

IRIDEX CORP
Form 10-Q
May 06, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 30, 2013

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 April 22, 2013 was 8,568,375.

Table of Contents

TABLE OF CONTENTS

Items	Page
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Consolidated Financial Statements</u>	3
<u>Unaudited Condensed Consolidated Balance Sheets as of March 30, 2013 and December 29, 2012</u>	3
<u>Unaudited Condensed Consolidated Statements of Operations for the three months ended March 30, 2013 and March 31, 2012</u>	4
<u>Unaudited Condensed Consolidated Statements of Comprehensive Income for the three months ended March 30, 2013 and March 31, 2012</u>	5
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 30, 2013 and March 31, 2012</u>	6
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	15
<u>Item 4. Controls and Procedures</u>	15
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	16
<u>Item 1A. Risk Factors</u>	16
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
<u>Item 3. Defaults Upon Senior Securities</u>	23
<u>Item 4. Mine Safety Disclosures</u>	23
<u>Item 5. Other Information</u>	23
<u>Item 6. Exhibits</u>	23
<u>Signature</u>	25
<u>Exhibit Index</u>	26

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (unaudited)
IRIDEX Corporation****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited, in thousands except share and per share data)**

	March 30, 2013	December 29, 2012 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,581	\$ 11,901
Accounts receivable, net of allowance for doubtful accounts of \$200 at March 30, 2013 and \$146 at December 29, 2012	6,031	5,480
Inventories	8,147	8,035
Prepaid expenses and other current assets	1,123	1,129
Current assets of discontinued operations	510	510
Total current assets	27,392	27,055
Property and equipment, net	440	483
Other intangible assets, net	489	554
Goodwill	533	533
Other long-term assets	298	287
Total assets	\$ 29,152	\$ 28,912
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,280	\$ 2,105
Accrued compensation	1,442	1,563
Accrued expenses	1,372	1,242
Accrued warranty	446	453
Deferred revenue	943	1,004
Total current liabilities	5,483	6,367
Long-term liabilities:		
Other long-term liabilities	542	640
Total liabilities	6,025	7,007
Stockholders' equity:		
Convertible preferred stock, \$0.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: 500,000 shares at March 30, 2013 and at December 29, 2012	5	5
Liquidation preference of \$5,000		
Common stock, \$0.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 8,558,006 and 8,452,971 shares at March 30, 2013 and December 29, 2012, respectively	95	94

Edgar Filing: IRIDEX CORP - Form 10-Q

Additional paid-in capital	39,305	38,958
Accumulated deficit	(16,278)	(17,152)
Total stockholders' equity	23,127	21,905
Total liabilities and stockholders' equity	\$ 29,152	\$ 28,912

- (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 December 29, 2012.

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

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

	Three Months Ended March 30, 2013	Three Months Ended March 31, 2012
Total revenues	\$ 8,939	\$ 8,305
Cost of revenues	4,708	4,319
Gross profit	4,231	3,986
Operating expenses:		
Research and development	996	1,182
Sales and marketing	1,625	1,864
General and administrative	1,186	1,176
Proceeds from demutualization of insurance carrier	(473)	0
Total operating expenses	3,334	4,222
Income (loss) from continuing operations	897	(236)
Other expense, net	(18)	(27)
Income (loss) from continuing operations before provision for income taxes	879	(263)
Provision for income taxes	5	2
Income (loss) from continuing operations, net of tax	874	(265)
Loss from discontinued operations, net of tax	0	(162)
Gain on sale of discontinued operations, net of tax	0	2,032
Income from discontinued operations, net of tax	0	1,870
Net income	\$ 874	\$ 1,605
Net income (loss) per share:		
Basic -		
Continuing operations	\$ 0.10	\$ (0.03)
Discontinued operations	0.00	0.21
Net income	\$ 0.10	\$ 0.18
Diluted -		
Continuing operations	\$ 0.09	\$ (0.03)
Discontinued operations	0.00	0.21
Net income	\$ 0.09	\$ 0.18
Weighted average shares used in computing net income (loss) per common share - basic	8,511	8,933

Edgar Filing: IRIDEX CORP - Form 10-Q

Weighted average shares used in computing net income (loss) per common share - diluted	9,802	8,933
--	-------	-------

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

Table of Contents

Condensed Consolidated Statements of Comprehensive Income

(Unaudited, in thousands)

	Three Months Ended	
	March 30, 2013	March 31, 2012
Net income	\$ 874	\$ 1,605
Other comprehensive income, net of tax:		
Recognition of accumulated foreign currency translation loss related to sale of foreign operations	0	35
Comprehensive income	\$ 874	\$ 1,640

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)**

	Three Months Ended March 30, 2013	Three Months Ended March 31, 2012
Operating activities:		
Net income	\$ 874	\$ 1,605
Less income from discontinued operations	0	1,870
Income (loss) from continuing operations	874	(265)
Adjustments to reconcile net income (loss) from continuing operations to net cash used in operating activities:		
Depreciation and amortization	126	113
Change in fair value of earn-out liability	19	29
Stock compensation cost recognized	161	147
Provision for doubtful accounts	54	(24)
Changes in operating assets and liabilities, net of assets and liabilities acquired:		
Accounts receivable	(605)	433
Inventories	(112)	(379)
Prepaid expenses and other current assets	6	(708)
Other long-term assets	(11)	16
Accounts payable	(825)	(36)
Accrued compensation	(121)	307
Accrued expenses	108	(751)
Accrued warranty	(7)	(17)
Deferred revenue	(61)	(107)
Other long-term liabilities	(12)	0
Net cash used in operating activities	(406)	(1,242)
Investing activities:		
Acquisition of property and equipment	(18)	(121)
Payment on earn-out liability	(83)	(86)
Net cash used in investing activities	(101)	(207)
Cash flows from financing activities:		
Proceeds from stock option exercises	273	236
Repurchase of common stock	(46)	(188)
Payment of legal costs in connection with tender offer	(40)	0
Net cash provided by financing activities	187	48
Net cash used in operating activities from discontinued operations	0	(199)
Net cash provided by investing activities from discontinued operations	0	4,632
Effect of foreign exchange rate changes from discontinued operations	0	35
Net cash provided by discontinued operations	0	4,468

Edgar Filing: IRIDEX CORP - Form 10-Q

Net (decrease) increase in cash and cash equivalents	(320)	3,067
Cash and cash equivalents, beginning of period	11,901	10,789
Cash and cash equivalents, end of period	\$ 11,581	\$ 13,856

Supplemental disclosure of cash flow information:

Cash paid during the year for:

Income taxes	\$ 10	\$ 13
--------------	-------	-------

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, we, our, or us) have been prepared in accordance with generally accepted accounting principles in the United States (US GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP 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 consolidated financial statements and notes thereto, together with management's discussion and analysis of the Company's financial condition and results of operations, contained in our Annual Report on Form 10-K for the fiscal year ended December 29, 2012, which was filed with the Securities and Exchange Commission (SEC) on March 28, 2013. The results of operations for the three months ended March 30, 2013 are not necessarily indicative of the results for the year ending December 28, 2013 or any future interim period.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended December 29, 2012, which was filed with the SEC on March 28, 2013.

Financial Statement Presentation.

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

Use of Estimates.

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

Discontinued operations.

Discontinued operations are presented and accounted for in accordance with Accounting Standards Codification (ASC) 360, *Impairment or Disposal of Long-Lived Assets*, (ASC 360). When a qualifying component of the Company is disposed of or has been classified as held for sale, the operating results of that component are removed from continuing operations for all periods presented and displayed as discontinued operations if: (a) elimination of the component's operations and cash flows from the Company's ongoing operations has occurred (or will occur) and (b) significant continuing involvement by the Company in the component's operations does not exist after the disposal transaction.

On December 30, 2011, we entered into an agreement to sell our aesthetics business to Cutera, Inc. The sale of the aesthetics business was completed on February 2, 2012. The operating results of our aesthetics business were therefore classified as discontinued operations, and the associated assets and liabilities were classified as discontinued operations for all periods presented under the requirements of ASC 360.

(in thousands)

Edgar Filing: IRIDEX CORP - Form 10-Q

	Three Months Ended March 30, 2013	Three Months Ended March 31, 2012
Total revenues	\$ 0	\$ 929
(Loss) income from discontinued operations	\$ 0	\$ (162)
Gain on sales of aesthetics business	\$ 0	\$ 1,149
Income from discontinued operations, before income taxes	\$ 0	\$ 987
Income tax (benefit) expense	\$ 0	\$ 883
Income from discontinued operations, net of tax	\$ 0	\$ 1,870

Current assets of discontinued operations as of March 30, 2013 and December 29, 2012 comprised of restricted cash in the amount of \$0.5 million. In accordance with the terms of the sale of the aesthetics segment to Cutera, Inc., 10% of the total purchase price had to be deposited and held in an escrow account for a period of twelve months from the date of closing and will be used to resolve certain claims by Cutera, Inc., if any, which the Company has indemnified. The release of the restricted cash to the Company is three months following the end of the twelve month escrow period. As of March 30, 2013, there had been no claims made by Cutera, Inc.

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 or other deliverables. For revenue arrangements such as these, we recognize revenue in accordance with ASC 605, *Revenue Recognition, Multiple-Element Arrangements*. The Company allocates revenue among deliverables in multiple-element arrangements using the relative selling price method. Revenue allocated to each element is recognized when the basic revenue recognition criteria is met for each element. The Company is required to apply a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence of selling price (VSOE), (ii) third-party evidence of selling price (TPE) and (iii) best estimate of the selling price (ESP). In general, the Company is unable to establish VSOE or TPE for all of the elements in the arrangement; therefore, revenue is allocated to these elements based on the Company's ESP, which the Company determines after considering multiple factors such as management approved pricing guidelines, geographic differences, market conditions, competitor pricing strategies, internal costs and gross margin objectives. These factors may vary over time depending upon the unique facts and circumstances related to each deliverable. As a result, the Company's ESP for products and services could change. Revenues for post-sales obligations are recognized as the obligations are fulfilled.

Table of Contents

In international regions, 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.

Royalty revenues are typically based on licensee's net sales of products that utilize our technology and are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured, such as upon the earlier of the receipt of a royalty statement from the licensee or upon payment by the licensee.

Taxes Collected from Customers and Remitted to Governmental Authorities.

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

Shipping and Handling Costs.

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

Deferred Revenue.

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 three months ended March 30, 2013 and March 31, 2012 is as follows:

(in thousands)	Three Months Ended	
	March 30, 2013	March 31, 2012
Balance, beginning of period	\$ 1,004	\$ 1,014
Additions to deferral	269	148
Revenue recognized	(330)	(255)
Balance, end of period	\$ 943	\$ 907

Warranty.

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 revenues. A reconciliation of the changes in the Company's warranty liability for the three months ended March 30, 2013 and March 31, 2012 is as follows:

(in thousands)	Three Months Ended	
	March 30, 2013	March 31, 2012
Balance, beginning of period	\$ 453	\$ 556
Accruals for product warranties	67	42
Cost of warranty claims and adjustments	(74)	(59)
Balance, end of period	\$ 446	\$ 539

Recently Issued and Adopted Accounting Standards.

In February 2013, the Financial Accounting Standards Board issued 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (AOCI)*, which aims to improve the reporting of reclassifications out of AOCI. This update requires an entity to report the effect of significant reclassifications out of AOCI on the respective line items in net income if the amount being reclassified is required under US GAAP to be reclassified in its entirety to net income. For other amounts that are not required under US GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under US GAAP that provide additional detail about those amounts. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. For public entities, the amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company adopted this standard in the first quarter of fiscal year 2013. The adoption of this standard did not have a material effect on our consolidated financial position, results of operations, or cash flows.

3. Inventories, net

The components of the Company's inventories as of March 30, 2013 and December 29, 2012 are as follows:

(in thousands)	March 30, 2013	December 29, 2012
Raw materials and work in process	\$ 5,225	\$ 5,357
Finished goods	2,922	2,678
Total inventories	\$ 8,147	\$ 8,035

4. Goodwill and Intangible Assets

Goodwill.

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

Balance, December 29, 2012	\$ 533
Additions as a result of acquisitions	0
Balance, March 30, 2013	\$ 533

Table of Contents*Intangible Assets.*

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

	March 30, 2013			December 29, 2012			Amortization Life
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Patents	\$ 720	\$ 423	\$ 297	\$ 720	\$ 362	\$ 358	Varies
Customer Relations	240	48	192	240	44	196	12.1 years
	\$ 960	\$ 471	\$ 489	\$ 960	\$ 406	\$ 554	

Amortization expense totaled \$65 thousand and \$45 thousand for the three months ended March 30, 2013 and March 31, 2012, respectively. The amortization of Customer Relations was charged to sales and marketing expense and the amortization of Patents was charged to cost of revenues.

Future estimated amortization expense (in thousands):	
2013 (nine months)	\$ 189
2014	30
2015	52
2016	86
2017	16
Thereafter	116
Total	\$ 489

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.

Edgar Filing: IRIDEX CORP - Form 10-Q

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

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

The carrying amounts of the Company's financial assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses at March 30, 2013 and December 29, 2012, approximate fair value because of the short maturity of these instruments.

Table of Contents

As of March 30, 2013 and December 29, 2012, 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):

	March 30, 2013 Fair Value Measurements				December 29, 2012 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	\$ 10,839			\$ 10,839	\$ 10,839			\$ 10,839
Liabilities:								
Earn-out liability			\$ 588	\$ 588			\$ 652	\$ 652

The Company's Level 1 financial assets are money market funds whose fair values are based on quoted market prices. The Company does not have any Level 2 financial assets or liabilities. The fair value of the earn-out liability arising from the acquisitions of RetinaLabs and OcuNetics is classified within Level 3 of the fair value hierarchy since it is based on significant unobservable inputs. The significant unobservable inputs include projected royalties and discount rates to present value the payments. A significant increase (decrease) in the projected royalty payments in isolation could result in a significantly higher (lower) fair value measurement and a significant increase (decrease) in the discount rate in isolation could result in a significantly lower (higher) fair value measurement. The fair value of the earn-out liability is calculated on a quarterly basis by the Company based on a collaborative effort of the Company's operations, finance and accounting groups based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the statement of operations of that period.

The following table presents quantitative information about the inputs and valuation methodologies used for our fair value measurements classified in Level 3 of the fair value hierarchy as of March 30, 2013.

As of March 30, 2013	Fair Value (in thousands)	Valuation Technique	Significant	Weighted
			Unobservable	Average
			Input	(range)
Earn-out liability	\$588	Discounted cash flow	Projected royalties	\$1,662
			(in thousands)	(414 - 1,934)
			Discount rate	21.99%

(20.91% - 27.00%)

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

	Three Months Ended	
	March 30, 2013	March 31, 2012
Balance at the beginning of the period	\$ 652	\$ 765
Payments against earn-out	(83)	(86)
Change in fair value of earn-out liability	19	29
Balance at the end of the period	\$ 588	\$ 708

The earn-out liability is included in accrued expenses and other long-term liabilities in the condensed consolidated balance sheets.

6. Stock Based Compensation*2008 Equity Incentive Plan*

For the three months ended March 30, 2013, the only active share-based compensation plan was the 2008 Equity Incentive Plan (the Incentive Plan). The terms of awards granted during the three months ended March 30, 2013 were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 29, 2012.

Summary of Stock Options

The following table summarizes information regarding activity in our stock option plan during the three months ended March 30, 2013:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (thousands)
Outstanding at December 29, 2012	1,570,543	\$ 3.64	
Granted	32,400	\$ 4.74	
Exercised	(114,956)	\$ 2.38	
Canceled or forfeited	(45,503)	\$ 4.06	
Outstanding at March 30, 2013	1,442,484	\$ 3.76	\$ 1,513

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of March 29, 2013, that would have been received by option holders had all option holders exercised their stock options as of that date.

The weighted-average grant date fair value of the options granted under the Company's stock plans as calculated using the Black-Scholes option-pricing model was \$3.05 and \$2.88 per share for the three months ended March 30, 2013 and March 31, 2012, respectively.

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

	Three Months Ended	
	March 30, 2013	March 31, 2012
Average risk free interest rate	0.59%	0.92%
Expected life (in years)	4.5 years	4.55 years
Dividend yield	0.0%	0.0%
Average volatility	86%	93%

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 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 months ended March 30, 2013 and March 31, 2012 (in thousands):

	Three Months Ended	
	March 30, 2013	March 31, 2012
Cost of revenues	\$ 22	\$ 18
Research and development	20	19
Sales and marketing	22	29
General and administrative	97	81
	\$ 161	\$ 147

Approximately \$11 thousand and \$9 thousand of the stock-based compensation expense recognized was capitalized into inventory as a component of overhead at March 30, 2013 and March 31, 2012, respectively.

Information regarding stock options outstanding, exercisable and expected to vest at March 30, 2013 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
Options outstanding	1,442,484	\$ 3.76	3.38	\$ 1,513
Options vested and expected to vest	1,374,031	\$ 3.75	3.23	\$ 1,475
Options exercisable	1,023,008	\$ 3.70	2.24	\$ 1,271

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of March 29, 2013, that would have been received by option holders had all option holders exercised their stock options as of that date. This amount changes based on the fair market value of the Company's stock. The total intrinsic value of options exercised for the three months ended March 30, 2013 and March 31, 2012 were approximately \$259 thousand and \$127 thousand, respectively.

As of March 30, 2013, there was \$1.3 million of total unrecognized compensation cost, net of expected 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 3.23 years.

Summary of Restricted Stock Units and Awards

Information regarding the restricted stock units activity for the three months ended March 30, 2013 is summarized below:

	Number of Shares
Outstanding at December 29, 2012	55,999

Edgar Filing: IRIDEX CORP - Form 10-Q

Restricted stock units granted	220,000
Restricted stock units released	0
Restricted stock units forfeited	0
Outstanding at March 30, 2013	275,999

The weighted grant date fair value for restricted stock units awarded during the period was \$258 thousand. The stock price on the date of grant was \$4.45 per share.

On March 25, 2013, the Company granted a restricted stock unit award for up to 220,000 shares of the Company's common stock (the Market Performance Award) under the terms of the Company's 2008 Equity Incentive Plan, as amended, to the Company's President and Chief Executive Officer. The number of shares issuable pursuant to the Market Performance Award will be based upon the Company's average stock price performance during the two months prior to and two months following the date the service condition is met, or the fair market value of the Company's common stock in the event vesting is triggered by a change of control of the Company. The Market Performance Award is expected to vest on December 31, 2014, as we do not anticipate the other vesting triggers to occur prior to that date. To the extent that the market condition is not met, the Market Performance Award will not vest and will be cancelled. Since the market conditions will affect the vesting of the Market Performance Award, the Company cannot use the Black-Scholes option-pricing model to value the award; instead, a binomial model must be used. The Company utilized the Monte Carlo simulation technique, which incorporated assumptions for the expected holding period, risk-free interest rate, stock price volatility and dividend yield. Compensation expense is recognized ratably until such time as the market condition is satisfied.

There were no restricted stock awards granted, vested, released and or forfeited for the three months ended March 30, 2013.

Table of Contents*Stock Repurchase Program*

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. In February 2012, the Company approved an extension of its stock repurchase program authorizing the Company to purchase up to \$4.0 million worth of our common stock, from time to time prior to March 2013. In February 2013, the Board of Directors approved a new one year \$3.0 million stock repurchase program that replaced the prior two year \$4.0 million stock repurchase program. For the three months ended March 30, 2013, the Company has purchased 9,921 shares at an average price of \$4.60 per share. As of March 30, 2013, the Company still has the authorization to purchase up to \$2.9 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.

7. Income Taxes*Provision for Income Tax*

Under ASC topic 740-270, *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 \$5 thousand for the three months ended March 30, 2013 and \$2 thousand for the three months ended March 31, 2012. Our income tax provision is benefiting from a reduction in the valuation allowance that fully offsets the Company's deferred tax asset.

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 December 29, 2012, the Company had a deferred tax asset of approximately \$10.1 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.

The American Taxpayer Relief Act of 2012 was enacted on January 2, 2012. The Act reinstated the research and development credit retroactively to January 1, 2012 and extended it through 2013.

Uncertain Tax Positions

The Company accounts for its uncertain tax positions in accordance with ASC 740. As of December 29, 2012, the Company had \$0.9 million of unrecognized tax benefits which would impact the income statement if recognized.

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. The tax years 2007 to 2012 remain open in several jurisdictions, none of which have individual significance.

8. Computation of Basic and Diluted Net Income (Loss) Per Common Share

Basic net income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of shares outstanding during the period.

Diluted net income (loss) per share is computed as follows:

In periods of net income from continuing operations, 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, at March 30, 2013, stock options to purchase 755,013 shares were excluded from the

Edgar Filing: IRIDEX CORP - Form 10-Q

computation of diluted weighted average shares outstanding.

In periods of net loss from continuing operations, the basic and diluted weighted average shares of common stock and common stock equivalents are the same because inclusion of common stock equivalents would be anti-dilutive. Accordingly, for the three months ended March 31, 2012 there was no difference between the denominators used for the calculation of basic and diluted net loss per share. For the three months ended March 31, 2012, there were 1,000,000 common stock equivalent relating to the Company's preferred shares, stock options to purchase 1,670,524 shares, restricted stock units of 90,189 shares, and restricted stock awards of 10,126 shares that were excluded from the computation of diluted weighted average shares outstanding.

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

	Three Months Ended	
	March 30, 2013	March 31, 2012
Numerator:		
Income (loss) from continuing operations	\$ 874	\$ (265)
Income from discontinued operations	0	1,870
Net income	\$ 874	\$ 1,605
Denominator:		
Weighted average shares of common stock (basic)	8,511	8,933
Effect of dilutive preferred shares	1,000	0
Effect of dilutive stock options	261	0
Effect of dilutive contingent shares	30	0
Weighted average shares of common stock (diluted)	9,802	8,933
Per share data:		
Basic income (loss) per share:		
Income (loss) before discontinued operations	\$ 0.10	\$ (0.03)
Discontinued operations	0.00	0.21
Net income	\$ 0.10	\$ 0.18
Diluted income (loss) per share:		
Income (loss) before discontinued operations	\$ 0.09	\$ (0.03)
Discontinued operations	0.00	0.21
Net income	\$ 0.09	\$ 0.18

Table of Contents**9. Business Segments**

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

Revenue information shown by geographic region, based on the location at which each sale originates, is as follows (in thousands):

(in thousands)	Three Months Ended	
	March 30, 2013	March 31, 2012
United States	\$ 4,209	\$ 4,222
Europe	1,973	1,845
Rest of Americas	850	702
Asia/Pacific Rim	1,907	1,536
	\$ 8,939	\$ 8,305

Revenues are attributed to countries based on location of end customers. No individual country accounted for more than 10% of the Company's sales, except for the United States, which accounted for 47.1% and 50.8% of sales for the three months ended March 30, 2013 and March 31, 2012, respectively.

No one customer accounted for more than 10% of total revenue for the three months ended March 30, 2013 and March 31, 2012, respectively.

10. Subsequent Events

The Company has evaluated subsequent events and has concluded that no additional subsequent events that require disclosure in the financial statements have occurred since the quarter ended March 30, 2013.

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, long term growth, market acceptance and adoption of our products and operating results; license revenue; gross margins; managing cash flows; general economic conditions and levels of international sales; corporate strategy; effects of seasonality; FDA inspections; 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 28, 2013 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 sight-threatening eye diseases in ophthalmology. Our ophthalmology products are sold in the United States predominantly through a direct sales force and internationally through approximately 70 independent distributors into over 100 countries.

Edgar Filing: IRIDEX CORP - Form 10-Q

We manage and evaluate our business in one segment ophthalmology. We break down this segment by geography Domestic (U.S.) and International (the rest of the world). In addition, 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 service and support activities. Our current family of IQ products includes IQ 532, IQ 577 and IQ 810 laser photocoagulation systems and our OcuLight products include OcuLight TX, OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Certain of our laser systems are capable of performing traditional continuous wavelength photocoagulation and our patented Fovea-Friendly MicroPulse laser photocoagulation. Towards the end of 2012, we introduced the TxCell Scanning Laser Delivery System which saves significant time in a variety of laser photocoagulation procedures in allowing physicians to deliver the laser in a multi-spot scanning mode, a more efficient method for these procedures than the traditional single spot mode. Our current family of laser probes includes a wide variety of products in 20, 23 and 25 gauge for vitreoretinal surgery and glaucoma surgery.

Table of Contents

In March 2013, the Company entered into a global distribution and supply agreement with Peregrine Surgical Ltd. (Peregrine) which was completed on April 1, 2013. Under the agreement, IRIDEX will become a worldwide distributor for Peregrine labeled products and Peregrine will become part of the IRIDEX supply chain.

Sales to international distributors are made on open credit terms or letters of credit and are currently denominated in U.S. dollars and accordingly, are not subject to risks associated with currency fluctuations.

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; warranty, royalty and amortization of intangible assets; and depot service costs.

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

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

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

Results of Operations

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

	Three Months Ended	
	March 30, 2013	March 31, 2012
Revenues	100.0%	100.0%
Cost of revenues	52.7%	52.0%
Gross margin	47.3%	48.0%
Operating expenses:		
Research and development	11.1%	14.2%
Sales and marketing	18.2%	22.4%
General and administrative	13.3%	14.2%
Proceeds from demutualization of insurance carrier	(5.3)%	0.0%
Total operating expenses	37.3%	50.8%
Income (loss) from continuing operations	10.0%	(2.8)%
Other expense, net	(0.2)%	(0.3)%
Income (loss) from continuing operations before income taxes	9.8%	(3.1)%
Provision for income taxes	0.1%	0.1%
Income (loss) from continuing operations, net of tax	9.7%	(3.2)%
Income from discontinued operations, net of tax	0.0%	22.5%
Net income	9.7%	19.3%

The following comparisons are between the three month periods ended March 30, 2013 and March 31, 2012:

Revenues.

Edgar Filing: IRIDEX CORP - Form 10-Q

(in millions)	Three Months Ended March 30, 2013	Three Months Ended March 31, 2012	Change in \$	Change in %
Systems domestic	\$ 1.4	\$ 1.3	\$ 0.1	11.0%
Systems international	2.9	2.6	0.3	11.8%
Recurring revenues	4.5	4.4	0.1	3.8%
OEM	0.1	0.0	0.1	0.0%
Total revenues	\$ 8.9	\$ 8.3	\$ 0.6	7.6%

Both domestic and international system sales increased continuing the trend in orders we saw at the end of the prior year and driven by increasing adoption of our MicroPulse enabled laser systems and the successful introduction of our new high speed delivery device, TxCell. Recurring revenues improved due to the continued success of our licensing and distribution agreement with Alcon. Competition for consumable products remains strong with increased price sensitivities amongst our customers. We believe the distribution and supply agreement we entered into with Peregrine will help address this issue by providing us with more consumable products to allow us to differentiate our offering and over time reduce the cost of certain existing consumable products; and therefore provide us more pricing strategies.

Gross Profit and Gross Margin.

Gross profit was \$4.2 million compared to \$4.0 million in the prior period, an increase of \$0.2 million or 6.1%. The increase in gross profit was driven from increased revenues, although the impact was mitigated by a reduction in the gross margin. Gross margin decreased in the current quarter to 47.3% of revenues from 48.0% in the quarter ended March 31, 2012. Manufacturing and service spending remained constant across both time periods. The reduction was due to a shift in product mix to more system sales, particularly internationally through our distributor channel where we obtain a lower average selling price, and also due to the introduction of TxCell. Historically, our newer products have a higher cost component at introduction and as the product matures we take steps to reduce costs and these steps are underway. Our short term goal for gross margin remains at 50%.

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.*

Table of Contents

Research and Development.

Research and development (R&D) expenses decreased \$0.2 million or 15.7% from \$1.2 million to \$1.0 million as a result of reduced headcount and associated expenses.

Sales and Marketing.

Sales and marketing expenses decreased by 12.8% from \$1.9 million to \$1.6 million. The decrease is attributable to a decrease in headcount and related costs and to a reduced focus on traditional selling and marketing expenditures, such as trade shows, to an increased focus on online and social media-based marketing and selling programs.

General and Administrative.

General and administrative expenses remained constant at \$1.2 million, despite the inclusion of additional costs of approximately \$0.1 million associated with the medical device tax.

Proceeds from demutualization of insurance carrier.

During the period we received \$0.5 million as a result of the demutualization and acquisition of our product and liability insurance carrier.

Interest and Other Expense, Net.

Interest and other expense, net consisted primarily of additional expense recorded for the fair value remeasurement of the contingent earn-out liabilities incurred as a result of the Company's recent acquisitions.

Income Taxes.

The Company recorded an income tax provision of \$5 thousand and \$2 thousand for continuing operations for the quarter ended March 30, 2013 and March 31, 2012, respectively. Our income tax provision is benefiting from a reduction in the valuation allowance that fully offsets the Company's deferred tax asset.

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 March 30, 2013, we had cash and cash equivalents of \$11.6 million, working capital of \$21.9 million and \$0.5 million of cash held in escrow compared to cash and cash equivalents of \$11.9 million, working capital of \$20.7 million and \$0.5 million of cash held in escrow as of December 29, 2012. For the quarter ended March 30, 2013, \$0.4 million was used in operating activities which resulted from net income of \$0.9 million and the add back of \$0.3 million non-cash items which were more than offset by the changes in operating assets and liabilities of \$1.6 million. We used \$0.1 million of net cash in investing activities, primarily in paying down the earn-out liability associated with prior acquisition. \$0.2 million was generated by financing activities, which represented the net effect of stock options exercised by employees, offset by shares repurchased by the Company.

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 US 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 US 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. As we continue to expand our international sales, our non-US dollar denominated revenue and our exposure to gains and losses on international currency transactions may increase. 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.

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 March 30, 2013. 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.

Table of Contents

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We believe there is no litigation currently pending that could have, individually or in the aggregate, a material adverse effect on our operations or financial condition.

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 28, 2013.*

In February 2012, We Sold our Aesthetics Business Unit and Our Operating Results Will Be Adversely Affected in the Near Term as a Result of this Sale.

In February 2012, we completed the sale of our aesthetics business. Prior to the sale, our aesthetics business covered its direct costs and therefore contributed to the profitability of the overall Company. In addition, we provided the purchaser typical indemnification provisions associated with this type of transaction, and there is a risk that an adverse event may occur that requires us to fulfill our indemnity obligation. In the near term, these factors will have a material adverse effect on our business, financial condition and results of operations.

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 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;

Edgar Filing: IRIDEX CORP - Form 10-Q

our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;

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

our ability to address our liquidity issues should the need occur;

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.

Table of Contents

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

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such 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.

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. In addition, the trading price of our common stock has been significantly adversely affected by our recent operating performance. For the first quarter of fiscal 2013, the trading price of our common stock fluctuated from a low of \$3.76 per share to a high of \$4.95 per share. There can be no assurance that our common stock trading price will not suffer declines. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes and therefore broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

We Rely on Continued Market Acceptance of Our Existing Products and Any Decline in Sales of Our Existing Products Would Adversely Affect Our Business and Results of Operations.

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

acceptance of product performance, features, ease of use, scalability and durability;

recommendations and opinions by ophthalmologists, 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 where healthcare systems and healthcare operators are becoming increasingly price sensitive;

availability of competing products, technologies and alternative treatments; and

level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation including our 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.

Edgar Filing: IRIDEX CORP - Form 10-Q

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 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., Quantel Medical SA, and Lumenis Ltd. Most of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Also within ophthalmology, pharmaceutical alternative treatments for AMD and DME such as Lucentis/Avastin (Genentech), Eylea (Regeneron), and to a lesser extent Visudyne (Novartis), Macugen (OSI Pharmaceuticals) and Ozurdex (Allergan) compete rigorously with traditional laser procedures. A number of these competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do, including greater name recognition, and benefit from long-standing customer relationships. 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.

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

The recent decision to uphold the Patient Protection and Affordable Care Act means that we will be required to pay a 2.3% tax on our products sold in the US. If we are not able to pass this tax onto our customers, our profits will be significantly reduced or losses significantly enlarged.

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.

Table of Contents

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 Depend on International Sales for a Significant Portion of Our Operating Results.

We derive, and expect to continue to derive, a large portion of our revenues from international sales. For the first quarter of fiscal 2013, our international ophthalmology sales were \$4.7 million or 52.9% of total revenue. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. For our continuing ophthalmology business, none of our international revenues and costs has been denominated in foreign currencies. 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. Our international operations and sales are subject to a number of risks and potential costs, including:

impact of recessions in global economies and availability of credit;

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

fluctuations in foreign currency exchange rates;

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

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;

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.

As we expand our existing international operations we may encounter new risks. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenues and profitability.

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 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.

Table of Contents

We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications.

We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and innovation and clinical testing of our products. Commercially, we currently have a distribution and licensing agreement with Alcon for our GreenTip SoftTip Cannula. Sales of and royalties from the GreenTip Soft Tip cannula are dependent upon the sales performance of Alcon, which depends on their efforts which is beyond our control. Historically, we have collaborated with Bausch & Lomb to design and manufacture a solid-state green wavelength (532nm) laser photocoagulator module for Bausch & Lomb, called the Millennium Endolase module. Bausch & Lomb has introduced a new product to replace the product that included the Millennium Endolase module and as such we have seen sales to Bausch & Lomb decline and we anticipate that sales will continue to decline. The failure to obtain any additional future clinical or commercial collaborations and the resulting failure or success of such arrangements of any current or future clinical or commercial 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.

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. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. 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.

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

difficulties integrating any acquired products into our existing business;

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

Edgar Filing: IRIDEX CORP - Form 10-Q

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.

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.

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.

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.

Table of Contents

** We Rely on Our U.S. Direct and Independent Sales Forces 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 and independent sales forces within the United States and relationships with independent distributors outside the United States. Currently our direct and independent sales forces within the United States consists of 11 employees and approximately 10 independent representatives, respectively. We maintain relationships with approximately 70 independent distributors internationally selling our products into over 100 countries, managed by a team of 5 people. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches the terms of its distribution agreement with us or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may harm our revenues and our ability to maintain market share. Similarly, our independent and distributor agreements are generally terminable at will by either party and independents and distributors may terminate their relationships with us, which would affect our sales and results of operations.

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 26 United States patents and 17 foreign patents on the technologies related to our products and processes. We have nine pending patent applications in the United States and seven foreign pending patent applications that have been filed. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

Patents have a limited lifetime and once a patent expires competition may increase. 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. 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.

Edgar Filing: IRIDEX CORP - Form 10-Q

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.

Table of Contents

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 whose operations may be disrupted or discontinued at any time. There are risks associated with the use of independent manufacturers, including the following:

unavailability of shortages or limitations on the ability to obtain supplies of components 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 .

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.

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 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 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.

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 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. 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 as those described in the 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.

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 may 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.

Edgar Filing: IRIDEX CORP - Form 10-Q

Some of Our Laser Systems Are Complex in Design and May Contain Defects That Are Not Detected Until Deployed By Our Customers, Which Could Increase Our Costs and Reduce Our Revenues.

Laser systems are inherently complex in design and require 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;

Table of Contents

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. 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	Average Price
		Paid Per Share
	(1)	(2)
December 30, 2012 – February 2, 2013	0	\$ 0.00
February 3, 2013 – March 2, 2013	0	\$ 0.00
March 3, 2013 – March 30, 2013	9,921	\$ 4.60
Total	9,921	\$ 4.60

- (1) On February 28, 2013, the Board of Directors announced a \$3.0 million stock repurchase program expiring in February 2014. The above table reflects the repurchase of shares of our common stock in the open market or privately negotiated transactions in accordance with the share repurchase program. Each repurchase was financed by available cash balances and cash from operations.

Edgar Filing: IRIDEX CORP - Form 10-Q

(2) Average price paid per share of common stock repurchased represents the execution price, including commissions paid to brokers.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits

Exhibit

No.	Exhibit Title
10.1	Restricted Stock Unit Award Agreement granted to William M. Moore under the Company's 2008 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-k filed on March 27, 2013.)
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.DEF	XBRL Taxonomy Extension Definition 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.

Table of Contents

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, and EndoProbe, are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, DioLite, IQ 810, IQ 577, IQ 532, MicroPulse, TxCell, OtoProbe, Symphony, VariLite, ScanLite, 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: May 6, 2013

By: /s/ WILLIAM M. MOORE
Name: William M. Moore
Title: President and Chief Executive Officer

(Principal Executive Officer)

Table of Contents**Exhibit Index**

Exhibit	
No.	Exhibit Title
10.1	Restricted Stock Unit Award Agreement granted to William M. Moore under the Company's 2008 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-k filed on March 27, 2013.)
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.DEF	XBRL Taxonomy Extension Definition 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.