costs and product margin objectives, and pricing practices. We regularly review and update our VSOE, TPE and BESP information and obtain formal approval by appropriate levels of management. The relative selling price method allocates total arrangement consideration proportionally to each deliverable on the basis of its estimated selling price.

We use the residual method to allocate total arrangement consideration between delivered and undelivered items for any arrangements entered into prior to January 2, 2011. We also use the residual method of allocating the arrangement consideration in certain circumstances where we do not have VSOE on one or more elements of the arrangement. Under the residual method, the amount allocated to the undelivered elements equals VSOE of fair value of these elements. Any remaining amounts are attributed to the delivered items and are recognized when those items are delivered.

The adoption of the new revenue recognition guidance did not result in changes in what we identify as the individual deliverables to which revenue is allocated, or the timing of revenue recognition related to these individual deliverables. The change in the allocation method from residual to relative selling price did not have a material impact on our financial statements during the three months and nine months ended October 1, 2011.

In international regions outside of France, we utilize distributors to market and sell our products. We recognize revenue upon shipment for sales to these independent, third party distributors as we have no continuing obligations subsequent to shipment. Generally our distributors are responsible for all marketing, sales, installation, training and warranty labor coverage for our products. Our standard terms and conditions do not provide price protection or stock retention rights to any of our distributors.

*Deferred Revenue*

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. A reconciliation of the changes in the Company's deferred revenue balance for the nine months ended October 1, 2011 and October 2, 2010 is as follows:

(in thousands)	Nine Months Ended	
	October 1, 2011	October 2, 2010
Balance, beginning of period	\$ 2,134	\$ 2,405
Additions to deferral	3,611	3,874
Revenue recognized	(3,613)	(4,040)
Balance, end of period	\$ 2,132	2,239

*Warranty*

## Edgar Filing: IRIDEX CORP - Form 10-Q

The Company accrues for estimated warranty cost upon shipment of products. Actual warranty costs incurred have not materially differed from those accrued. 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 sales. A reconciliation of the changes in the Company's warranty liability for the nine months ended October 1, 2011 and October 2, 2010 is as follows:

(in thousands)	<b>Nine Months Ended</b>	
	<b>October 1, 2011</b>	<b>October 2, 2010</b>
Balance, beginning of period	\$ 956	\$ 1,165
Accruals for product warranties	168	136
Cost of warranty claims and adjustments	(322)	(258)
Balance, end of period	\$ 802	\$ 1,043

### *Goodwill*

The carrying amount of goodwill and the changes in those balances are as follows (in thousands):

Balance, January 2, 2010	\$ 0
Goodwill as a result of RetinaLabs acquisition	473
Balance, January 1, 2011	473
Goodwill as a result of Ocunetics, Inc. acquisition	60
Balance, October 1, 2011	\$ 533

**Table of Contents**

Goodwill is tested for impairment at least annually or whenever there is a change in circumstances that indicates the carrying value of these assets may be impaired. The determination of whether any potential impairment of goodwill exists is based upon a two-step impairment test performed in accordance with ASC 350, Intangibles-Goodwill and Other. The carrying value of goodwill was \$533 thousand at October 1, 2011 and \$473 thousand at January 1, 2011. There was no impairment of goodwill recognized during the nine months ended October 1, 2011 and October 2, 2010.

*Intangible Assets*

The purchase method of accounting for acquisitions requires estimates and assumptions to allocate the purchase price to the fair value of net tangible and intangible assets acquired. The amounts allocated to, and the useful lives estimated for, intangible assets, affect future amortization. There are a number of generally accepted valuation methods used to estimate fair value of intangible assets, and we primarily use a discounted cash flow method, which requires management judgment to forecast the future operating results and to estimate the discount factors used in the analysis. An asset is considered impaired if its carrying amount exceeds the value of future net cash flow the asset is expected to generate. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. The Company did not record any impairment for the three and nine months ended October 1, 2011 and October 2, 2010.

Future changes in events or circumstances, such as an inability to achieve the cash flows determined above, may indicate that the recorded value of the intangible assets will not be recovered through future cash flows and the Company may be required to record an impairment charge for the intangible assets or modify the period of expected lives for the intangible assets.

Intangible assets consist of the following (in thousands):

	October 1, 2011			January 1, 2011			Amortization Life
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Services - Contractual Customer Relationships	\$ 2,132	\$ (1,278)	\$ 854	\$ 2,132	\$ (1,156)	\$ 976	8 years
Patents - RetinaLabs	600	(18)	582	600	(7)	593	Varies
Patents - Ocunetics	120	0	120	0	0	0	Varies
Customer Relations	240	(24)	216	240	(12)	228	15 years
	\$ 3,092	\$ (1,320)	\$ 1,772	\$ 2,972	\$ (1,175)	\$ 1,797	

Amortization expense totaled \$145 thousand and \$147 thousand for the nine months ended October 1, 2011 and October 2, 2010, respectively.

Future estimated amortization expense (in thousands):	
2011 (three months)	\$ 232
2012	\$ 270
2013	\$ 289
2014	\$ 335
2015	\$ 335
Thereafter	\$ 311
Total	\$ 1,772

*Stock Repurchases*

In March 2011, the Company purchased the remaining 75,698 shares of our common stock held by American Medical Systems Holdings, Inc (AMS) that were issued to AMS as part of a 2007 purchase transaction at \$4.00 per share. In May 2011, the Company approved a stock repurchase program authorizing the Company to purchase in open market or privately negotiated transactions, up to \$2.0 million worth of our common stock, from time to time during the next 12 months. For the three and nine months ended October 1, 2011, the Company has purchased 32,778 and 133,876 shares at an average price of \$3.66 and \$3.89 per share, respectively. There were no shares repurchased for the three and

nine month periods ending October 2, 2010. As of October 1, 2011, the Company still has the authorization to purchase up to \$1.8 million in common shares under the stock repurchase program. See Item 2, Unregistered Sales of Equity Securities and Use of Proceeds in Part II, Other Information, for additional information.

### **3. Business Combinations**

#### **Ocunetics, Inc:**

On September 15, 2011, the Company acquired certain assets of Ocunetics, Inc. The purchase price for the acquired assets consisted of \$75 thousand in cash consideration and an earn-out provision fair valued at \$105 thousand. The earn-out is tied to future revenues and could result in additional cash and share consideration being paid to Ocunetics, Inc. based on the future performance of the acquired products and intellectual property.

In accordance with ASC 805, Business Combinations, the acquisition has been accounted for as a business combination. Under the purchase method of accounting, the assets acquired from Ocunetics, Inc. at the date of acquisition are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$60 thousand. This goodwill is expected to be non-deductible for tax purposes. The purchase price includes the fair value of the cash earn-out which is recorded as a long-term liability. No value was attributed to the contingent equity-based consideration because management does not believe certain targets will be achieved in the future. Costs incurred associated with the acquisition were immaterial. The financial results of Ocunetics, Inc. prior to the acquisition were immaterial for purposes of pro forma financial disclosures. As of the end of the reporting period, there has been no revenues or earnings generated by the acquiree since the acquisition date.

**Table of Contents**

*Identifiable intangible assets.* Intangible assets included in the purchase price allocation consist of technology patents of \$120 thousand, assigned an economic useful life whereby the economic value of the asset is its ability to provide the Company relief from royalty and is being amortized as a percentage of revenues generated per units sold.

*Goodwill.* Approximately \$60 thousand has been allocated to goodwill. Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. In accordance with ASC 350-20, goodwill, is not amortized but instead is tested for impairment at least annually (more frequently if certain indicators are present). In the event that management determines that the value of goodwill has become impaired, an accounting charge for the amount of impairment is incurred in the fiscal quarter in which the determination is made. The Company believes the goodwill realized was the result of a number of factors, including expected revenue growth opportunities for existing products and the opportunity to commercialize acquired intellectual property.

**RetinaLabs:**

On April 8, 2010, the Company acquired substantially all of the assets of RetinaLabs. Pursuant to the terms of the purchase agreement, the Company acquired RetinaLabs' existing product family together with certain additional intellectual property that the Company anticipates incorporating into future products. The purchase price for the acquired assets consisted of \$250 thousand in cash consideration and 115 thousand unregistered shares of the Company's common stock issued at closing, and an earn-out. The earn-out is tied to future revenues and could result in additional cash and share consideration being paid to RetinaLabs based on the future performance of the acquired products and intellectual property.

In accordance with ASC 805, Business Combinations, the acquisition has been accounted for as a business combination. Under the purchase method of accounting, the assets acquired from RetinaLabs at the date of acquisition are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$473 thousand. This goodwill is expected to be non-deductible for tax purposes. The purchase price includes the fair value of the cash earn-out which is recorded as a long-term liability and the fair value of the contingent consideration for additional shares which is recorded in equity.

We incurred \$76 thousand of direct costs associated with the acquisition that were expensed as a component of general and administrative expense in the second quarter of fiscal year 2010. The amounts of revenue and earnings of the acquiree since the acquisition date are included in the consolidated statement of operations for the reporting period and have been immaterial to the consolidated financial statements. The financial results of RetinaLabs prior to the acquisition are immaterial for purposes of pro forma financial disclosures.

The determination of estimated fair value of acquired assets and liabilities requires management to make significant estimates and assumptions. We determined the fair value by applying established valuation techniques, based on information that management believed to be relevant to this determination. The following table summarizes the purchase price allocation of the fair value of the assets acquired at the date of acquisition:

The purchase price was as follows (in thousands):

At time of acquisition:

Cash, net of escrow	\$ 225
Shares issued, net of escrow	444
Earn-out:	
Net present value of additional cash including escrow	380
Net present value of additional shares including escrow	264
 Total purchase price	 \$ 1,313

The cost of the acquisition was allocated as follows (in thousands):



## Edgar Filing: IRIDEX CORP - Form 10-Q

Identifiable intangible assets:	
Patents	\$ 600
Customer-related	240
Goodwill	473
Total purchase price	\$ 1,313

Valuing certain components of the acquisition, including primarily identifiable intangible assets, goodwill, and the earn-out liability, required us to make estimates that may be adjusted in the future. As of October 1, 2011, the earn-out liability was remeasured and increased by \$55 thousand as a result of the Company's latest estimate of future performance. The additional expense was recorded as a charge to interest and other income (expense), net in the condensed consolidated statement of operations.

**Table of Contents**

*Identifiable intangible assets.* Intangible assets included in the purchase price allocation consist of: (a) technology patents of \$600 thousand, assigned an economic useful life whereby the economic value of the asset is its ability to provide the Company relief from royalty and is being amortized as a percentage of revenues generated per units sold, and (b) customer-related intangible assets of \$240 thousand, assigned an economic life of 15 years being amortized on the straight line method.

*Goodwill.* Approximately \$473 thousand has been allocated to goodwill. Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. In accordance with ASC 350-20, Goodwill, is not amortized but instead is tested for impairment at least annually (more frequently if certain indicators are present). In the event that management determines that the value of goodwill has become impaired, an accounting charge for the amount of impairment is incurred in the fiscal quarter in which the determination is made. The Company believes the goodwill realized was the result of a number of factors, including expected revenue growth opportunities for existing products and the opportunity to commercialize acquired intellectual property.

**4. Inventories, net**

The components of the Company's inventories as of October 1, 2011 and January 1, 2011 are as follows:

(in thousands)	October 1, 2011	January 1, 2011
Raw materials and work in process	\$ 6,230	\$ 5,222
Finished goods	3,946	3,990
<b>Total inventories</b>	<b>\$ 10,176</b>	<b>\$ 9,212</b>

**5. Fair Value Measurement**

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.

## Edgar Filing: IRIDEX CORP - Form 10-Q

The carrying amounts of the Company's financial assets and liabilities, including cash and cash equivalents, accounts receivable, and accounts payable at October 1, 2011 and January 1, 2011, approximate fair value because of the short maturity of these instruments.

As of October 1, 2011 and January 1, 2011, 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 was as follows (in thousands):

	October 1, 2011 Fair Value Measurements				January 1, 2011 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Money market funds	\$ 7,531	0	0	\$ 7,531	\$ 8,158	0	0	\$ 8,158
<b>Liabilities:</b>								
Earn-out-cash	\$ 0	0	540	\$ 540	\$ 0	0	380	\$ 380

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 Company's Level 3 financial liabilities are related to the fair value of the contingent consideration (the earn-out to be paid in cash) in connection with the RetinaLabs and Ocunetics, Inc. acquisitions. At October 1, 2011, observable market information was not available to determine the fair value of the Company's earn-out. Therefore, the fair value is based on valuation models that relied on Level 3 inputs including those that are based on probability of outcomes, expected cash flow streams, market discount rates and overall capital market liquidity. The valuation of the earn-out liability related to the RetinaLabs and Ocunetics, Inc. acquisitions is subject to uncertainties that are difficult to predict.

The following table provides a reconciliation of the beginning and ending balances of the earn-out - cash (Level 3 liabilities) (in thousands):

	January 1, 2011	January 2, 2010
Balance at the beginning of the period	\$ 380	\$ 0
Addition of earn-out - cash related to RetinaLabs acquisition	0	380
Addition of earn-out - cash related to Ocunetics, Inc. acquisition	105	0
Change in fair value of earn-out liability -RetinaLabs	55	0
<b>Balance at the end of the period</b>	<b>\$ 540</b>	<b>\$ 380</b>

## Table of Contents

### 6. Bank Borrowings

The Company has a Loan and Security Agreement ( *Loan Agreement* ) with Silicon Valley Bank ( *Lender* ) providing for a \$5.0 million secured revolving loan facility, with availability in certain circumstances, subject to an accounts receivable borrowing base formula. As of October 1, 2011, no loans have been requested or made under the *Loan Agreement*.

Borrowings under the revolving loan facility accrue interest at a per annum rate equal to the *Lender*'s prime rate as in effect from time to time plus a margin, subject to a minimum interest rate of 4.00%. Interest on borrowings under the revolving loan facility is payable monthly. The Company may borrow, repay and reborrow funds under the revolving loan facility until June 11, 2012, at which time the revolving loan facility matures and all outstanding amounts must be repaid. In certain circumstances, the Company may be required to immediately repay principal amounts outstanding when it receives payments on its accounts receivable. On June 11, 2011, the Company paid the annual non refundable commitment fee of \$12,500. In the event the Company elects to terminate the revolving loan facility before the maturity date, the Company is required to pay a fee in the amount of \$50,000.

All obligations under the *Loan Agreement* are secured by substantially all of the property of the Company, excluding the Company's intellectual property but including any proceeds derived from the Company's intellectual property.

The *Loan Agreement* contains covenants that include, among others, covenants that limit the Company's and its subsidiaries' ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on the Company's capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. The *Loan Agreement* also contains a financial covenant requiring the Company to maintain a certain adjusted quick ratio. As of October 1, 2011, the Company was in compliance with all the loan covenants.

### 7. Stock Based Compensation

#### *2008 Equity Incentive Plan*

For the nine months ended October 1, 2011, the only active share-based compensation plan was the 2008 Equity Incentive Plan (the *Incentive Plan* ). The terms of awards granted during the nine months ended October 1, 2011 were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended January 1, 2011.

#### Summary of Stock Options

The following table summarizes information regarding activity in our stock option plan during the nine months ended October 1, 2011 and October 2, 2010:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding at January 1, 2011	1,618,066	\$ 3.65	
Granted	125,300	\$ 3.79	
Exercised	(99,291)	\$ 3.24	
Canceled or forfeited	(68,461)	\$ 4.88	
Outstanding at October 1, 2011	1,575,614	\$ 3.63	\$ 1,213
	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding at January 2, 2010	1,583,508	\$ 3.91	
Granted	193,300	\$ 3.99	

Edgar Filing: IRIDEX CORP - Form 10-Q

Exercised	(22,235)	\$	2.82	
Canceled or forfeited	(102,837)	\$	7.64	
<b>Outstanding at October 2, 2010</b>	<b>1,651,736</b>	<b>\$</b>	<b>3.69</b>	<b>\$ 1,118</b>

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of September 30, 2011, that would have been received by option holders had all option holders exercised their stock options as of that date.

For the three month period ended October 1, 2011, there were 85,000 shares in stock options granted under the Company's stock plans. For the three month period ended October 2, 2010, there were no stock options granted.

The weighted-average grant date fair value of the options granted under the Company's stock plans as calculated using Black-Scholes was \$2.57 for the three months ended October 1, 2011. The weighted-average grant date fair value of the options granted under the Company's stock plans as calculated using Black-Scholes was \$2.60 and \$2.71 per share for the nine months ended October 1, 2011 and October 2, 2010, respectively.

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October 1, 2011</b>	<b>October 2, 2010</b>	<b>October 1, 2011</b>	<b>October 2, 2010</b>
Average risk free interest rate	0.94%	1.89%	1.23%	2.03%
Expected life (in years)	4.69	4.75	4.71	4.75
Dividend yield	0.0%	0.0%	0.0%	0.0%
Average volatility	91%	88%	91%	88%

**Table of Contents**

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 Company had elected to use the simplified method for estimating the expected term prior to July 3, 2011. Effective July 3, 2011, 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.

The following table shows stock-based compensation expense included in the Condensed Consolidated Statements of Operations for the three and nine month periods ended October 1, 2011 and October 2, 2010 (in thousands):

	Three Months Ended		Nine Months Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
Cost of revenues	\$ 29	\$ 27	\$ 84	\$ 89
Research and development	16	23	52	71
Sales and marketing	28	33	89	96
General and administrative	50	62	149	159
	\$ 123	\$ 145	\$ 374	\$ 415

Approximately \$10 thousand and \$9 thousand of the stock based compensation expense recognized was capitalized into inventory as a component of overhead at October 1, 2011 and October 2, 2010, respectively.

Information regarding stock options outstanding, exercisable and expected to vest at October 1, 2011 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
As of October 1, 2011				
Options outstanding	1,575,614	\$ 3.63	3.75	\$ 1,213
Options vested and expected to vest	1,489,523	\$ 3.67	3.67	\$ 1,134
Options exercisable	1,221,100	\$ 3.79	3.28	\$ 937

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the Nasdaq Global Market on the last trading day of the quarter, September 30, 2011 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on October 1, 2011. This amount changes based on the fair market value of the Company's stock. The total intrinsic value of options exercised for the three months periods ended October 1, 2011 and October 2, 2010 were approximately \$15 thousand and \$0 thousand, respectively. The total intrinsic value of options exercised for the nine months periods ended October 1, 2011 and October 2, 2010 were approximately \$84 thousand and \$28 thousand, respectively.

As of October 1, 2011, there was \$653 thousand of total unrecognized compensation cost, net of forfeitures, related to non-vested share-based compensation arrangements under the Incentive Plan. The cost is expected to be recognized over a weighted average period of 2.37 years.

**Restricted Stock Awards/Restricted Stock Units**

Effective for the 2011 fiscal year, each non-employee member of the Board will receive an annual equity award of either restricted stock or a restricted stock unit (RSU), at the election of such Board member, in each case equal to \$20,000 worth of our common stock (determined at the fair market value of the shares at the time such award is granted) under the Company's 2008 Equity Incentive Plan. Each equity award or RSU vests in full on the one-year anniversary of the date of grant provided that the non-employee member continues to serve on the Board through

such date.

### Summary of Restricted Stock Units and Awards

The Company recognizes the estimated compensation expense of restricted stock units and awards, net of estimated forfeitures, over the vesting term. The estimated compensation expense is based on the fair value of the Company's common stock on the date of grant.

Information regarding the restricted stock units outstanding, vested and expected to vest as of October 1, 2011 is summarized below:

	Number of Shares	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (thousands)
As of October 1, 2011			
Restricted stock units outstanding	15,189	0.75	\$ 56
Restricted stock units vested and expected to vest	13,720	0.75	\$ 51

The intrinsic value of the restricted stock units is calculated based on the closing price of IRIDEX shares as quoted on the Nasdaq Global Market on the last trading day of the quarter, September 30, 2011 of \$3.70.

For the three months ended October 1, 2011, there were no restricted stock units granted. For the nine months ended October 1, 2011, the Company granted 15,189 shares of restricted units to the Board of Directors with a weighted average grant date fair value of approximately \$56,000 or \$3.70 per share. There were no restricted stock units or awards granted in 2010. There was no restricted stock units vested, released and or forfeited during the three and nine month periods ended October 1, 2011.

Information regarding the restricted stock awards activity during the nine months ended October 1, 2011 is summarized below:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2011	0	0
Restricted stock awards granted	10,126	\$ 3.70
Outstanding at October 1, 2011	10,126	\$ 3.70

**Table of Contents****8. Income Taxes***Provision for Income Tax*

Under Accounting ASC topic 270-740, Interim Reporting-Income Taxes, we are required to make our best estimate of the annual effective tax rate for the full fiscal year and use that rate to provide for income taxes on a current year-to-date basis. The Company recorded a provision for income tax of \$307 thousand and \$165 thousand for the nine months ended October 1, 2011 and October 2, 2010, respectively. The Company's estimated annual effective tax rate was 14.85% and 10.15%, for the nine months ended October 1, 2011 and October 2, 2010, respectively. The increase in our annual effective tax rate was associated primarily with the federal income tax which resulted from the limitation of utilizing federal research & development credit and the state taxes due to the decrease in available state net operating losses to offset the Company's taxable income.

*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 January 1, 2011, the Company had deferred tax assets of approximately \$12.1 million which is fully offset by a valuation allowance. When realized, the asset will be reflected on the Company's balance sheet and the reversal of the corresponding valuation allowance will result in a tax benefit being recorded in the statement of operations in the respective period.

*Uncertain Tax Positions*

The Company accounts for its uncertain tax positions in accordance with ASC 740. If the balance of \$865 thousand of unrecognized tax benefits at January 1, 2011 were recognized; \$55 thousand of the recognition would affect the income tax rate. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company has recorded an uncertain tax position of \$157 thousand related to the 2010 tax return during the current quarter. 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 files U.S. federal and state returns as well as foreign returns in France and the UK. The tax years 2001 to 2010 remain open in several jurisdictions, none of which have individual significance.

**9. Computation of Basic and Diluted Net Income Per Common Share**

Basic net income per share is computed by dividing net income for the period by the weighted average number of shares outstanding during the period. Diluted net income per share is computed by dividing net income for the period by the weighted average number of shares, plus common stock equivalents outstanding during the period which includes 1,000,000 shares of common stock issuable upon the conversion of 500,000 shares of convertible Series A Preferred Stock. Common stock equivalents also include the effect of outstanding dilutive stock options and awards computed using the treasury stock method.

A reconciliation of the numerator and denominator of basic and diluted net income per common share is provided as follows (in thousands, except per share amounts):

	Three Months Ended		Nine Months Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
Numerator:				
Net income	\$ 349	\$ 910	\$ 1,824	\$ 2,209
Denominator:				
Basic weighted average shares outstanding	8,965	8,974	8,963	8,930
Effect of dilutive preferred shares	1,000	1,000	1,000	1,000



Edgar Filing: IRIDEX CORP - Form 10-Q

Effect of dilutive stock options and awards	276	162	258	170
Effect of dilutive contingent shares	12	12	12	12
Diluted weighted average shares outstanding	10,253	10,148	10,233	10,112
Basic net income per common share	\$ 0.04	\$ 0.10	\$ 0.20	\$ 0.25
Diluted net income per common share	\$ 0.03	\$ 0.09	\$ 0.18	\$ 0.22

The Company excludes options from the computation of diluted weighted average shares outstanding if the exercise price of the options is greater than the average market price of the shares because the inclusion of these options would be anti-dilutive to earnings per share. Accordingly, for the three months ended October 1, 2011 and October 2, 2010, respectively, stock options to purchase 639,246 and 1,004,511 shares were excluded from the computation of diluted weighted average shares outstanding. For the nine months ended October 1, 2011 and October 2, 2010, respectively, stock options to purchase 661,491 and 852,290 shares were excluded from the computation of diluted weighted average shares outstanding.

#### 10. Business Segments

The Company operates in two reportable segments: the ophthalmology segment and the aesthetics segment. In each segment the Company develops, manufactures, and markets medical devices. Our revenues arise from the sale of consoles, delivery devices, consumables and service and support activities.

Information on reportable segments for the three and nine month periods ended October 1, 2011 and October 2, 2010 is as follows:

(in thousands)	Three Months Ended October 1, 2011			Three Months Ended October 2, 2010		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Revenues	\$ 8,258	\$ 2,535	\$ 10,793	\$ 7,999	\$ 2,819	\$ 10,818
Direct cost of revenues	2,626	781	3,407	2,189	825	3,014
Direct gross profit	\$ 5,632	\$ 1,754	7,386	\$ 5,810	\$ 1,994	7,804
Total unallocated indirect costs			(7,001)			(6,856)
Pre-tax income			\$ 385			\$ 948

**Table of Contents**

(in thousands)	Nine Months Ended October 1, 2011			Nine Months Ended October 2, 2010		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Revenues	\$ 24,539	\$ 8,264	\$ 32,803	\$ 23,271	\$ 8,195	\$ 31,466
Direct cost of revenues	7,453	2,611	10,064	6,562	2,438	9,000
Direct gross profit	\$ 17,086	\$ 5,653	22,739	\$ 16,709	\$ 5,757	22,466
Total unallocated indirect costs			(20,608)			(20,092)
Pre-tax income			\$ 2,131			\$ 2,374

Direct cost of revenues includes standard product cost (direct material, labor and fringe) and any warranty and unit royalty due. Indirect costs of manufacturing, research and development, sales and marketing, and general and administrative costs are not allocated to the segments.

Our revenues by reportable segment by geographic region, based on the location at which each sale originates, is summarized as follows:

(in thousands)	Three Months Ended October 1, 2011			Three Months Ended October 2, 2010		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Domestic	\$ 4,403	\$ 1,435	\$ 5,838	\$ 4,949	\$ 1,584	\$ 6,533
International	3,855	1,100	4,955	3,050	1,235	4,285
Total revenues	\$ 8,258	\$ 2,535	\$ 10,793	\$ 7,999	\$ 2,819	\$ 10,818

(in thousands)	Nine Months Ended October 1, 2011			Nine Months Ended October 2, 2010		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Domestic	\$ 13,368	\$ 4,426	\$ 17,794	\$ 13,029	\$ 4,866	\$ 17,895
International	11,171	3,838	15,009	10,242	3,329	13,571
Total revenues	\$ 24,539	\$ 8,264	\$ 32,803	\$ 23,271	\$ 8,195	\$ 31,466

No one customer accounted for more than 10% of total revenue for the three months ended October 1, 2011 and October 2, 2010, respectively.

The Company's assets and liabilities are not evaluated on a segment basis. Accordingly, no disclosure of segment assets and liabilities is provided.

**11. Subsequent Event**

On October 8, 2011, the Company had made no claims relating to the escrow in connection with the Company's acquisition of substantially all of the assets of RetinaLabs and released to RetinaLabs all funds and shares held in escrow. The Company has evaluated subsequent events and has concluded that no subsequent events other than the one mentioned above have occurred since the quarter ended October 1, 2011 that required additional disclosure in the consolidated financial statements.

---

## **Table of Contents**

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

*This Quarterly Report on Form 10-Q contains trend analysis and other 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, such as statements relating to levels of future sales and operating results; gross margins; managing cash flows; general economic conditions and levels of international sales; corporate strategy; effects of seasonality; FDA inspections; and our current and future liquidity and capital requirements; and levels of future investment in research and development efforts. 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. 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, including as a result of the factors set forth under Factors That May Affect Future Operating Results and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2011 and detailed from time to time in our reports filed with the Securities and Exchange Commission. 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.*

#### **Overview**

IRIDEX Corporation is a leading worldwide provider of therapeutic based laser systems, delivery devices and consumable instrumentation used to treat eye diseases in ophthalmology and skin conditions in aesthetics. Our products are sold in the United States (US) predominantly through a direct sales force and internationally through approximately 100 independent distributors into 107 countries except for our aesthetics products which are sold, marketed and serviced directly in France.

We manage and evaluate our business in two segments - ophthalmology and aesthetics. We further break down these segments by geography Domestic (US) and International (the rest of the world). In addition, within ophthalmology, we review trends by laser system sales (consoles and durable delivery devices) and recurring sales (single use consumable laser probes and other associated instrumentation ( consumables ), service and support).

Our ophthalmology revenues arise primarily from the sale of our IQ and OcuLight laser systems, consumables and revenues from service and support activities. Our current family of IQ products includes IQ 532, IQ 577 and IQ 810 laser photocoagulation systems and our family of OcuLight products includes OcuLight TX, OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. We also produce a family of vitreoretinal instrumentation which includes MoistAir, GreenTip and Endoview.

Our aesthetics revenues arise primarily from the sales of our aesthetics systems and service contracts. Our current family of systems includes the VariLite, DioLite, Gemini, Venus-i, Lyra-i and Aura-i Laser Systems.

Sales to international distributors are made on open credit terms or letters of credit and are currently denominated in United States dollars and accordingly, are not subject to risks associated with international monetary conditions and currency fluctuations. Sales of aesthetics products to end customers from our French subsidiary are denominated in Euros.

Cost of revenues consists primarily of the cost of purchasing components and sub-systems, assembling, packaging, shipping and testing components at our facility, direct labor and associated overhead, and our U.S. field service organization which supports our aesthetics products domestically.

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 personnel costs, sales commissions, travel expenses and advertising and promotional expenses.

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

#### **Results of Operations**

## Edgar Filing: IRIDEX CORP - Form 10-Q

The following table sets forth certain operating data as a percentage of revenues for the periods included.

	Three Months Ended		Nine Months Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
<b>Revenues:</b>				
Product revenues	81.9%	80.8%	81.7%	79.7%
Service revenues	18.1%	19.2%	18.3%	20.3%
<b>Total revenues</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Cost of revenues</b>	<b>54.6%</b>	<b>51.5%</b>	<b>54.2%</b>	<b>52.3%</b>
<b>Gross margin</b>	<b>45.4%</b>	<b>48.5%</b>	<b>45.8%</b>	<b>47.7%</b>
<b>Operating expenses:</b>				
Research and development	8.3%	8.5%	8.4%	9.2%
Sales and marketing	20.6%	21.4%	21.5%	22.2%
General and administrative	11.7%	10.4%	11.1%	11.1%
<b>Total operating expenses</b>	<b>40.6%</b>	<b>40.3%</b>	<b>41.0%</b>	<b>42.5%</b>
<b>Income from operations</b>	<b>4.8%</b>	<b>8.2%</b>	<b>4.8%</b>	<b>5.2%</b>
Legal settlement	0.0%	0.0%	2.4%	2.5%
Interest and other income (expense), net	(1.3)%	0.6%	(0.7)%	(0.2)%
<b>Income before provision for income tax</b>	<b>3.5%</b>	<b>8.8%</b>	<b>6.5%</b>	<b>7.5%</b>
Provision for income taxes	0.3%	0.4%	0.9%	0.5%
<b>Net income</b>	<b>3.2%</b>	<b>8.4%</b>	<b>5.6%</b>	<b>7.0%</b>

**Table of Contents***Revenues.*

(in millions)	Three Months Ended October 1, 2011	Three Months Ended October 2, 2010	Change in \$	Change in %
Ophthalmology systems - domestic	\$ 1.6	\$ 2.0	\$ (0.4)	(20.0)%
Ophthalmology systems - international	2.6	1.7	0.9	52.9%
Ophthalmology recurring revenues	4.0	4.2	(0.2)	(4.8)%
Ophthalmology OEM	0.1	0.1	0.0	0.0%
<b>Total Ophthalmology revenues</b>	<b>\$ 8.3</b>	<b>\$ 8.0</b>	<b>\$ 0.3</b>	<b>3.8%</b>
Aesthetics systems - domestic	\$ 0.5	\$ 0.6	\$ (0.1)	(16.7)%
Aesthetics systems - international	0.7	0.9	(0.2)	(22.2)%
Service revenues	1.3	1.3	0.0	0.0%
<b>Total Aesthetics revenues</b>	<b>\$ 2.5</b>	<b>\$ 2.8</b>	<b>\$ (0.3)</b>	<b>(10.7)%</b>
<b>Total revenues</b>	<b>\$ 10.8</b>	<b>\$ 10.8</b>	<b>\$ 0.0</b>	<b>0.0%</b>

(in millions)	Nine Months Ended October 1, 2011	Nine Months Ended October 2, 2010	Change in \$	Change in %
Ophthalmology systems - domestic	\$ 4.9	\$ 4.2	\$ 0.7	16.7%
Ophthalmology systems - international	7.2	6.3	0.9	14.3%
Ophthalmology recurring revenues	12.0	12.2	(0.2)	(1.6)%
Ophthalmology OEM	0.4	0.6	(0.2)	(33.3)%
<b>Total Ophthalmology revenues</b>	<b>\$ 24.5</b>	<b>\$ 23.3</b>	<b>\$ 1.2</b>	<b>5.2%</b>
Aesthetics systems - domestic	\$ 1.6	\$ 1.8	\$ (0.2)	(11.1)%
Aesthetics systems - international	2.9	2.3	0.6	26.1%
Service revenues	3.8	4.1	(0.3)	(7.3)%
<b>Total Aesthetics revenues</b>	<b>\$ 8.3</b>	<b>\$ 8.2</b>	<b>\$ 0.1</b>	<b>1.2%</b>
<b>Total revenues</b>	<b>\$ 32.8</b>	<b>\$ 31.5</b>	<b>\$ 1.3</b>	<b>4.1%</b>

For the three months ended October 1, 2011, total revenue was \$10.8 million, unchanged from the same three month period in 2010. For the nine months ended October 1, 2011, total revenue was \$32.8 million compared to \$31.5 million for the same nine month period in 2010.

For the comparable three month period:

Our Ophthalmology revenues increased 3.8%, due mainly from an increase in our system sales. Our newer systems, the IQ577 and the IQ532, have been performing well. The increase was due mainly to an increase in international system sales, partially offset by a decrease in domestic system sales and to a lesser extent, a decrease in Ophthalmology recurring revenues. Our Aesthetics revenues decreased 10.7%. The aesthetics market as a whole remains challenging. Aesthetics systems revenues can fluctuate period to period due to the timing of individual deals because of the relatively high price and low volume of systems being sold. This effect is magnified for international sales where distributors often place multiple system orders at one time.

For the comparable nine month period:

Our Ophthalmology revenues increased 5.2%, due mainly from an increase in our system sales, partially offset by a decrease in Ophthalmology recurring revenues and a decrease in OEM line, as this product reaches its end of life. Our Aesthetics revenues remained fairly constant, increasing 1.2%.

*Gross Profit and Gross Margin.*

For the comparable three month period:

Gross profit for the three months ended October 1, 2011 was \$4.9 million compared with \$5.2 million for the same three month period in 2010, a decrease of 5.8% or \$0.3 million. Gross margins decreased to 45.4% of revenues from 48.5% of revenues. The decrease was primarily due to product mix with a higher proportion of our aggregate revenues being generated by systems sales; ophthalmology and aesthetics system sales generate a lower margin than ophthalmology recurring revenues, and within system sales a heavier weighting towards international ophthalmology system sales which occur through our distribution channel where we receive a lower margin compared to domestic ophthalmology system sales which occur through our direct channel that resulted in a decrease of 3.7% in direct margins. The decrease was partially offset by a 0.6% improvement in manufacturing and service costs.

For the comparable nine month period:

Gross profit for the nine months ended October 1, 2011 was \$15.0 million, unchanged from the same nine month period a year earlier. Gross margins decreased to 45.8% of revenues from 47.7% of revenues. The decrease was primarily due to product mix with a higher proportion of our aggregate revenues being generated by systems sales; ophthalmology and aesthetics system sales generate a lower margin than our ophthalmology recurring revenues, which resulted in a decrease of 2.1% in direct margins. The decrease was partially offset by a 0.2% improvement in manufacturing and service costs.

Gross margins as a percentage of revenues will continue to fluctuate due to changes in the relative proportions of domestic and international sales, the product mix of sales, manufacturing variances, total unit volume changes that lead to greater or lesser production efficiencies and a variety of other factors. See Item 1A. Risk Factors-Factors That May Affect Future Results- Our Operating Results May Fluctuate from Quarter to Quarter and Year to Year.

*Research and Development.*

Research and development ( R&D ) expenses remained unchanged at \$0.9 million for the three months ended October 1, 2011 compared to the same three month period in 2010 and decreased 3.4% to \$2.8 million from \$2.9 million for the nine months ended October 1, 2011 compared to the same nine month period in 2010. The decrease is primarily attributable to headcount turnover and related costs. We anticipate an increase in our R&D spending as we add replacement headcount and also to support an increased rate of new product introductions.

---

**Table of Contents***Sales and Marketing.*

Sales and marketing expenses decreased by 4.3% to \$2.2 million from \$2.3 million for the three months ended October 1, 2011 compared to the same three month period in 2010. The decrease is primarily attributable to the timing of marketing and advertising promotions. Sales and marketing expenses increased by 1.4% to \$7.1 million from \$7.0 million for the nine months ended October 1, 2011 compared to the same nine month period in 2010. The increases were attributable to an increase in headcount and related cost and to an increase in associated selling and marketing expenses due to and in support of the increase in sales. We anticipate an increase in our sales and marketing spending with the objective of driving increased sales.

*General and Administrative.*

General and administrative expenses increased by \$0.2 million or 18.2%, to \$1.3 million from \$1.1 million for the three months ended October 1, 2011 compared to the same three month period in 2010. General and administrative expenses increased by \$0.1 million or 2.9%, to \$3.6 million from \$3.5 million for the nine months ended October 1, 2011 compared to the same nine month period in 2010. The increases are attributable to increases in legal and public company expenses.

*Legal Settlement.*

The legal settlement relates to monies received from Synergetics associated with a 2007 settlement of legal claims for patent infringement. The settlement called for an initial payment of \$2.5 million which was received in the second quarter of 2007 and five subsequent annual payments of \$0.8 million, totaling \$6.5 million. Four annual payments of \$0.8 million have been received in the second quarter of fiscal years 2008, 2009, 2010 and 2011, leaving a balance of \$0.8 million expected to be received in the second quarter of fiscal 2012.

*Interest and Other Income (Expense), Net.*

For the three month period ended October 1, 2011, interest and other income (expense), net consisted primarily of foreign currency exchange losses and additional expense recorded for the fair value remeasurement of the RetinaLabs earn-out liability. For the same period a year earlier, interest and other income (expense), net consisted primarily of foreign currency exchange gains. For the nine months ended October 1, 2011, interest and other income (expense), net consisted primarily of the recognition of accumulated foreign currency translation loss related to the closure of the UK subsidiary and additional expense recorded for the fair value remeasurement previously mentioned. For the same period a year earlier, interest and other expense consisted primarily of interest expense due to the bank borrowings in 2010.

*Income Taxes.*

Significant components affecting the effective tax rate include pre-tax income, changes in valuation allowance, federal and state R&D tax credits, the state composite tax rate and recognition of certain deferred tax assets subject to valuation allowance. For the nine month periods ended October 1, 2011 and October 2, 2010, the Company recorded an income tax provision of \$0.3 million and \$0.2 million, respectively. As of January 1, 2011, the Company had a deferred tax asset of approximately \$12.1 million which is fully offset by a valuation allowance. When realized, the asset will be reflected on the Company's balance sheet and the reversal of the corresponding valuation allowance will result in a tax benefit being recorded in the income statement in the respective period. In subsequent periods the effective tax rate recorded in the income statement will reflect a more normal rate, currently estimated to be between 30% to 40%.

*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 October 1, 2011, we had cash and cash equivalents of \$9.5 million and working capital of \$19.5 million compared to cash and cash equivalents of \$9.0 million and working capital of \$17.2 million as of January 1, 2011. For the nine months ended October 1, 2011, we had a net increase in cash and cash equivalents of \$0.5 million. The net cash provided by operations of \$0.9 million for the nine months ended October 1, 2011 resulted primarily from the net income of \$1.8 million, an adjustment for non-cash stock-based compensation and depreciation expense of \$0.4 million and \$0.3 million, respectively, partially offset by an increase in inventories by \$1.0 million, a decrease in accrued compensation by \$0.8 million and a decrease in accounts receivable of \$0.2 million. The net cash used in investing activities of \$0.2 million for the nine months ended October 1, 2011 related to \$0.1 million purchase of property and equipment and \$0.1 million paid for the purchase of Ocutetics, Inc. The net cash used in financing activities of \$0.2 million for the nine months ended October 1, 2011 related primarily to \$0.5 million and repurchase of our common stock held by American Medical Systems Holdings, Inc. and under the stock repurchase program, partially offset by \$0.3 million

proceeds from exercise of stock options. See Item 2, Unregistered Sales of Equity Securities and Use of Proceeds in Part II, Other Information, for additional information.

Management is of the opinion that the Company's current cash and cash equivalents together with our ability to generate cash flows from operations and our current credit facility provide sufficient liquidity to operate for the next 12 months.

**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. We transact the majority of our business in U.S. dollars and therefore changes in foreign currency rates will not have a significant impact on our income statement or cash flows. However, increases in the value of the U.S. dollar 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. Our French subsidiary, which is responsible for selling our aesthetics products in France, transacts business in its geography in its local currency, and therefore, changes in the U.S. dollar versus the Euro may impact our income statement or cash flows. We currently do not engage in transactions to hedge against the risk of the currency fluctuation, but we may do so in the future.

**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 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.



## **Table of Contents**

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 Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of October 1, 2011. Based on the foregoing, our Chief Executive Officer and 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**

None.

### **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 operation. You should carefully consider the risks described below before making an investment decision.

*We have marked with an asterisk (\*) those risk factors below that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K filed with the SEC on March 25, 2011.*

#### *Our Operating Results May Fluctuate from Quarter to Quarter and Year to Year.*

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

general economic uncertainties and political concerns;

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 and aesthetics 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;

## Edgar Filing: IRIDEX CORP - Form 10-Q

fluctuations in our product mix between ophthalmology and aesthetics products and foreign and domestic sales;

the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;

introduction of new products, product enhancements and new applications by our competitors, entry of new competitors into our markets, pricing pressures and other competitive factors;

our long and highly variable sales cycle;

changes in the prices at which we can sell our products;

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; 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 domestic equipment sales are generally higher in the fourth quarter due to customers' budget cycles whereas our European sales are generally lower in the third quarter 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. We encountered this adverse effect on our operating results during our recent history starting with the quarter ended March 31, 2007 through the quarter ended January 3, 2009. 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 quarter. 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.

---

**Table of Contents**

*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 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. 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. In the three month period ended October 1, 2011, the trading price of our common stock fluctuated from a low of \$3.48 per share to a high of \$4.10 per share. There can be no assurance that our common stock trading price will not suffer declines.

*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 and aesthetics markets. 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;

recommendations and opinions by ophthalmologists, dermatologists, plastic surgeons, other clinicians, and their associated opinion leaders;

clinical study outcomes;

price of our products and prices of competing products and technologies particularly in light of the current macro-economic environment, in which the availability of credit is limited and purchasers may delay capital investments or place additional emphasis on price when making their purchase decision;

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 from recurring sales of consumable instrumentation, including consumable EndoProbe devices and service. 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 our products, 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 devices used for ophthalmic and aesthetics treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Alcon Inc., Carl Zeiss Meditec AG, Nidek Co. Ltd., Synergetics, Topcon Corporation, Ellex Medical Lasers, Ltd. and Lumenis Ltd. Most of these companies currently offer a competitive, semiconductor-based laser system and consumable instrumentation for ophthalmology. Also within ophthalmology, pharmaceutical alternative treatments for AMD and DME such as Lucentis/Avastin (Genentech), and to a lesser extent Visudyne (Novartis) and Macugen (OSI Pharmaceuticals), compete rigorously with traditional laser procedures. In aesthetics, our principal competitors are Cutera, Syneron, Palomar Technologies, Inc., Sciton,

## Edgar Filing: IRIDEX CORP - Form 10-Q

Lumenis Ltd. and Cynosure. These competitors have more sales representatives supporting broader product lines. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do.

In both markets, some companies also have greater name recognition than we do and benefit from long-standing customer relationships. In addition, some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

*If There is Not Sufficient Demand for the Aesthetics Procedures Performed with Our Products, Practitioner Demand for Our Products Could be Inhibited, Resulting in Unfavorable Operating Results and Reduced Growth Potential.*

The global aesthetics market has seen a continued contraction and we have seen reduced demand for our products because most procedures performed using our aesthetics products are elective procedures not reimbursable through government or private health insurance, with the costs borne by the patient. The decision to purchase our aesthetics products may therefore be influenced by a number of factors, including:

consumer confidence, which may be impacted by economic and political conditions;

the success of our sales and marketing efforts;

evolving customer needs;

the introduction of new products and technologies;

evolving surgical practices;

evolving industry standards;

the cost of procedures performed using our products; and

the cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser or other light-based technologies and treatments which use pharmaceutical products.

---

## **Table of Contents**

If, as a result of these factors, there is not sufficient demand for the procedures performed with our aesthetics products, practitioner demand for our aesthetics products could be reduced, resulting in unfavorable operating results and lower growth potential.

### *Our Operating Results May be Adversely Affected by Uncertainty Regarding Healthcare Reform Measures and Changes in Third Party Coverage and Reimbursement Policies.*

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. 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, or what effect such legislation or regulation may have on us. However, denial of coverage and reimbursement of our products would have a material adverse effect on our business, results of operations and financial condition.

Our ophthalmology 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. Third-party payers are increasingly scrutinizing and challenging 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.

### *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.

### *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 nine months ended October 1, 2011, our international sales were \$15.0 million or 45.8% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies, other than sales made by our French subsidiary. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets. The factors stated above could have a material adverse effect on our business, financial condition or results of operations. Our international operations and sales are subject to a number of other risks and potential costs, including:

impact of international conflicts, terrorist and military activity, civil unrest;

impact of recessions in global economies and availability of credit;

fluctuations in foreign currency exchange rates;

performance of our international channel of distributors;

longer accounts receivable collection periods;

differing local product preferences and product requirements;

cultural differences;

changes in foreign medical reimbursement and coverage policies and programs;

political and economic instability;

difficulty in staffing and managing foreign operations;

foreign certification requirements, including continued ability to use the CE mark in Europe, and other local regulatory requirements;

reduced or limited protections of intellectual property rights in jurisdictions outside the United States;

potentially adverse tax consequences; and

multiple protectionist, adverse and changing foreign governmental laws and regulations.

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

*If We Cannot Increase Our Sales Volumes, Reduce Our Costs or Introduce Higher Margin Products to Offset Anticipated Reductions in the Average Unit Price of Our Products, Our Operating Results May Suffer.*

---

## **Table of Contents**

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.

*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 6 acquisitions. As part of our growth strategy we are seeking to acquire additional 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 additional acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These additional efforts could divert the attention of our management and key personnel from our business operations. If we complete additional acquisitions, we may also experience:

difficulties integrating any acquired products into our existing business;

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.

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

Furthermore, additional acquisitions could materially impair our operating results by causing us to amortize acquired assets, incur acquisition expenses and add debt.

*Inability of Customers Obtaining 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 will be harder to obtain or more expensive to our customers, which may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer

*We Rely on Our Direct Sales Force and Network of International Distributors to Sell Our Products and Any Failure to Maintain Our Direct Sales Force and Distributor Relationships Could Harm Our Business.*

Our ability to sell our products and generate revenues depends upon our direct sales force within the United States and France and relationships with independent distributors outside the United States. Currently our direct sales force consists of 11 employees focused on Ophthalmology and 4 employees and 1 independent representative focused on aesthetics and we maintain relationships with approximately 100 independent distributors internationally selling our products into 107 countries. 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. Apart from sales of our aesthetics products in France, our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches terms of its distribution agreement 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.

## Edgar Filing: IRIDEX CORP - Form 10-Q

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 limit our revenues and our ability to maintain market share. The loss of the services of these key personnel would harm our business. Similarly, our distributor agreements are generally terminable at will by either party and distributors may terminate their relationships with us, which would affect our international sales and results of operations.

*Our Future Levels of Indebtedness May Limit Our Ability to Operate Our Business, Finance Acquisitions and Pursue Business Strategies.*

As of October 1, 2011, our cash balance was \$9.5 million and we had no debt outstanding. If we are unable to maintain positive cash flows we may need to incur debt to sustain our operations. In addition it is our goal to seek growth through investments in internal programs and acquisitions both of which may result in us incurring debt. Increased levels of debt and obligations may, among other things:

make it more difficult for us to meet our payments and other obligations to other third parties;

increase our vulnerability to, and limit our flexibility in planning for, adverse economic and industry conditions;

increase our sensitivity to interest rate increases on our indebtedness with variable interest rates;

result in an event of default if we fail to comply with the financial and other restrictive covenants contained in our debt agreements, which event of default could result in all of our debt becoming immediately due and payable;

affect our credit rating;

limit our ability to obtain additional financing to fund future working capital, capital expenditures, additional acquisitions and other general corporate requirements;



---

**Table of Contents**

create competitive disadvantages compared to other companies with less indebtedness; and

limit our ability to apply proceeds from an offering or asset sale to purposes other than the repayment of debt.

Our ability to service any future indebtedness will depend on our future performance, which will be affected by prevailing economic conditions and financial, business, regulatory and other factors. Some of these factors are beyond our control. In addition credit markets remain fragile. We cannot assure you that financing or refinancing will be available on a timely basis or on satisfactory terms, if at all.

*Our Future Success Depends on Our Ability to Develop and Successfully Introduce New Products and New Applications.*

Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. 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 may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration, or 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 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. We have been issued twenty six United States patents and thirteen foreign patents on the technologies related to our products and processes. We have approximately five pending patent applications in the United States and six foreign pending patent applications that have been filed. Our patent applications may not be approved. Along with the acquisition of the AMS/Laserscope aesthetic products, we acquired a royalty-free license to eleven of the AMS/Laserscope patents. In addition, we acquired a license to a Palomar patent under which royalties are paid to Palomar based upon a percentage of sales of certain products acquired from AMS/Laserscope. The acquisition of the RetinaLabs assets included five additional patents. 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. For example our Connector Patent used to connect our delivery devices (consumable & durable) to our laser consoles expired in 2010. Delivery devices which do not utilize our Connector Patent technology are not recognized by our laser consoles. We derive, and expect to continue to derive, a large portion of our recurring revenue and profits from sales of our consumable EndoProbe devices. Expiration of this patent may increase competition from our competitors for our consumable EndoProbe device business and there can be no guarantees that we will maintain our market share of this business.

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. Until recently patent applications were maintained in secrecy in the United States until the patents were issued. 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 with regards to international patent applications, we cannot assure 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. For example, during fiscal year 2007, the Company settled patent litigations with Synergetics, Inc., which was time-consuming, costly and a diversion of technical and management personnel. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

*If We 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.

*While We Devote Significant Resources to Research and Development, Our Research and Development May Not Lead to New Products that Achieve Commercial Success.*

The Company's ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, including 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. Because of the complexities and uncertainties associated with ophthalmic and aesthetics 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. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products of current or future competitors. Therefore, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

---

## **Table of Contents**

*The Clinical Trial Process Required to Obtain Regulatory Approvals is Costly and Uncertain, and Could Result in Delays in New Product Introductions or Even an Inability to Release a Product.*

The clinical trials required to obtain regulatory approvals for our products are complex and expensive and their outcomes are uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in the commercial sale of a product. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products may 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 may suspend or terminate clinical trials at any time if they or we believe the trial participants face unacceptable health risks.

*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 assure 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.

*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 the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. 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 component and materials 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 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 that may discontinue their operations 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 in the quantities that we require;

delays in delivery or failure of suppliers to deliver critical components on the dates we require;

failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and

inability to obtain components 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. 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 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 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 in the quantity and quality desired and at the prices we have budgeted.

*\* 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. The failure to obtain any additional future clinical collaborations and the resulting failure or success of such arrangements of any current or future clinical 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 Fail to Maintain Our Relationships With Health Care Providers, Customers May Not Buy Our Products and Our Revenue and Profitability May Decline.*

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

*We Face Manufacturing Risks.*

---

## **Table of Contents**

The manufacture of our infrared and visible laser consoles and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and substantially all of our final products at our facility in Mountain View, California. We may experience manufacturing difficulties, quality control issues or assembly constraints, particularly with regard to new products that we may introduce. If our sales increase substantially, including increases in the sales of our aesthetics products, 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 and as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

### *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.

### *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 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 undergo rigorous testing and an extensive regulatory review process implemented by the FDA under federal law. Unless otherwise exempt, a device manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval application (PMA) 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 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 additional regulations on manufacturers of approved medical devices. We are required to comply with the applicable Quality System regulations and our manufacturing facilities are subject to ongoing periodic inspections by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before being utilized for commercial manufacturing. Noncompliance with the applicable requirements can result in, among other things, 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.

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.

### *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 Quality System Regulation, or 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, such

## Edgar Filing: IRIDEX CORP - Form 10-Q

as those described in the preceding risk factor above, which would cause our sales and business to suffer.

*If We Modify One of Our FDA Approved Devices, We May Need to Seek Reapproval, Which, if Not Granted, 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 premarket approval. 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.

*Because We Do Not Require Training for Users of Our Products, and Sell Our Products to Non-physicians, There Exists an Increased Potential for Misuse of Our Products, Which Could Harm Our Reputation and Our Business.*

Federal regulations restrict the sale of our products to or on the order of licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states by non-physicians, including nurse practitioners and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

*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.*

---

## **Table of Contents**

Laser systems are inherently complex in design and require ongoing 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.

*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 design or manufacture. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales.

*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 and skin conditions on and near a patient's face. We believe we maintain adequate levels of product liability insurance but 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.

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

Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share
July 3, 2011- August 6, 2011	0	\$ 0.00
August 7, 2011 - September 3, 2011	(32,778)	\$ (3.66)
September 4, 2011 - October 1, 2011	0	\$ 0.00
<b>Total</b>	<b>(32,778)</b>	<b>\$ (3.66)</b>

- (1) Reflects the repurchase of shares of our common stock in the open market in accordance with the stock repurchase program approved by the Board of Directors of the Company on May 5, 2011. Each repurchase was financed by available cash balances and cash from operations.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Removed and Reserved**

**Item 5. Other Information**

None



**Table of Contents****Item 6. Exhibits**

Exhibit	
No.	Exhibit Title
10.1	Employment Agreement by and between the Registrant and Dominik Beck, dated as of August 16, 2011. (1)
10.2	Executive Transition Agreement by and between the Registrant and Theodore A. Boutacoff, dated October 10, 2011. (1)
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

The financial information contained in these XBRL documents is unaudited and is furnished, not filed with the Securities and Exchange Commission.

(1) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on October 12, 2011.

**Trademark Acknowledgments**

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe, Apex, Aura, Lyra, Gemini, Venus, Coolspot and Dermastat are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, DioLite, IQ 810, IQ 577, MicroPulse, OtoProbe, ScanLite, Symphony, VariLite, 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.

**Table of Contents**

**SIGNATURE**

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 3, 2011

By: /s/ DR. DOMINIK BECK

Name: Dr. Dominik Beck

Title: President and Chief Executive Officer

(Principal Executive Officer)

**Table of Contents**

**Exhibit Index**

Exhibit	
No.	Exhibit Title
10.1	Employment Agreement by and between the Registrant and Dominik Beck, dated as of August 16, 2011. (1)
10.2	Executive Transition Agreement by and between the Registrant and Theodore A. Boutacoff, dated October 10, 2011. (1)
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

The financial information contained in these XBRL documents is unaudited and is furnished, not filed with the Securities and Exchange Commission.

(1) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on October 12, 2011.