IRIDEX CORP
Form 10-Q
May 15, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended April 4, 2009

Or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**77-0210467**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1212 Terra Bella Avenue	
Mountain View, California	**94043-1824**

(Address of principal executive offices) **(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 þ 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 þ

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

The number of shares of common stock, $.01 par value, issued and outstanding as of May 12, 2009 was 8,844,301.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

IRIDEX Corporation

Condensed Consolidated Balance Sheets

(Unaudited, in thousands)

	April 4, 2009	January 3, 2009 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 5,662	$ 5,307
Accounts receivable, net	7,809	8,199
Inventories, net	11,164	11,644
Prepaids and other current assets	516	540
Total current assets	25,151	25,690
Property and equipment, net	710	832
Other intangible assets, net	1,394	1,474
Other long term assets	310	229
Total assets	$ 27,565	$ 28,225
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,951	$ 2,415
Bank line of credit	5,477	6,000
Accrued compensation	1,823	1,729
Accrued expenses	2,151	2,249
Accrued warranty	1,294	1,345
Deferred revenue	2,733	2,741
Total current liabilities	15,429	16,479
Stockholders equity:		
Convertible preferred stock	5	5
Common stock	89	89
Additional paid-in capital	39,244	39,105
Accumulated other comprehensive loss	(165)	(192)
Treasury stock, at cost	(430)	(430)
Accumulated deficit	(26,607)	(26,831)
Total stockholders equity	12,136	11,746
Total liabilities and stockholders equity	$ 27,565	$ 28,225

(1) Derived from the consolidated audited financial statements included in our report filed on Form 10-K with the SEC for the year ended January 3, 2009.

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

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IRIDEX Corporation

Condensed Consolidated Statements of Operations

(Unaudited, in thousands except per share data)

	Three Months Ended	
	April 4, 2009	March 29, 2008
Revenues	$ 10,736	$ 11,474
Cost of revenues	5,688	6,669
Gross profit	5,048	4,805
Operating expenses:		
Research and development	841	1,025
Sales and marketing	2,351	2,613
General and administrative	1,493	1,905
Total operating expenses	4,685	5,543
Income (loss) from operations	363	(738)
Interest and other expense, net	(139)	(154)
Income (loss) before income taxes	224	(892)
Provision for income taxes		
Net income (loss)	$ 224	$ (892)
Net income (loss) per share - basic and diluted	$ 0.03	$ (0.10)
Shares used in computing net income (loss) per share - basic and diluted	8,825	8,824

Condensed Consolidated Statements of Comprehensive Income (Loss)

(Unaudited, in thousands)

	Three Months Ended	
	April 4, 2009	March 29, 2008
Net income (loss)	$ 224	$ (892)
Foreign currency translation adjustments	27	(40)
Comprehensive income (loss)	$ 251	$ (932)

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

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IRIDEX Corporation

Condensed Consolidated Statements of Cash Flows

(Unaudited, in thousands)

	Three Months Ended	
	April 4, 2009	March 29, 2008
Operating activities:		
Net income (loss)	$ 224	$ (892)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	234	823
Stock compensation recognized	139	32
Provision for doubtful accounts	102	29
Provision for inventory reserves	120	(45)
Changes in operating assets and liabilities:		
Accounts receivable	288	408
Inventories	360	(2)
Prepaids and other current assets	24	(45)
Other long term assets	(81)	65
Accounts payable	(464)	1,517
Accrued compensation	94	(457)
Accrued expenses	(98)	(1,804)
Accrued warranty	(51)	(395)
Deferred revenue	(8)	(96)
Net cash provided by (used in) operating activities	883	(862)
Investing activities:		
Purchases of property and equipment	(32)	(96)
Net cash used in investing activities	(32)	(96)
Financing activities:		
Proceeds of credit facility, net of issuance costs		5,281
Repayment of credit facility		(9,879)
Release of restriction of funds under debt facility		3,800
Proceeds from borrowings	10,871	
Repayment of borrowings	(11,394)	
Net cash used in financing activities	(523)	(798)
Effect of foreign exchange rate changes	27	(40)
Net increase (decrease) in cash and cash equivalents	355	(1,796)
Cash and cash equivalents at beginning of period	5,307	5,809
Cash and cash equivalents at end of period	$ 5,662	$ 4,013

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

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IRIDEX Corporation

Notes to Unaudited Consolidated Financial Statements

1. Basis of Presentation

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

The condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto, together with management s discussion and analysis of financial condition and results of operations, contained in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on April 1, 2009. The results of operations for the three month period ended April 4, 2009 are not necessarily indicative of the results for the year ending January 2, 2010 or any future interim period.

The Company has generated cash from operations for the last two quarters; however, prior to that, the Company incurred substantial losses and had negative cash flows from operations for the preceding three fiscal years. The Company has historically required, and continues to require, debt to fund its operations. Management believes that the Company s current cash and cash equivalents and its credit facility with Wells Fargo Bank provides sufficient liquidity to operate for the next 12 months and that the covenants contained in the Wells Fargo Bank credit facility are reasonable and management expects to be able to meet those covenants based on its operating plan for 2009. If the Company is not able to perform in accordance with its operating plan for 2009 and fails to maintain compliance with its debt covenants, Wells Fargo Bank would be entitled to exercise its remedies under this credit facility which include declaring all outstanding obligations due and payable, and disposing of the collateral if obligations are not paid.

Recent Accounting Pronouncements

In May 2008, the FASB issued SFAS 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS 162). SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with GAAP for nongovernmental entities. SFAS 162 is effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles. The Company does not expect the adoption of SFAS 162 will have a material impact on the Company s consolidated financial statements.

Recently Adopted Accounting Standards

In April 2008, FASB Staff Position SFAS 142-3, Determination of the Useful Life of Intangible Assets, (FSP 142-3) was issued. FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, Goodwill and Other Intangible Assets, (SFAS 142). FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The guidance for determining the useful life of a recognized intangible asset in paragraphs 7 11 of this FSP shall be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements in paragraphs 13 15 shall be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. In January 2009, the Company adopted FSP 142-3. The adoption of FSP 142-3 did not have a material impact on its consolidated financial statements.

2. Summary of Significant Accounting Policies

The Company s significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended January 3, 2009, which was filed with the Securities and Exchange Commission on April 1, 2009.

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Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumable laser probes (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. Our Company s sales may include post-sales obligations for support activities. When these obligations are fulfilled after product shipment, the Company recognizes revenue in accordance with the multiple element accounting guidance set forth in Emerging Issues Task Force No. 00-21, Revenue Arrangements with Multiple Deliverables. When the Company has objective and reliable evidence of fair value of the undelivered elements, it defers revenue attributable to the post-sale obligations and recognizes such revenue when the obligation is fulfilled. Otherwise, the Company defers all revenue related to the transaction until all elements are delivered. Revenue relating to extended support contracts is recognized on a straight line basis over the period of the applicable support contract. We recognize repair service revenue upon completion of the work.

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

Deferred Revenue

Revenue related to extended service contracts is deferred and recognized on a straight line basis over the period of the applicable service period. Costs associated with these service arrangements are recognized as incurred. The reduction in the deferred revenue balance is attributable to the fact that revenue being recognized from existing contracts exceeds the revenue being deferred from new or renewed contracts due to the decline in the aesthetics business. A reconciliation of the changes in the Company s deferred revenue balance for the three months ended April 4, 2009 and January 3, 2009 is as follows:

	Three Months Ended	
(in thousands)	**April 4, 2009**	**January 3, 2009**
Balance, beginning of period	$ 2,741	$ 2,805
Additions to deferral	1,593	1,669
Revenue recognized	(1,601)	(1,733)
Balance, end of period	$ 2,733	$ 2,741

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 a cost of sales. A reconciliation of the changes in the Company s warranty liability for the three months ended April 4, 2009 and January 3, 2009 is as follows:

	Three Months Ended	
(in thousands)	**April 4, 2009**	**January 3, 2009**
Balance, beginning of period	$ 1,345	$ 1,258
Accrual for warranties issued during the period	268	190
Settlements made in kind during the period	(319)	(103)
Balance, end of period	$ 1,294	$ 1,345

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Valuation of Goodwill and Intangible Assets.

The purchase method of accounting for acquisitions requires estimates and assumptions to allocate the purchase price to the fair value of net tangible and intangible assets acquired. The amounts allocated to, and the useful lives estimated for, intangible assets, affect future amortization. There are a number of generally accepted valuation methods used to estimate fair value of intangible assets, and we use primarily a discounted cash flow method, which requires significant management judgment to forecast the future operating results and to estimate the discount factors used in the analysis. Purchased intangible assets were initially recorded in the first quarter of 2007 in conjunction with the acquisition of the aesthetics business of Laserscope. An asset is considered impaired if its carrying amount exceeds the future net cash flow the asset is expected to generate. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value.

Future changes in events or circumstances, such as an inability to achieve the cash flows determined above, may indicate that the recorded value of the intangible assets will not be recovered through future cash flows, or if the fair value of the Laserscope Aesthetics business unit is determined to be less than its carrying value, the Company may be required to record an additional impairment charge for the intangible assets or further modify the period of expected lives for the intangible assets.

3. Inventories, net

The components of the Company s inventories as of April 4, 2009 and January 3, 2009 are as follows:

(in thousands)	April 4, 2009	January 3, 2009
Raw materials and work in process	$ 8,014	$ 7,753
Finished goods	3,150	3,891
Total inventories	$ 11,164	$ 11,644

4. Fair Value Measurement

On December 30, 2007, the Company adopted Statement of Financial Accounting Standards (SFAS) 157, Fair Value Measurements (SFAS 157) which defines fair value, establishes a framework for using fair value to measure assets and liabilities, and expands disclosures about fair value measurements. SFAS 157 applies whenever other statements require or permit assets or liabilities to be measured at fair value. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years, with early adoption of SFAS 157 permitted, except for the impact of FASB Staff Position (FSP) 157-2. FSP 157-2 deferred the adoption of SFAS 157 for nonfinancial assets and liabilities until fiscal years beginning after November 15, 2008.

SFAS 157 includes a fair value hierarchy that is intended to increase the consistency and comparability in fair value measurements and related disclosures. The fair value hierarchy is based on inputs to valuation techniques that are used to measure fair value that are either observable or unobservable. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources while unobservable inputs reflect a reporting entity s pricing an asset or liability based upon their own market assumptions. The fair value hierarchy consists of the following three levels:

Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets.

Level 2 instrument valuations are obtained from readily-available pricing sources for comparable instruments.

Level 3 instrument valuations are obtained without observable market values and require a high-level of judgment to determine the fair value.

At April 4, 2009, the Company had $5.7 million in cash and cash equivalents. Of this amount, approximately $2.0 million were in money market funds whose fair market value was obtained from real-time quotes for transactions in active markets involving identical assets. At April 4, 2009, the Company had $5.5 million outstanding against the bank line of credit. The book value of this bank line of credit approximates fair value due

to its floating rate nature. The Company did not have any Level 2 or Level 3 assets or liabilities at April 4, 2009.

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5. Bank Borrowings

The Company has a borrowing agreement with Wells Fargo Bank that provides for an asset-based revolving line of credit of up to $8.0 million secured by a lien on substantially all of the Company s assets. Interest is set at the greater of 5% or prime as published in the Wall Street Journal, plus 2% on Floating Rate Advances and 3.5% on LIBOR Advances.

As of April 4, 2009, the Company was in compliance with the loan covenants in the Agreement and the total amount outstanding under the revolving line of credit was $5.5 million.

6. Stock Based Compensation

For the three months ended April 4, 2009, the Company had one active stock plan. The 1998 Stock Plan expired in February 2008. On June 11, 2008, the shareholders approved the adoption of the 2008 Equity Incentive Plan, (the Incentive Plan). There were no material changes in the Incentive Plan from the 1998 Stock Plan. The maximum aggregate number of shares that may be awarded and sold under the Incentive Plan is 300,000 shares plus any shares subject to stock options or similar awards granted under the 1998 Stock Plan that expire or otherwise terminate without having been exercised in full and shares issued pursuant to awards granted under the 1998 Stock Plan that are forfeited to the Company on or after the date the 1998 Stock Plan expires.

The following table summarizes information regarding activity in our stock option plan during the three months ended April 4, 2009:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 3, 2009	2,051,815	$ 4.81	$
Granted	15,500	0.86	
Exercised			
Canceled or forfeited	(55,494)	4.73	
Outstanding at April 4, 2009	2,011,821	$ 4.79	$ 76,305

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company s closing price as of April 4, 2009, that would have been received by option holders had all options holders exercised their stock options as of that date. There were no options exercised during the three months ended April 4, 2009.

The weighted-average grant fair value of the options granted under the Company s stock plans was $0.58 and $1.96 per share for the three months ended April 4, 2009 and March 29, 2008, respectively.

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

	Three Months Ended	
	April 4, 2009	March 29, 2008
Average risk free interest rate	1.68%	3.25%
Expected life (in years)	4.75 years	6 years
Dividend yield	0.0%	0.0%
Average volatility	87.0%	70.0%

Option-pricing models require the input of various subjective assumptions, including the option s expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of the Company s stock price history over a period commensurate with the expected term of the options, trading volume of the Company s stock, look-back volatilities and Company specific events that affected volatility in a prior period. The Company has elected to use the simplified method for estimating the expected term as discussed in Staff

Accounting Bulletin No. 107 and Staff Accounting Bulletin No. 110. 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.

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The following table shows stock-based compensation expense included in the Condensed Consolidated Statements of Operations for the three months periods ended April 4, 2009 and March 29, 2008 (in thousands):

	Three Months Ended	
	April 4, 2009	March 29, 2008
Cost of revenues	$ 37	$ 23
Research and development	22	30
Sales and marketing	30	(24)
General and administrative	50	3
	$ 139	$ 32

Approximately $9 thousand and $5 thousand of the stock based compensation expense recognized was capitalized into inventory as a component of overhead at April 4, 2009 and March 29, 2008, respectively.

7. Income Taxes

Provision for Income Tax

Under Accounting Principles Board Opinion No. 28, Interim Financial Reporting, 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 $0 income tax provision for both the three months ended April 4, 2009 and March 29, 2008. The Company s effective tax rate was 0% for both the three months ended April 4, 2009 and March 29, 2008. The zero effective tax rate for the three months ended April 4, 2009 was associated primarily with the un-benefitted loss incurred in the U.S. operations.

Deferred Income Taxes

The Company accounts for income taxes in accordance with SFAS 109, Accounting for Income Taxes (SFAS 109), 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. SFAS 109 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. A valuation allowance is provided for the majority of the Company s deferred tax assets, as the Company believes that it is more likely than not that those deferred tax assets will not be fully realized.

Uncertain Tax Positions

The company accounts for its uncertain tax positions in accordance with Financial Accounting Standards Interpretation number 48, or FIN 48. The balance of gross unrecognized tax benefits as of April 4, 2009 was $585 thousand. If all of our uncertain tax positions were sustained in our favor, the Company would not recognize an aggregate tax benefit due to our valuation allowance against our deferred tax assets.

At April 4, 2009, the Company has accrued $67 thousand for estimated interest and penalties related to uncertain tax positions.

The Company is currently unaware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation in this estimate during the fiscal year.

The Company s tax returns remain open to examination for tax years 2001 through 2007.

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

Net income (loss) per share is computed in accordance with SFAS 128, Earnings per Share. Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options and the conversion of Series A Preferred Stock into common stock and are calculated under the treasury stock method. Common stock equivalent shares from unexercised stock options and the conversion of Series A Preferred Stock are excluded from the computation for periods in which the Company incurs a loss as their effect is anti-dilutive or if the exercise price of such options is greater than the average market price of the stock for the period.

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Options to purchase 2,011,821 shares of common stock at a weighted average exercise price of $4.79 were outstanding as of April 4, 2009, but were not included in the computation of diluted net income per share because the options would be anti-dilutive under the treasury stock method. In addition, 1,000,000 shares of common shares issuable upon the conversion of 500,000 Series A Preferred Stock which automatically converts into common shares in the event the common stock of the Company trades at or above $5.00 per share for a period of 30 consecutive trading days, also were not included in the computation of diluted net income per common share because of their effect is anti-dilutive. These shares could dilute earnings per share in future periods.

Options to purchase 2,014,198 shares of common stock at a weighted average exercise price of $5.50 were outstanding as of March 29, 2008.

9. Business Segments

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

Information on reportable segments for the three month periods ended April 4, 2009 and March 29, 2008 is as follows:

	Three Months Ended April 4, 2009			Three Months Ended March 29, 2008		
(in thousands)	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Revenues	$ 7,544	$ 3,192	$ 10,736	$ 7,536	$ 3,938	$ 11,474
Direct cost of revenues	2,092	1,248	3,340	2,069	1,653	3,722
Direct gross profit	5,452	1,944	7,396	5,467	2,285	7,752
Total unallocated indirect costs			(7,172)			(8,644)
Pre-tax income (loss)			$ 224			$ (892)

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

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

	Three Months Ended April 4, 2009			Three Months Ended March 29, 2008		
(in thousands)	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Domestic	$ 4,321	$ 2,044	$ 6,365	$ 4,430	$ 1,488	$ 5,918
International	3,223	1,148	4,371	3,106	2,450	5,556
Total revenues	$ 7,544	$ 3,192	$ 10,736	$ 7,536	$ 3,938	$ 11,474

No one customer accounted for more than 10% of total revenue for the three months ended April 4, 2009 and March 29, 2008, respectively.

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

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

This Quarterly Report on Form 10-Q contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results; gross margins; managing cash flows; general economic conditions and levels of international sales, and our current and future liquidity and capital requirements; and levels of future investment in research and development efforts. In some cases, forward-looking statements can be identified by terminology, such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, intends, potential, continue, or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements, including as a result of the factors set forth under Factors That May Affect Future Operating Results and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2009 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, consumable laser probes and delivery devices used to treat eye diseases in ophthalmology and skin conditions in aesthetics.

Our products are sold in the United States (U.S.) predominantly through a direct sales force and internationally through approximately 100 independent distributors into 107 countries except for our aesthetics products which are sold, marketed and serviced directly in France.

We manage and evaluate our business in two segments ophthalmology and aesthetics. We further break down these segments by geography Domestic (U.S.) and International (the rest of the world). In addition, within ophthalmology, we review trends by laser system sales (consoles and delivery devices) and recurring sales (consumables, service and support).

Our ophthalmology revenues arise primarily from the sale of our IRIS Medical OcuLight and IQ 810 laser systems, consumables and revenues from service and support activities. Our current family of OcuLight systems includes the OcuLight TX, the OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems as well as the IRIS Medical IQ 810 laser system. We also produce the Millennium Endolase module which is sold exclusively to Bausch & Lomb and incorporated into their Millennium Microsurgical System.

Our aesthetics revenues arise primarily from the sales of our aesthetics systems including: the Gemini, Venus-*i*, Lyra-*i* and Aura-*i* Laser Systems, the VersaStat 10 mm, VersaStat- *i,* and Dermastat handpieces along with an articulated arm for the Venus- *i* Laser System, as well as our VariLite and DioLite XP laser systems.

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

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

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

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

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

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Results of Operations

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

	Three Months Ended	
	April 4, 2009	March 29, 2008
Revenues	100.0%	100.0%
Cost of revenues	53.0%	58.1%
Gross Margin	47.0%	41.9%
Operating expenses:		
Research and development	7.8%	8.9%
Sales and marketing	21.9%	22.8%
General and administrative	13.9%	16.6%
Total operating expenses	43.6%	48.3%
Income (loss) from operations	3.4%	(6.4)%
Interest and other expense, net	(1.3)%	(1.4)%
Income (loss) before income tax	2.1%	(7.8)%
Provision for income taxes	%	%
Net income (loss)	2.1%	(7.8)%

Revenues.

Total revenue decreased by 6.4% to $10.7 million for the three months ended April 4, 2009 from $11.5 million for the three months ended March 29, 2008. Ophthalmology revenues remained constant and the decrease is directly attributable to the reduction in aesthetics revenues. The decline in revenue was primarily due to the global economic environment which significantly affected demand for our aesthetic products during the first quarter ended April 4, 2009.

Ophthalmology revenues in total remained constant. Ophthalmology recurring revenues consisting of consumables and service increased $0.3 million, or 6.7%, from $4.1 million to $4.4 million. Domestic ophthalmology systems decreased $0.4 million, or 31.6%, from $1.2 million to $0.8 million. We believe the reduction was caused by customers delaying capital equipment expenditures in the quarter due to the uncertain economic circumstances. International ophthalmology systems increased $0.1 million, or 7.1%, from $1.8 million to $1.9 million. OEM revenues remained constant at $0.4 million. OEM revenues are generated from a long standing relationship and the demand for this product is dependent on the OEM s market demand.

Aesthetics revenues in total decreased $0.8 million or 18.9%, from $4.0 million to $3.2 million. Service revenues decreased $0.2 million or 11.2%, from $1.8 million to $1.6 million. International aesthetics system revenues decreased $1.1 million or 59.5%, from $1.9 million to $0.8 million and domestic aesthetics system revenues increased $0.6 million or 300.8%, from $0.2 million to $0.8 million. Aesthetics systems revenues fluctuate period to period due to the timing of individual deals because of the relatively high price and low volume of systems being sold. This effect is magnified for international sales where distributors often place multiple system orders at one time.

Gross profit and gross margin.

Gross profit for the quarter ended April 4, 2009 was $5.0 million compared with $4.8 million for the comparable quarter of the prior year, an increase of $0.2 million even though revenues decreased by $0.7 million. This was because gross margins improved to 47.0% of revenues for the quarter ended April 4, 2009 compared with 41.9% of revenues for the same quarter a year earlier.

We are no longer incurring amortization expenses related to intangible assets that were previously being charged to cost of revenues which positively impacted margins by 4.0%. Manufacturing and service expenses declined but due to a proportionally bigger reduction in revenues negatively impacted margins by 0.5%. Other manufacturing expenses including inventory reserve adjustments also declined, resulting in an improvement to margins of 0.4% and a reduction in direct costs as a percentage of revenues improved margins by 1.2%. Gross margins as a percentage of sales will continue to fluctuate due to changes in the relative proportions of domestic and international sales, the product mix of sales, costs associated with future product introductions and 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.*

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Research and development.

Research and development (R&D) expenses decreased by $0.2 million or 18%, to $0.8 million from $1.0 million for the quarter ended April 4, 2009 compared to the same period of the prior year. R&D expenses benefited from transferring $0.1 million of previously expensed project materials into inventory in connection with a project completion. In the future, with increasing profitability, we expect to target our research and development spending level to approximate 10% of our revenues to maintain a consistent level of new product introductions.

Sales and marketing.

Sales and marketing expenses decreased by $0.2 million or 10.0% to $2.4 million from $2.6 million for the quarter ended April 4, 2009 compared to the same period of the prior year. The decrease in sales and marketing spending is primarily attributable to decreases in amortization of intangible assets and lower commission expenses as a result of lowers sales.

General and administrative.

General and administrative expenses decreased by $0.4 million or 21.6%, to $1.5 million from $1.9 million for the quarter ended April 4, 2009 compared to the same period of the prior year. The decrease in general and administrative spending is primarily attributable to decreases in consulting and temporary help of $0.3 million and accounting and other public company expenses of $0.1.

Interest and other expense, net.

Interest and other expense consist primarily of $0.1 million of interest expense and $0.1 million in foreign exchange losses for the quarter ended April 4, 2009, compared with $0.3 million of interest expense and $0.1 million in foreign exchange gains for the quarter ended March 29, 2008. The interest expense relates to the bank debt outstanding in the respective periods offset by interest earned on cash deposits.

Income Taxes.

Significant components affecting the effective tax rate include pre-tax net profit, changes in valuation allowance, federal and state R&D tax credits, income from tax-exempt securities, the state composite tax rate and recognition of certain deferred tax assets subject to valuation allowance. The Company recorded $0 income tax provision for both the three months ended April 4, 2009 and March 29, 2008.

Liquidity and Capital Resources.

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

As of April 4, 2009, we had cash and cash equivalents of $5.7 million and working capital of $9.8 million. For the three months ended April 4, 2009, net cash provided by operating activities was $0.9 million.

The Company has historically required, and continues to require, debt to fund its operations. Management believes that the Company s current cash and cash equivalents and its credit facility with Wells Fargo Bank See Note 5 of Notes to Consolidated Financial Statements in this report for more information regarding the credit facility provides sufficient liquidity to operate for the next 12 months and that the covenants contained in the Wells Fargo Bank credit facility are reasonable and management expects to be able to meet those covenants based on its operating plan for 2009. If the Company is not able to perform in accordance with its operating plan for 2009 and fails to maintain compliance with its debt covenants, Wells Fargo Bank would be entitled to exercise its remedies under this credit facility which include declaring all outstanding obligations due and payable, and disposing of the collateral if obligations are not paid. As of April 4, 2009 the Company was in compliance with the debt covenants on the credit facility.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Market risk represents the risk of loss that may impact the financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We transact the majority of our business in U.S. dollars and therefore changes in foreign currency rates will not have a significant impact on our income statement or cash flows. However, increases in the value of the U.S. dollar against any local currencies could cause our products to become relatively more expensive to customers in a particular country or region, leading

to reduced revenue or profitability in that country or region. Our French subsidiary, which is responsible for selling our aesthetics products in France, transacts business in its geography in its local currency, and therefore, changes in the U.S. dollar versus the Euro may impact our income statement or cash flows. We currently do not engage in transactions to hedge against the risk of the currency fluctuation, but we may do so in the future.

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The Company currently requires debt to fund its operations and movements in the credit market will impact the availability and the cost of this funding. The Company s current credit facility with Wells Fargo Bank has a variable interest rate and therefore the Company s interest expense will increase or decrease depending upon the prime interest rate. The facility expires in March 2011 and the ability of the Company to acquire a new facility, should one be required, will depend upon the state of the financial credit markets at that time.

Item 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures, as such term is defined in Rule 13a-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 April 4, 2009. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Factors That May Affect Future Results

In addition to the other information contained in this Annual Report Form 10-K, 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 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 cause a slowdown in 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.

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Recent macro-economic issues involving the broader financial markets, including the housing and credit system and general liquidity issues in the securities markets, have negatively impacted the economy and may negatively affect our growth. In addition, weak economic conditions and declines in consumer spending and consumption may harm our operating results. Purchases of our products are often discretionary. If the economic climate deteriorates further, customers or potential customers could delay, reduce or forego their purchases of our products and services, which could impact our business in a number of ways, including lower prices for our products and services and reduced or delayed sales. There could be a number of follow-on effects from the current financial crisis 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 increased expense or inability to obtain future financing.

If the negative macro-economic conditions persist, or if the economy enters a prolonged period of decelerating growth, our results of operations may be harmed.

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

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

- acceptance of product performance, features, ease of use, scalability and durability;
- recommendations and opinions by ophthalmologists, dermatologists, plastic surgeons, other clinicians, and their associated opinion leaders;
- clinical study outcomes;
- price of our products and prices of competing products and technologies particularly in light of the current macro-economic, environment, in which the availability of credit is limited and purchasers may delay capital investments or place additional emphasis on price when making their purchase decision;
- availability of competing products, technologies and alternative treatments; and
- level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales from recurring revenues including consumable EndoProbe devices and service. Our ability to increase recurring revenues from the sale of consumable EndoProbe devices will depend primarily upon the features of our current products and product innovation, ease of use and prices of our products, including the relationship to prices of competing delivery devices. 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 or services may have a material adverse effect on our business, results of operations and financial condition.

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

The global aesthetics market has seen a sharp contraction since 2008 and we have seen reduced demand for our products because most procedures performed using our aesthetics products are elective procedures not reimbursable through government or private health insurance, with the costs borne by the patient. The decision to purchase our aesthetics products may therefore be influenced by a number of factors, including:

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

the success of our sales and marketing efforts;

evolving customer needs;

the introduction of new products and technologies;

evolving surgical practices;

evolving industry standards;

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the cost of procedures performed using our products; and

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

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

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 quarter ended April 4, 2009, our international sales were $4.4 million or 40.7% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues, particularly ophthalmology, in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies, other than sales made by our French subsidiary. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets. The factors stated above could have a material adverse effect on our business, financial condition or results of operations. Our international operations and sales are subject to a number of other risks and potential costs, including:

impact of recessions in global economies and availability of credit;

fluctuations in foreign currency exchange rates;

performance of our international channel of distributors;

longer accounts receivable collection periods;

differing local product preferences and product requirements;

cultural differences;

changes in foreign medical reimbursement and coverage policies and programs;

political and economic instability;

difficulty in staffing and managing foreign operations;

foreign certification requirements, including continued ability to use the CE mark in Europe;

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.

We Face Strong Competition in Our Markets and Expect the Level of Competition to Grow in the Foreseeable Future.

Competition in the market for devices used for ophthalmic and aesthetics treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Alcon Inc., Carl Zeiss Meditec AG, Nidek Co. Ltd., Synergetics, Ellex Medical Lasers, Ltd. 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 such as Lucentis/Avastin (Genentech), and to a lesser extent Visudyne (Novartis) and Macugen (OSI Pharmaceuticals) compete rigorously with traditional laser procedures.

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In aesthetics, our principal competitors are Cutera, Candela Corporation, Palomar Technologies, Inc., Sciton, Lumenis Ltd. and Cynosure. These competitors have more sales representatives supporting broader product lines. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do.

In both markets, some companies also have greater name recognition than we do and long-standing customer relationships. In addition to other companies that manufacture photocoagulators, we compete with pharmaceuticals, other technologies and other surgical techniques. 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.

We Have More Indebtedness and Fewer Liquid Resources After the Acquisition of the Aesthetics Business of AMS and Laserscope, Which Adversely Affects Our Cash Flows and Business.

In order to complete the Laserscope acquisition, we entered into financing arrangements and used the majority of our liquid resources. Prior to the acquisition, we had no debt outstanding but now we have $5.5 million outstanding against our current line of credit. The increased levels of debt and obligations do among other things:

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

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

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

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

affect our credit rating;

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

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

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

We Believe There May be a Risk as to Whether Our Current Liquidity and Capital Resources Will be Sufficient to Meet Our Planned Operating Requirements for the Next 12 Months.

The Company s credit facility with Wells Fargo Bank is an asset-based revolving line of credit. The amount of money the Company may borrow at any particular time is determined by the amount of eligible accounts receivables and inventory the Company has on hand at that particular time (the Borrowing Base). If at any time the amount outstanding under the credit line exceeds the Borrowing Base the Company will be required to pay the difference between the outstanding amount and the Borrowing Base immediately. With the current crisis in the global economy it is possible that customers will take longer to pay and or default on their payments. Under such circumstances the Borrowing Base may be reduced significantly, which will reduce the Company s ability to borrow and will have a direct negative impact on the Company s cash position.

Management is of the opinion that the Company s current cash and cash equivalents together with its credit facility provides sufficient liquidity to operate for the next 12 months, that the covenants contained in the Company s credit facility with Wells Fargo Bank are reasonable and management expects to be able to meet these covenants. However if the Company is not able to perform as projected in its operating plan and becomes out of compliance with its debt covenants, Wells Fargo Bank would be entitled to exercise its remedies under the credit facility which include declaring all outstanding obligations thereunder due. For example, in August 2008 the Company was not in compliance with the debt service covenant contained in the credit facility with Wells Fargo Bank; however, the Company has obtained a waiver from the bank and was in compliance with the covenants at April 4, 2009.

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

Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. Successful commercialization of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

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

The Company s ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, including clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Because of the complexities and uncertainties associated with ophthalmic and aesthetics research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products of current or future competitors. Therefore, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

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 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.

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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 sixteen United States patents and five foreign patents on the technologies related to our products and processes. We have approximately six pending patent applications in the United States and six foreign pending patent applications that have been filed. Our patent applications may not be approved. Along with the acquisition of the AMS/Laserscope aesthetic products, we acquired a royalty-free license to eleven of the AMS/Laserscope patents. In addition, we acquired a license to a Palomar patent under which royalties are paid to Palomar based upon a percentage of sales of certain products acquired from AMS/Laserscope. 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 will expire in 2009. Delivery devices which do not utilize our Connector Patent technology are not recognized by our laser consoles. We derive, and expect to continue to derive, a large portion of our recurring revenue and profits from sales of our consumable EndoProbe devices. Expiration of this patent may increase competition from our competitors for our consumable EndoProbe device business and there can be no guarantees that we will maintain our market share of this business.

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

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Numerous patents are held by others, including academic institutions and our competitors. Until recently patent applications were maintained in secrecy in the United States until the patents were issued. Patent applications filed in the United States after November 2000 generally will be published eighteen months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, both within the United States and with regards to international patent applications, we cannot assure you that our technology does not infringe any patents or patent applications held by third parties. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable.

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop non-infringing technology or to enter into royalty or licensing agreements. For example, during fiscal year 2007, the Company settled patent litigations with Synergetics, Inc., which was time-consuming, costly and a diversion of technical and management personnel. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

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

Our ability to sell our products and generate revenues depends upon our direct sales force within the United States and relationships with independent distributors outside the United States. Currently our direct sales force consists of 16 employees and we maintain relationships with approximately 100 independent distributors internationally selling our products into 107 countries. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches terms of its distribution agreement or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

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

We have Remediated the Material Weakness in Our Internal Controls and Procedures but still have Significant Deficiencies which could Harm Our Operating Results or Cause Us to Fail to Meet Our Regulatory or Reporting Obligations.

We evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, management concluded that our disclosure controls and procedures were effective at the reasonable assurance level and that the material weakness in our internal control over financial reporting related to our financial reporting process identified in our Annual Report on Form 10-K for the year ended December 29, 2007 has been remediated. See Item 9A of Part II of the Annual Report on Form 10-K for the year ended January 3, 2009.

During the evaluation we did note several significant deficiencies, which related to our need to: establish additional controls over our accounting close process; improve our controls over demo and loaner inventory; and institute more stringent data backup and recovery procedures. A significant deficiency is a deficiency or a combination of deficiencies in internal control over financial reporting that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the company s financial reporting.

We are taking steps designed to remedy the significant deficiencies noted above. However, if despite our remediation efforts, we fail to remediate the significant deficiencies, we could be subject to regulatory scrutiny and a loss of public confidence in our disclosure controls and procedures. It is also possible that failure to remediate the significant deficiencies discussed above or other matters may result in the Company concluding in future periods that there is a material weakness in our disclosure controls and procedures.

Even if we are to successfully remediate such significant deficiencies, because of inherent limitations, our disclosure controls and procedures may not prevent or detect misstatements or material omissions. Projections or any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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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. On October 16, 2007, Barry G. Caldwell resigned as the Company s President and Chief Executive Officer and as a member of the Company s Board of Directors, effective as of that date. Upon Mr. Caldwell s resignation, Theodore A. Boutacoff, the Company s current Chairman of the Board, returned to serve as President and Chief Executive Officer. Mr. Boutacoff was the Company s President and Director from 1989 until 2005. On July 20, 2007, Meryl A. Rains resigned as the Company s Chief Financial Officer. An interim Chief Financial Officer was hired for the interim period until James H. Mackaness was hired as full time Chief Financial Officer on January 2, 2008. Key personnel, including certain members of our aesthetics sales force who joined the Company in connection with the acquisition of the aesthetics business of Laserscope, have left the Company in the past and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of Company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

If We Fail to Accurately Forecast Demand For Our Product and Component Requirements For the Manufacture of Our Product, We Could Incur Additional Costs or Experience Manufacturing Delays and May Experience Lost Sales or Significant Inventory Carrying Costs.

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

We Depend on Sole Source or Limited Source Suppliers.

We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies that may discontinue their operations at any time. For example, Synergetics Inc. currently is the sole source supplier of the Company s line of adjustable laser probes under a non-exclusive agreement. 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.

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

We Face Risks Associated with Our Collaborative and OEM Relationships.

Our collaborators may not pursue further development and commercialization of products resulting from collaborations with us or may not devote sufficient resources to the marketing and sale of such products. We cannot provide assurance that these types of relationships will continue over a longer period. Our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. If a collaborator elects to terminate its agreement with us, our ability to develop, introduce, market and sell the product may be significantly impaired and we may be forced to discontinue altogether the product resulting from the collaboration. We may not be able to negotiate alternative collaboration agreements on acceptable terms, if at all. The failure of any current or future collaboration efforts 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.

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 entered into a Product Supply Agreement with AMS in connection with the acquisition of the aesthetics business of Laserscope, pursuant to which AMS manufactured several of our aesthetics products. With the exception of some service parts, we transitioned the manufacturing for the majority of these products to our facilities during the fourth quarter of 2007. We are party to a Manufacture and Supply Agreement with Synergetics, Inc. pursuant to which Synergetics manufactures the Company s line of adjustable laser probes on a non-exclusive basis. 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 collaborate with Bausch & Lomb to design and manufacture a solid-state green wavelength (532nm) laser photocoagulator module for Bausch & Lomb, called the Millennium Endolase module. The Millennium Endolase module is designed to be a component of Bausch & Lomb s ophthalmic surgical suite product offering and is not expected to be sold as a stand-alone product. Sales of the Millennium Endolase module are dependent upon the actual order rate from and shipment rate to Bausch & Lomb, which depends on the efforts of our partner and is beyond our control. We cannot assure you that our relationship with Bausch & Lomb will result in further sales of our Millennium Endolase module. 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.

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.

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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, including increases in the sales of our aesthetics products, we may need to increase our production capacity and may not be able to do so in a timely, effective, or cost efficient manner. We may not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations and as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

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

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

- general economic uncertainties and political concerns;
- the timing of the introduction and market acceptance of new products, product enhancements and new applications;
- changes in demand for our existing line of ophthalmology and aesthetics products;
- the cost and availability of components and subassemblies, including the willingness and ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;
- our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- fluctuations in our product mix between ophthalmology and aesthetics 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.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors. Our European sales during the third quarter is generally lower.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. We encountered this adverse effect on our operating results during several of the last eight quarters ended starting with the quarter ended March 31, 2007 through the quarter ended January 3, 2009. In addition, we have historically made a significant portion of each quarter s product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarter. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

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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 and by liquidity issues. For the quarter ended April 4, 2009, the trading price of our common stock fluctuated from a high of $1.34 per share to a low of $0.55 per share. There can be no assurance our common stock trading price will not suffer additional declines. From time to time, we meet with investors and potential investors. In addition, we receive attention from securities analysts and present at some analyst meetings. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes. These broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

Inability of Obtaining Credit or Material Increases in Interest Rates May Harm Our Sales.

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

We Are Subject To Government Regulations Which May Cause Us to Delay or Withdraw the Introduction of New Products or New Applications for Our Products.

The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the Federal Food, Drug and Cosmetic Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the product must undergo rigorous testing and an extensive regulatory review process implemented by the FDA under federal law. Unless otherwise exempt, a device manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval application (PMA) process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes additional regulations on manufacturers of approved medical devices. We are required to comply with the applicable Quality System regulations and our manufacturing facilities are subject to ongoing periodic inspections by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before being utilized for commercial manufacturing. Noncompliance with the applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations.

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products CE marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directive and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition.

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If We Fail to Comply With the FDA s Quality System Regulation and Laser Performance Standards Our Manufacturing Operations Could Be Halted, and Our Business Would Suffer.

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

If We Modify One of Our FDA Approved Devices, We May Need to Seek Reapproval, Which, if Not Granted, Would Prevent Us from Selling Our Modified Products or Cause Us to Redesign Our Products.

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

The Requirements of Complying with the Sarbanes-Oxley Act of 2002 Might Strain Our Resources, Which May Adversely Affect Our Business and Financial Condition.

We are subject to a number of requirements, including the reporting requirements of the Securities Exchange Act of 1934, as amended, and the Sarbanes-Oxley Act of 2002. We are now required to comply with certain requirements of Section 404 of the Sarbanes-Oxley Act which require management to perform an assessment of internal control over financial reporting. These requirements might place a strain on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. As a result, our management s attention might be diverted from other business concerns, which could have a material adverse effect on our business, financial condition, and operating results. In addition, we might need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and we might not be able to do so in a timely fashion.

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.

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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;

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 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.

If Product Liability Claims are Successfully Asserted Against Us, We may Incur Substantial Liabilities That May Adversely Affect Our Business or Results of Operations.

We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue and skin conditions on and near a patient s face. We believe we maintain adequate levels of product liability insurance but product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

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

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.

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.

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.

Our Business is Subject to Environmental Regulations.

Our facilities and operations are subject to federal, state and local environmental and occupational health and safety requirements of the United States and foreign countries, including those relating to discharges of substances to the air, water and land the handling, storage and disposal of hazardous materials and wastes and the cleanup of properties affected by pollutants. Failure to maintain compliance with these regulations could have a material adverse effect on our business or financial condition.

In the future, federal, state or local governments in the United States or foreign countries could enact new or more stringent laws or issue new or more stringent regulations concerning environmental and worker health and safety matters that could affect our operations. Also, in the future, contamination may be found to exist at our current or former facilities or off-site locations where we have sent wastes. We could be held liable for such newly discovered contamination which could have a material adverse effect on our business or financial condition. In addition, changes in environmental and worker health and safety requirements could have a material adverse effect on our business or financial condition.

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

As previously reported on the Company s Current Report on Form 8-K filed on April 6, 2009, on March 31, 2009 (the Effective Date), the Company and each of BlueLine Capital Partners, LP, BlueLine Capital Partners II, LP and BlueLine Capital Partners III, LP (collectively, the BlueLine Entities) entered into an amendment (the Amendment) to that certain Investor Rights Agreement, dated as of August 27, 2007, by and among the Company and the BlueLine Entities.

In order to induce the BlueLine Entities to enter into the Amendment, on the Effective Date, the Company issued to the BlueLine Entities unregistered warrants to purchase an aggregate of 20,000 shares of the Company s common stock at an exercise price of $0.01 per share (the Warrants). The Warrants will expire on September 30, 2009. The issuance of the Warrants was unregistered and was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None

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Item 6. Exhibits

Exhibit No.	Exhibit Title
10.1	Amendment No. 1 to Investor Rights Agreement, dated as of March 31, 2009 *(which is incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on April 6, 2009).*
10.2	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners, LP *(which is incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the Commission on April 6, 2009).*
10.3	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners II, LP *(which is incorporated herein by reference to Exhibit 4.4 to the Current Report on Form 8-K filed with the Commission on April 6, 2009).*
10.4	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners III, LP *(which is incorporated herein by reference to Exhibit 4.5 to the Current Report on Form 8-K filed with the Commission on April 6, 2009).*
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.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe, Apex, Aura, Lyra, Gemini, Venus, Coolspot and Dermastat are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, DioLite, IQ 810, IQ 577, MicroPulse, OtoProbe, ScanLite, Symphony, VariLite and EasyFit product names are our trademarks. All other trademarks or trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

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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 15, 2009

By: /s/ THEODORE A. BOUTACOFF
Name: Theodore A. Boutacoff
Title: President and Chief Executive Officer

(Principal Executive Officer)

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