

IRIDEX CORP  
Form 10-Q  
November 04, 2008  
Table of Contents

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

**b** **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 27, 2008

Or

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

Commission file number: 0-27598

**IRIDEX CORPORATION**

(Exact name of registrant as specified in its charter)

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

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

**1212 Terra Bella Avenue**  
**Mountain View, California**  
(Address of principal executive offices)

**94043-1824**  
(Zip Code)

Registrant's telephone number, including area code: (650) 940-4700

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller  
reporting company)

Smaller reporting company

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

### APPLICABLE ONLY TO CORPORATE ISSUERS:

The number of shares of common stock, \$.01 par value, issued and outstanding as of October 31, 2008 was 8,824,301.

**Table of Contents**

**TABLE OF CONTENTS**

<b>Items</b>	<b>Page</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	20
<u>Item 4T. Controls and Procedures</u>	20
<b>PART II. OTHER INFORMATION</b>	
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
<u>Item 3. Defaults Upon Senior Securities</u>	35
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	35
<u>Item 5. Other Information</u>	35
<u>Item 6. Exhibits</u>	35
<u>Signature</u>	36
EXHIBIT 31.1	
EXHIBIT 31.2	
EXHIBIT 32.1	
EXHIBIT 32.2	

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

	September 27, 2008	December 29, 2007 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,974	\$ 5,809
Restricted cash		3,800
Accounts receivable, net	9,215	8,876
Inventories, net	13,527	15,967
Prepays and other current assets	1,264	1,051
Total current assets	26,980	35,503
Property and equipment, net	1,128	1,621
Goodwill	3,239	3,239
Other intangible assets, net	4,185	5,944
Other long term assets	224	347
Total assets	\$ 35,756	\$ 46,654
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,593	\$ 2,887
Bank line of credit	6,000	4,863
Accrued compensation	1,680	2,024
Accrued expenses	3,235	7,809
Accrued warranty	1,258	1,895
Deferred revenue	2,805	3,350
Bank term loan - current portion		5,016
Total current liabilities	17,571	27,844
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Convertible preferred stock, \$.01 par value:		
Authorized: 2,000,000 shares; Issued and outstanding: 500,000 shares in 2008 and 2007	5	5
Common stock, \$.01 par value:		
Authorized: 30,000,000 shares; Issued and outstanding: 8,824,301 shares in 2008 and 2007	89	89
Additional paid-in capital	39,087	38,695
Accumulated other comprehensive loss	(238)	(88)
Treasury stock, at cost	(430)	(430)
Accumulated deficit	(20,328)	(19,461)
Total stockholders' equity	18,185	18,810

Edgar Filing: IRIDEX CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 35,756	\$ 46,654
--	-----------	-----------

- (1) Derived from the consolidated audited financial statements included in our report filed on Form 10-K with the SEC for the year ended December 29, 2007.

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

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 27, 2008</b>	<b>September 29, 2007</b>	<b>September 27, 2008</b>	<b>September 29, 2007</b>
Revenues	\$ 11,987	\$ 13,575	\$ 36,383	\$ 41,390
Cost of revenues	6,997	7,390	21,257	23,412
<b>Gross profit</b>	<b>4,990</b>	<b>6,185</b>	<b>15,126</b>	<b>17,978</b>
Operating expenses:				
Research and development	972	1,319	2,995	4,636
Selling, general and administrative	4,248	5,920	13,356	21,740
<b>Total operating expenses</b>	<b>5,220</b>	<b>7,239</b>	<b>16,351</b>	<b>26,376</b>
Loss from operations	(230)	(1,054)	(1,225)	(8,398)
Legal settlement			800	2,500
Interest and other expense, net	(54)	(184)	(426)	(603)
Loss before income taxes	(284)	(1,238)	(851)	(6,501)
Benefit (provision) for income taxes	35		(16)	
<b>Net loss</b>	<b>\$ (249)</b>	<b>\$ (1,238)</b>	<b>\$ (867)</b>	<b>\$ (6,501)</b>
Net loss per share basic and diluted	\$ (0.03)	\$ (0.15)	\$ (0.10)	\$ (0.80)
Shares used in computing net loss per share basic and diluted	8,824	8,218	8,824	8,165

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 27, 2008</b>	<b>September 29, 2007</b>	<b>September 27, 2008</b>	<b>September 29, 2007</b>
Net loss	\$ (249)	\$ (1,238)	\$ (867)	\$ (6,501)
Foreign currency translation adjustments	(149)	(3)	(150)	(24)
<b>Comprehensive loss</b>	<b>\$ (398)</b>	<b>\$ (1,241)</b>	<b>\$ (1,017)</b>	<b>\$ (6,525)</b>

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

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

	Nine Months Ended	
	September 27, 2008	September 29, 2007
<b>Cash flows from operating activities:</b>		
Net loss	\$ (867)	\$ (6,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,417	3,079
Stock compensation recognized	392	1,033
Provision for doubtful accounts	(2)	1,412
Provision for excess and obsolete inventories	1,582	388
Changes in operating assets and liabilities:		
Accounts receivable	(337)	(3,875)
Inventories	858	(4,140)
Prepays and other current assets	(213)	(789)
Accounts payable	(294)	1,722
Accrued compensation and expenses	(4,918)	2,066
Accrued warranty	(637)	1,316
Deferred revenue	(545)	2,562
Net cash used in operating activities	(2,564)	(1,727)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(165)	(1,702)
Purchases of intangible assets		(16,618)
Goodwill		(10,509)
Other Assets	123	924
Net cash used in investing activities	(42)	(27,905)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock		2,889
Proceeds of credit facility, net of issuance costs	1,137	4,890
Repayment of credit facility	(5,016)	10,421
Restricted cash balance offset against credit facility	3,800	(3,800)
Net cash (used in) provided by financing activities	(79)	14,400
Effect of foreign exchange rate changes	(150)	(24)
Net decrease in cash and cash equivalents	(2,835)	(15,256)
Cash and cash equivalents at beginning of period	5,809	21,051
Cash and cash equivalents at end of period	\$ 2,974	\$ 5,795

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





---

**Table of Contents**

**IRIDEX Corporation**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

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

The 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 10, 2008. The independent accountant's report included a qualification paragraph that stated the Company's losses from operations and failure to meet certain debt covenants raised substantial doubt about the Company's ability to continue as a going concern. The results of operations for the three and nine month periods ended September 27, 2008 are not necessarily indicative of the results for the year ending January 3, 2009 or any future interim period.

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 2008. However, recent operating results indicate that there is significant risk in achieving the operating plan. If the Company is not able to perform in accordance with its operating plan for 2008 and fails to maintain compliance with its debt covenants, Wells Fargo Bank would be entitled to exercise its remedies under this facility which include declaring all outstanding obligations due and payable, and disposing of the collateral if obligations are not paid.

In August 2008 the Company was not in compliance with certain covenants contained in the credit facility relating to the Company's ability to sufficiently cover its debt service needs; however, the Company has obtained a waiver from Wells Fargo Bank and was in compliance with all of the covenants in the Agreement during September 2008.

These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's financial statements have been prepared on a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

**Recent Accounting Pronouncements**

In December 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No 141(R) (revised 2007), Business Combinations (SFAS 141R), which replaces SFAS 141. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and the goodwill acquired. SFAS 141R also establishes disclosure requirements that will enable users to evaluate the nature and financial effects of the business combination. SFAS 141R is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008 and will be adopted by the Company in the first quarter of fiscal year 2009. While the Company expects that SFAS 141R will have an impact on accounting for business combinations once adopted, the effect is dependent upon acquisitions at that time.

In December 2007, the FASB issued SFAS 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51 (SFAS 160). The standard changes the accounting for noncontrolling (minority) interests in consolidated financial statements including the requirements to classify noncontrolling interests as a component of consolidated stockholders' equity, and the elimination of minority interest accounting in results of operations with earnings attributable to noncontrolling interests reported as part of consolidated earnings. Additionally, SFAS 160 revises the accounting for both increases and decreases in a parent's controlling ownership interest. SFAS 160 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company believes it is unlikely that the adoption of SFAS 160 will have an impact on the consolidated financial statements because the Company does not hold a noncontrolling (minority) interest in another entity.



**Table of Contents**

On March 19, 2008, the FASB issued SFAS 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). SFAS 161 requires enhanced disclosures about an entity's derivative and hedging activities. These enhanced disclosures will discuss (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Currently, the Company does not engage in derivative and hedging activities.

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. FSP 142-3 will be adopted by the Company in the first quarter of fiscal year 2009. The Company does not expect the adoption of FSP 142-3 will have a material impact on its consolidated financial statements.

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 its consolidated financial statements.

**Recently Adopted Accounting Standards**

In September 2006, the FASB issued SFAS 157, Fair Value Measurements (SFAS 157), which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. 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 permitted, except for the impact of FASB Staff Position (FSP) 157-2. FSP 157-2 deferred the adoption of SFAS 157 for non financial assets and liabilities until years ended after November 15, 2008. On December 30, 2007, we adopted SFAS 157 for financial assets and liabilities. Carrying amounts of our financial instruments including cash and cash equivalents, accounts receivables, accounts payables and accrued liabilities approximate fair value due to their short maturities. The fair value of bank line of credit approximates fair value due to its floating rate nature.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 was issued to allow entities to voluntarily choose to measure certain financial assets and liabilities at fair value (fair value option). The fair value option may be elected on an instrument-by-instrument basis and is irrevocable, unless a new election date occurs. If the fair value option is elected for an instrument, SFAS 159 specifies that unrealized gains and losses for that instrument shall be reported in earnings at each subsequent reporting date. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. On December 30, 2007 we adopted SFAS 159 and have made no election under SFAS 159.

**2. Summary of Significant Accounting Policies**

The Company's significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended December 29, 2007 which was filed with the Securities and Exchange Commission on April 10, 2008.

*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



---

**Table of Contents**

initially recorded in the first quarter of 2007 in conjunction with the acquisition of the aesthetics business of Laserscope. We review our intangible assets for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. 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. In the fourth quarter of 2007 the Company determined that based on estimated future cash flows the carrying amount of specific intangible assets exceeded their fair value; accordingly an impairment loss was recognized.

Goodwill is not amortized, but is subject to an annual impairment test. To determine any goodwill impairment, a two-step process is performed on an annual basis, or more frequently if necessary, to determine 1) whether the fair value of the relevant reporting unit exceeds carrying value and 2) to measure the amount of an impairment loss, if any. Goodwill was initially recorded in the first quarter of 2007 in conjunction with the acquisition of the aesthetics business of Laserscope. In the fourth quarter of 2007 the Company performed an annual impairment test. We identified the Laserscope Aesthetics reporting unit as the appropriate reporting unit for this analysis. Reporting units are operating segments or components of operating segments for which discrete financial information is available. The conclusion was that the carrying value of the reporting unit exceeded the fair value. As a result, management performed the second step and determined the fair value of the assets and liabilities of the reporting unit to measure the amount of impairment loss. By establishing the fair value of the reporting unit and the fair value of assets and liabilities within the reporting unit, the Company determined the amount of impairment to goodwill.

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 goodwill or further modify the period of expected lives for the intangible assets.

*Revenue Recognition.*

Our revenues arise from the sale of laser consoles, delivery devices, disposables 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 the UK and 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.

**Table of Contents***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 nine months ending September 27, 2008 and September 29, 2007 is as follows:

(in thousands)	Nine Months Ended	
	September 27, 2008	September 29, 2007
Balance, beginning of period	\$ 3,350	\$ 1,415
Additions to deferral through acquisition		1,938
Additions to deferral	4,901	6,385
Revenue recognized	(5,446)	(5,761)
Balance, end of period	\$ 2,805	\$ 3,977

*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 nine months ending September 27, 2008 and September 29, 2007 is as follows:

(in thousands)	Nine Months Ended	
	September 27, 2008	September 29, 2007
Balance, beginning of period	\$ 1,895	\$ 866
Warranty accrual acquired through acquisition		1,771
Accrual for warranties issued during the period	165	(153)
Settlements made in kind during the period	(802)	(302)
Balance, end of period	\$ 1,258	\$ 2,182

**3. Business Combination**

On January 16, 2007, the Company acquired the aesthetics business of American Medical Systems Holdings (AMS) and Laserscope, a wholly owned subsidiary of AMS for \$28.6 million including the direct costs of acquisition for cash and 213,435 shares of common stock valued at \$9.43 per share. These financial statements include the results of operations for the acquired business from the acquisition date. The Company made the acquisition due to its complementary fit with the existing IRIDEX aesthetics laser business. At the time of the acquisition the Company recorded Goodwill of \$10.1 million and intangible assets of \$16.4 million. At the end of 2007 the Company conducted an impairment test in accordance with SFAS 142 Goodwill and Other Intangible Assets and determined that based on operating results for 2007 and the outlook for the aesthetics business for 2008 and beyond, there was significant impairment to the intangible assets and goodwill. In addition, the Company revisited the useful lives associated with the remaining intangible assets to ensure they reflected the revised outlook for the aesthetics business. The impact of this review was to write down goodwill by \$6.9 million from \$10.1 million to \$3.2 million and write down the gross carrying value of the intangible assets by \$7.8 million from \$16.4 million to \$8.6 million. The net carrying value of intangible assets after impairment which includes the amortization expense for the year as of December 29, 2007 was \$5.9 million and as of September 27, 2008 was \$4.2 million. Amortization of intangible assets associated with the acquisition was \$4.7 million and \$2.1 million for the nine months ended September 27, 2008 and September 29, 2007, respectively.

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

As part of the acquisition the Company acquired Laserscope's wholly owned subsidiaries in France and the United Kingdom (UK). In June 2008, the Company signed an agreement which transferred the responsibility for sales and service of our aesthetics products in the UK to an independent distributor along with a transfer of associated employees and assets.

**Table of Contents****4. Inventories, net**

The components of the Company's inventories are as follows:

(in thousands)	September 27, 2008	December 29, 2007
Raw materials	\$ 6,297	\$ 9,063
Work in progress	1,637	1,832
Finished goods	5,593	5,072
 Total inventories	 \$ 13,527	 \$ 15,967

During 2007 and the nine months ended September 27, 2008, the Company recorded a lower of cost or market (LCM) reserve associated with the inventory purchased from AMS totaling \$1.8 million. As a result of reviewing inventory on hand during the nine months ended September 27, 2008, the Company has reclassified \$1.7 million of this reserve to an excess and obsolete reserve and recognized \$0.1 million as a favorable purchase price variance. The balance on the LCM reserve was \$1.1 million and \$0 as of December 29, 2007 and September 27, 2008, respectively.

**5. 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 years ended 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 September 27, 2008, the Company had \$3.0 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 September 27, 2008, the Company had \$6.0 million outstanding against the bank line of credit which approximates fair value due to the line of credit's floating rate nature. The Company did not have any Level 2 or Level 3 assets or liabilities.

**6. Bank Borrowings**

In January 2007, the Company entered into a credit agreement with Mid-Peninsula Bank, part of Greater Bay Bank N.A. (the Prior Lenders) that provided for an asset-based revolving line of credit up to \$6 million revolving loan and a \$6 million term loan. The Company's obligations under all loans were secured by a lien on substantially all of the Company's assets. These credit facilities contained certain financial and other covenants. In the event of noncompliance by the Company with these covenants, the Prior Lenders would be entitled to exercise their remedies, which included declaring all obligations immediately due and payable and disposing of the collateral if the obligations were not paid. As of December 29, 2007 the Company was out of compliance with its debt covenants on its existing credit facilities with the Prior Lenders.



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

Subsequent to the year end the Company obtained a waiver for the default.

On March 28, 2008, the Company terminated the Credit Agreement with the Prior Lenders repaying all outstanding balances and entered into (i) a Borrowing Agreement and (ii) an Export-Import Bank Loan and Security Agreement with Wells Fargo Bank (together referred to as the Agreement). The Agreement provides for an asset-based revolving line of credit of up to \$8 million (the New Revolving Loans). Of the New Revolving Loans, up to \$5 million of the principal amount (the New Exim Sublimit) will be guaranteed by Exim Bank. The Company's obligations under the New Revolving Loans (including the New Exim Sublimit) are secured by a lien on substantially all of the Company's assets. Interest on the New Revolving Loans (including the New Exim Sublimit) is set at the greater of 5% or prime rate as published in the Wall Street Journal, plus 2.00%, subject to

---

**Table of Contents**

adjustment under certain circumstances including adjustments to the prime rate, late payment or the occurrence of an event of default. All outstanding amounts under the New Revolving Loans are payable in full on March 27, 2011. If at any time the amount outstanding under the New Revolving Loans exceeds the Borrowing Base as defined in the Agreement, the Company will be required to pay the difference between the outstanding amount and the Borrowing Base. The Company may prepay New Revolving Loans without penalty. These facilities contain certain financial and other covenants, including the requirement for the Company to maintain a certain level of net income (loss) and to be able to sufficiently cover its debt service needs. Other covenants include, but are not limited to, restricting the Company's ability to incur indebtedness, incur liens, enter into mergers or consolidations, dispose of assets, make investments, pay dividends, enter into transactions with affiliates, or prepay certain indebtedness. In the event of noncompliance by the Company with the covenants under this Agreement, Wells Fargo Bank and Export-Import Bank, would be entitled to exercise their remedies, which include declaring all obligations immediately due and payable and disposing of the collateral if obligations are not paid.

In August 2008 the Company was not in compliance with certain covenants contained in the Agreement relating to the Company's ability to sufficiently cover its debt service needs; however, the Company has obtained a waiver from Wells Fargo Bank and was in compliance with all of the covenants in the Agreement during September 2008.

As of September 27, 2008, the total amount outstanding under the New Revolving Loans was \$6 million and there was eligible collateral to support an additional \$1.3 million in borrowings.

**7. AMS Settlement**

On August 14, 2007, the Company, AMS and Laserscope (collectively the Parties), entered into a Settlement Agreement (the Settlement Agreement). The Parties entered into the Settlement Agreement to document their full and final agreement as to the amount of the adjustment contemplated by Section 1.5 of the Asset Purchase Agreement, by and among the Parties, dated November 30, 2006 (the Purchase Agreement); to amend the Product Supply Agreement between Laserscope and the Company, dated January 16, 2007 (the Product Supply Agreement); and to set forth the Parties' mutual understanding as to certain other matters.

As of December 27, 2007 \$4.8 million in obligations to AMS was outstanding and included in accrued liabilities and there were \$1.3 million of non-cancelable purchase orders outstanding with AMS for inventory to be delivered and paid for in 2008. As of September 27, 2008 all amounts due to AMS had been paid in full and there were no remaining non-cancelable purchase orders.

During the three months ended September 27, 2008 the Company determined that there was a probable underpayment of withholding tax concerning its overseas subsidiaries relating to periods prior to the Company's acquisition of these subsidiaries. The range of the underpayment including penalties and interest is estimated by management to be \$644,000 to \$1,877,000. In accordance with SFAS 5, Accounting for Contingencies, with no amount within the range being a better estimate of any other, the amount of \$644,000 was recorded in accrued expenses in connection with this potential liability. The acquisition of the overseas subsidiaries is governed by the Purchase Agreement which provides the Company with indemnification by AMS in certain situations, including situations relating to unpaid taxes, and as such the Company has recorded an asset in prepaids and other current assets equal to amount recorded in accrued expenses representing the recoverability of the liability in accordance with FASB Interpretation 39, Offsetting of Amounts Related to Certain Contracts, and as such, no charge to net income has been recorded. The Company is working towards resolution of this issue and currently does not have an estimate of timeframe for resolution.

**Table of Contents****8. Stock Based Compensation**

For the nine months ended September 27, 2008 the Company had one active stock plan at any given time. 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 are 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 terms and awards granted during the nine months ended September 27, 2008 under either plan were consistent with those described in our December 29, 2007 annual consolidated financial statements.

The following table summarizes information regarding activity in our stock option plans during the nine months ended September 27, 2008:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at Dec 29, 2007	1,859,537	\$ 6.09		
Granted	480,212	2.94		
Exercised				
Canceled or forfeited	(407,392)	6.63		
Outstanding at Sep 27, 2008	1,932,357	5.20	4.36	\$ 201,362
Exercisable at Sep 27, 2008	1,306,497	\$ 5.57	3.51	\$ 10,246

The aggregate intrinsic value in the table above represents the pre-tax intrinsic value, based on the Company's closing price as of September 27, 2008, 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 nine months ended September 27, 2008.

The weighted-average grant fair value of the options granted under the Company's stock plans was \$1.73 and \$4.56 per share for the nine months ended September 27, 2008 and September 29, 2007, 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		Nine Months Ended	
	September 27, 2008	September 29, 2007	September 27, 2008	September 29, 2007
Average risk free interest rate	3.03%	4.30%	3.27%	4.48%
Expected life (in years)	4.75 years	4.5 years	4.75 years	4.58 years
Dividend yield	0.0%	0.0%	0.0%	0.0%
Average volatility	69.0%	63.0%	70.0%	60.0%

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.

**Table of Contents**

The following table shows stock-based compensation expense included in the Consolidated Statements of Operations for the nine months periods ended September 27, 2008 and September 29, 2007 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 27, 2008	September 29, 2007	September 27, 2008	September 29, 2007
Cost of revenues	\$ 44	\$ 36	\$ 108	\$ 105
Research and development	5	35	70	147
Sales, general and administrative	116	222	214	781
	\$ 165	\$ 293	\$ 392	\$ 1,033

**9. Stock Option Awards***Exchange Offer*

On February 22, 2008, the Company offered (the Exchange Offer) to eligible employees to exchange all of their outstanding restricted common stock for new options to be granted under the 1998 Plan. The Exchange Offer covered 21,000 shares of restricted common stock granted to employees on February 13, 2007. The exchange ratio was 1.5 to one.

The Exchange Offer expired on February 22, 2008, at which time properly tendered restricted common stock for 21,000 shares were cancelled and new options for 31,500 shares were granted at the closing price of our common stock on the grant date. The fair value of modified awards granted approximated the fair value of the original awards cancelled.

All new options have an option expiration term of 7 years. Each new option has a four year vesting period, 1/48<sup>th</sup> of the shares subject to the option shall vest one month after the grant date and 1/48<sup>th</sup> of the shares subject to the option will vest each month thereafter.

*Incentive Plan*

On June 11, 2008, the shareholders approved the adoption of the 2008 Equity Incentive Plan, as described above.

**10. Income Taxes***Provision for Income Tax*

The Company recorded a benefit for income tax of \$35 thousand and \$0 for the three months ended September 27, 2008 and September 29, 2007, respectively. The Company's effective tax rate was (12.3)% and 0%, for the three months ended September 27, 2008 and September 29, 2007, respectively. The decrease in our effective tax rate for the three months ended September 27, 2008 was associated primarily with the loss incurred in the U.S. operations.

The Company has recorded a provision for income taxes of \$16 thousand and \$0 for the nine months ended September 27, 2008, and September 29, 2007, respectively. The Company's effective tax rate for the nine months ended September 27, 2008 was 1.9%.

*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 balance of gross unrecognized tax benefits as of September 27, 2008 was \$550 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 September 27, 2008, 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.

**Table of Contents**

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

**11. 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 Preferred A stock into common stock and are calculated under the treasury stock method. Common equivalent shares from unexercised stock options and the conversion of Preferred A 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.

Options to purchase 1,932,357 shares of common stock at a weighted average exercise price of \$5.20 were outstanding as of September 27, 2008, for the three and nine months ended, but were not included in the computation of diluted net income (loss) 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 Preferred A 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 (loss) per common share because of their effect is anti-dilutive. These shares could dilute earnings per share in future periods.

Options to purchase 2,095,015 shares of common stock at a weighted average exercise price of \$5.59 were outstanding as of September 29, 2007, for the three and nine months ended, but were not included in the computation of diluted net loss per share because the options would be anti-dilutive under the treasury stock method.

**12. 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, disposables and service and support activities.

Information on reportable segments for the three and nine month periods ended September 27, 2008 and September 29, 2007 is as follows:

(in thousands)	Three Months Ended September 27, 2008			Three Months Ended September 29, 2007		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Revenues	\$ 8,181	\$ 3,806	\$ 11,987	\$ 7,865	\$ 5,710	\$ 13,575
Direct cost of revenues	2,404	1,382	3,786	2,481	2,442	4,923
Direct gross profit	5,777	2,424	8,201	5,384	3,268	8,652
Total unallocated indirect costs			(8,485)			(9,890)
Pre-tax income (loss)			\$ (284)			\$ (1,238)

(in thousands)	Nine Months Ended September 27, 2008			Nine Months Ended September 29, 2007		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Revenues	\$ 23,889	\$ 12,494	\$ 36,383	\$ 23,443	\$ 17,947	\$ 41,390
Direct cost of revenues	6,818	5,116	11,934	6,991	9,153	16,144
Direct gross profit	17,071	7,378	24,449	16,452	8,794	25,246
Total unallocated indirect costs			(25,300)			(31,747)

Edgar Filing: IRIDEX CORP - Form 10-Q

Pre-tax loss	\$ (851)	\$ (6,501)
--------------	----------	------------

**Table of Contents**

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, marketing and selling, and general and administrative costs are not allocated to the segments.

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

(in thousands)	Three Months Ended September 27, 2008			Three Months Ended September 29, 2007		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Domestic	\$ 5,253	\$ 2,096	\$ 7,349	\$ 4,490	\$ 2,710	\$ 7,200
International	2,928	1,710	4,638	3,374	3,001	6,375
<b>Total revenues</b>	<b>\$ 8,181</b>	<b>\$ 3,806</b>	<b>\$ 11,987</b>	<b>\$ 7,864</b>	<b>\$ 5,711</b>	<b>\$ 13,575</b>

(in thousands)	Nine Months Ended September 27, 2008			Nine Months Ended September 29, 2007		
	Ophthalmology	Aesthetics	Total	Ophthalmology	Aesthetics	Total
Domestic	\$ 14,490	\$ 5,542	\$ 20,032	\$ 13,458	\$ 8,798	\$ 22,256
International	9,399	6,952	16,351	9,984	9,150	19,134
<b>Total revenues</b>	<b>\$ 23,889</b>	<b>\$ 12,494</b>	<b>\$ 36,383</b>	<b>\$ 23,442</b>	<b>\$ 17,948</b>	<b>\$ 41,390</b>

No one customer accounted for more than 10% of total revenue for the three and nine months ended September 27, 2008 and September 29, 2007, respectively.

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



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

*This Quarterly Report on Form 10-Q contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results; broadening our product line through product innovation; market acceptance of our products; expectations for future sales growth, generally, including expectations of additional sales from our new products and new applications of our existing products; our ability to integrate the acquired aesthetics business into our core business successfully and in a timely manner; the potential for production cost decreases and higher gross margins; our ability to develop and introduce new products through strategic alliances; our ability to reduce spending, including a reduction in headcount; our ability to remediate the material weakness identified in our disclosure controls and procedures; levels of interest income and expense; expectations regarding our effective tax rate; continued receipt of payments from the Synergetics Settlement; general economic conditions; levels of international sales; our current liquidity, ability to obtain additional financing, achieve financial stability, and meet the covenants of our existing financing agreement with Wells Fargo Bank, and the impact of concerns regarding our ability to generate sufficient cash flow to continue as a going concern; and the potential to record an impairment charge to goodwill and intangible assets and effects of recent accounting pronouncements on our financial position; effect of pending or known to be threatened litigation on operating results; and our ability to protect our proprietary information. 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 10, 2008 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 and delivery devices used to treat eye diseases in ophthalmology and skin conditions in aesthetics. In January 2007, the Company acquired Laserscope's aesthetics business including its subsidiaries in France and the United Kingdom (UK) from AMS.

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 the UK and France. In June 2008, we signed an agreement which transferred the responsibility for sales and service of our aesthetics products in the UK to an independent distributor along with a transfer of associated assets.

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 (single use disposable laser probes (disposables), service and support).

Our ophthalmology revenues arise primarily from the sale of our IRIS Medical OcuLight and IQ 810 laser systems, disposables 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.

**Table of Contents**

Cost of revenues consists primarily of the cost of purchasing components and sub-systems, assembling, packaging, shipping and testing components at our facility, direct labor and associated overhead and beginning in 2007, amortization of intangible assets acquired in the Laserscope acquisition, and the addition of the field service organization in the U.S. in support of the Laserscope aesthetics products.

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, general and administrative expenses consist primarily of costs of personnel, sales commissions, travel expenses, advertising and promotional expenses, facilities cost, legal and accounting fees, insurance and other expenses not allocated to other departments.

**Results of Operations**

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

	Three Months Ended		Nine Months Ended	
	September 27, 2008	September 29, 2007	September 27, 2008	September 29, 2007
Revenues	100.0%	100.0%	100.0%	100.0%
Cost of revenues	58.4%	54.4%	58.4%	56.6%
Gross Margin	41.6%	45.6%	41.6%	43.4%
Operating expenses:				
Research and development	8.1%	9.7%	8.2%	11.2%
Selling, general and administrative	35.4%	43.6%	36.8%	52.5%
Total operating expenses	43.5%	53.3%	45.0%	63.7%
Loss from operations	(1.9)%	(7.7)%	(3.4)%	(20.3)%
Legal settlement	0.0%	0.0%	2.2%	6.0%
Interest and other expense, net	(0.5)%	(1.3)%	(1.1)%	(1.4)%
Loss before income tax	(2.4)%	(9.0)%	(2.3)%	(15.7)%
Benefit (provision) for income taxes	0.3%	0.0%	(0.1)%	0.0%
Net loss	(2.1)%	(9.0)%	(2.4)%	(15.7)%

*Revenues.*

Total revenue decreased by 11.7% to \$12.0 million for the three months ended September 27, 2008 from \$13.6 million for the comparable three month period in 2007 and decreased 12.1% to \$36.4 million for the nine months ended September 27, 2008 from \$41.4 million for the comparable nine month period in 2007.

For the comparable three month periods in 2007 and 2008; total ophthalmology revenues increased \$0.3 million or 4.0% to \$8.2 million. Domestic ophthalmology system revenues increased \$0.1 million to \$1.7 million; international ophthalmology system revenues decreased \$0.5 million to \$1.8 million; aggregate ophthalmology recurring revenues consisting of disposables and service increased \$0.3 million to \$4.0 million and revenues from Original Equipment Manufactures (OEMs) were up \$0.3 million to \$0.7 million. Ophthalmology recurring revenues represented 49.3% of our aggregate ophthalmology business compared to 46.9% during the corresponding period in 2007.

For the comparable three month periods in 2007 and 2008; total aesthetics revenues decreased \$1.9 million or 33.3% to \$3.8 million. International aesthetics system revenues decreased \$1.2 million to \$1.2 million, domestic aesthetics system revenues decreased \$0.4 million to \$0.9 million and aggregate service revenues decreased \$0.3 million to \$1.7 million. The decrease in aesthetics revenue was due to the overall softening of the aesthetics market in general and the current economic uncertainties. International sales have been negatively impacted by the

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

recent run up in the strength of the U.S. dollar. Domestic sales have been negatively impacted by the difficulties we have experienced in the U.S. distribution channel during the latter part of 2007 resulting from the turnover in the sales force as illustrated by the fact that 14 people were involved in sales in September 2007 and 7 new people were involved in September 2008.

## Table of Contents

For the comparable nine month periods in 2007 and 2008; total ophthalmology revenues increased \$0.4 million or 1.9% to \$23.9 million. Domestic ophthalmology system revenues increased \$0.3 million to \$4.3 million; international ophthalmology system revenues decreased \$1.0 million to \$5.4 million; aggregate ophthalmology recurring revenues consisting of disposables and service increased \$0.9 million to \$12.6 million and revenues from OEM's were up \$0.2 million to \$1.5 million. Ophthalmology recurring revenues represented 52.8% of our aggregate ophthalmology business in 2008 compared to 49.8% in 2007.

For the comparable nine month periods in 2007 and 2008; total aesthetics revenues decreased \$5.4 million or 30.4% to \$12.5 million; international aesthetics system revenues decreased \$2.5 million to \$5.3 million; domestic aesthetics system revenues decreased \$3.2 million to \$1.8 million, and aggregate service revenues increased \$0.3 million to \$5.4 million. The decrease in aesthetics revenue was due to the overall softening of the aesthetics market in general and the current economic uncertainties. International sales have been negatively impacted by the recent run up in the strength of the U.S. dollar. Domestic sales have been negatively impacted by the difficulties we have experienced in the U.S. distribution channel during the latter part of 2007 resulting from the turnover in the sales force. In fiscal year 2008, we have taken steps to rebuild our U.S. aesthetics sales force.

### *Gross Profit.*

Gross profit decreased to \$5.0 million for the three months ended September 27, 2008 from \$6.2 million for the corresponding period in 2007. Gross profit decreased to \$15.1 million for the nine months ended September 27, 2008 from \$18.0 million for the corresponding period in 2007. The primary reason for the reduction in gross profit was the reduction in revenues for the respective periods.

Gross margin represented 41.6% of revenues for the three months ended September 27, 2008 and 45.6% of revenues for the comparable period in 2007. Gross margin represented 41.6% of revenues for the nine months ended September 27, 2008 and 43.4% of revenues for the comparable period in 2007. Items that favorably impacted gross margin in the respective periods were; a shift to products with lower direct costs and lower warranty costs. These items were more than offset by items that adversely impacted gross margin in the respective periods, which were; previously capitalized production expenses being released to the income statement in association with the reduction in inventories during the course of 2008, which amounted to a 4.3% reduction in gross margin in the three months ended September 27, 2008; amortization costs of intangible assets remaining constant but representing a higher percentage of cost of goods sold because of reduced revenues; and field service costs associated with servicing the aesthetics products remaining constant but representing a higher percentage of costs of goods sold because of reduced overall revenues.

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.*

### *Research and Development.*

Research and development expenses decreased by 26.3% to \$1.0 million from \$1.3 million for the three months ended September 27, 2008 compared to the corresponding period in 2007. The primary reasons for the decrease was reduced salary and related costs resulting from the reduction in headcount.

Research and development expenses decreased by 35.4% to \$3.0 million from \$4.6 million for the nine months ended September 27, 2008 compared to the corresponding period in 2007. The primary reasons for the decreases were reduced salary and related costs resulting from the reduction in headcount and reduced material costs incurred on product development.

In the future, upon reaching financial stability, 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.

### *Selling, General and Administrative*

Selling, general and administrative expenses decreased by 28.2% in the three months ended September 27, 2008 to \$4.2 million from \$5.9 million in the corresponding period in 2007. Selling expenses decreased \$0.3 million due to lower salary and related costs due to reduced headcount; and lower commissions as a result of lower sales for the comparable periods. Marketing



---

## **Table of Contents**

expenses decreased \$0.6 million primarily due to reduced spending on aesthetics related marketing programs; and lower salary and related costs due to reduced headcount. General and administrative expenses decreased \$0.7 million primarily due to a reduction in headcount related costs including stock compensation costs and costs associated with temporary help. Costs incurred by the overseas subsidiaries reduced by \$0.1 million primarily due to transferring the UK operations to a distributor and to a reduction in headcount and headcount related costs in France.

Selling, general and administrative expenses decreased by 38.6% in the nine months ended September 27, 2008 to \$13.4 million from \$21.7 million in the comparable period in 2007. Selling expenses decreased \$2.0 million primarily due to lower salary and related costs due to reduced headcount; and lower commissions as a result of lower sales for the comparable periods. Marketing expenses decreased \$3.2 million primarily due to reduced spending on aesthetics related marketing programs; and lower salary and related costs due to reduced headcount. General and administrative expenses decreased \$2.4 million primarily due to a reduction in headcount related costs including stock compensation costs and costs associated with temporary help; and legal fees. The legal fees incurred in 2007 were primarily in support of litigation which was resolved in 2007. Costs incurred by overseas subsidiaries reduced \$0.8 million primarily due to a reduction in headcount and headcount related costs in France and transferring the UK operations to a distributor.

### *Legal settlement, Interest and Other expense, net.*

The legal settlement reflected in the nine months ended September 27, 2008 relates to monies received from Synergetics associated with a settlement of legal claims for patent infringement. The settlement called for an initial payment of \$2.5 million, which was received in the second quarter of 2007 and five subsequent annual payments of \$0.8 million. The first annual payment of \$0.8 million was received in the second quarter of 2008. Interest and other expense relates to interest incurred on 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 loss, 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. For the three month periods ending September 27, 2008 and September 29, 2007, a tax benefit of \$35 thousand and \$0, respectively, were recorded. For the nine month periods ending September 27, 2008 and September 29, 2007, a tax provision of \$16 thousand and \$0, respectively, were recorded.

### *Liquidity and Capital Resources.*

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

As of September 27, 2008 we had cash and cash equivalents of \$3.0 million and working capital of \$9.4 million. The Company used \$2.6 million in operations in the nine months ended September 27, 2008, which included repaying the outstanding liability to AMS in full which amounted to \$4.8 million plus interest. As of September 27, 2008 we have no remaining contractual obligations to AMS - See Note 7 of Notes to Condensed Consolidated Financial Statements in this report for more information regarding the AMS Settlement.

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 problems experienced 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 with Wells Fargo Bank provide sufficient liquidity to operate for the next 12 months; that the covenants contained in the credit facility with Wells Fargo Bank are reasonable; and management expects to be able to meet these covenants based on its operating plan for 2008. However, recent operating results indicate that there is significant risk in achieving the operating plan. If the Company is not able to perform according to the Company's operating plan for 2008 and is unable to maintain compliance with its debt covenants, Wells Fargo Bank would be entitled to exercise its remedies which include declaring all outstanding obligations due and payable, and disposing of the collateral if obligations are not paid. 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 in September 2008.



---

**Table of Contents****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. As we continue to expand our international sales, our non-U.S. dollar denominated revenue and our exposure to gains and losses on international currency transactions may increase. In January 2007 we acquired two European subsidiaries as part of our acquisition of the assets of the aesthetics business of Laserscope. In June 2008, we signed an agreement which transferred the responsibility for sales and service of our aesthetics products in the UK to an independent distributor along with a transfer of associated assets. These entities do and did transact business in their geographies in their local currency. We currently do not engage in transactions to hedge against the risk of the currency fluctuation, but we may do so in the future. The Company's 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****(a) Evaluation of Disclosure Controls and Procedures**

Our management evaluated, with the participation of its Chief Executive Officer (CEO) and its Chief Financial Officer (CFO), the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13A-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934 (the '34 Act), as of the end of the period covered by this report.

Disclosure controls and procedures are designed with the objective of ensuring that (i) information required to be disclosed in our reports filed under the '34 Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Internal control procedures, which are designed with the objective of providing reasonable assurance that our transactions are properly authorized, recorded and reported, and our assets are safeguarded against unauthorized or improper use, are intended to permit the preparation of our financial statements in conformity with generally accepted accounting principles. To the extent that elements of our internal controls over financial reporting are included within our disclosure controls and procedures, they are included in the scope of our quarterly controls evaluation.

Based on that evaluation, and as a result of the material weakness in our internal controls over financial reporting discussed below, the CEO and CFO concluded that as of the end of the period covered by this report, the Company's disclosure controls and procedures were not effective.

A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management determined that the staffing levels in the finance function are inadequate and that this represented a control deficiency in the operation of our internal controls and processes over financial reporting that they considered to be a material weakness at September 27, 2008, because the control deficiency resulted in more than a remote likelihood that a material misstatement could occur in our quarterly financial statements and not be prevented or detected.

During the first half of 2008 the Company added a new Chief Financial Officer, a financial controller and an additional staff member to the finance function. The Company anticipates that the additional resources added during the first six months of 2008 will allow the company to remediate the material weakness described above during the course of fiscal 2008.

Even if we are to successfully remediate the material weakness described above, because of inherent limitations, our disclosure controls and procedures may not prevent or detect misstatements or material omissions. Projections of 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.



---

**Table of Contents**

(b) Changes in Internal Controls

There were no changes in our internal controls over financial reporting that occurred during the period covered by this Quarterly Report on 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**

Management believes that claims which are pending or known to be threatened, will not have a material adverse effect on the Company's financial position or results of operations and are adequately covered by the Company's liability insurance. However, it is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

**Item 1A. Risk Factors  
Factors That May Affect Future Results**

In addition to the other information contained in this Quarterly Report Form 10-Q, we have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, common stock price, 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. 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.

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, 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 believe there is significant risk as to whether our current liquidity and capital resources will be sufficient to meet our currently 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

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

management expects to be able to meet these covenants. However, recent operating results indicate that there is significant risk in achieving these goals. 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 in September 2008.

Our independent registered public accounting firm, Burr, Pilger, & Mayer LLP, issued an opinion in connection with their audit of our financial statements for the fiscal year ended December 29, 2007 which stated, that there was substantial doubt as to our ability to continue as a going concern.

*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 \$6 million outstanding against our current line of credit. The increased levels of debt and obligations do among other things:

require us to dedicate a substantial portion of our cash flow from operations to payments on our debt and obligations, thereby reducing funds available for working capital, capital expenditures, acquisitions and other purposes;

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;

---

**Table of Contents**

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.

*The Company May Not Realize The Anticipated Benefits of Our Acquisition of the Aesthetics Business of Laserscope.*

On January 16, 2007, we completed our acquisition of the aesthetics business of Laserscope (the Aesthetics Business), a wholly-owned subsidiary of AMS. To date, we have not realized the anticipated benefits of the acquisition and our ability to realize the anticipated benefits of the acquisition will depend, in part, on our ability to integrate the Aesthetics Business with our business and to take full advantage of the domestic and international sales channels. For example, immediately following the completion of the acquisition the domestic sales force consisted of 28 sales personnel; however, subsequent to the acquisition, there was a high turnover in the sales force, resulting in a significant decrease and as of December 29, 2007, the sales force consisted of 5 sales personnel. In fiscal year 2008, we are rebuilding our U.S. aesthetics sales force and as of September 27, 2008, the sales force consisted of 5 sales personnel. Integrating the Aesthetics Business has been expensive and time-consuming and we may not be able to successfully complete the process. These integration efforts have taken a significant amount of time, placed a significant strain on managerial, operational and financial resources and proven to be more difficult and more expensive than predicted. The diversion of our management's attention and any delays and difficulties encountered in connection with integrating the Aesthetics Business could continue to result in the disruption of our on-going business or inconsistencies in standards, controls, procedures and policies that could negatively affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. These disruptions could harm our operating results.

We cannot assure you that the combination of the Aesthetics Business with us will result in the realization of the full benefits anticipated from the acquisition.

*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.*

Continued expansion of the global market for laser- and other light-based aesthetics procedures is a material assumption of our growth strategy. 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 utilize our aesthetics products may therefore be influenced by a number of factors, including:

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

the success of our sales and marketing efforts;

evolving customer needs;

the introduction of new products and technologies;

evolving surgical practices;

evolving industry standards;

the cost of procedures performed using our products; and

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

---

**Table of Contents**

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

*Failure to Remediate the Material Weaknesses in Our Disclosure Controls and Procedures in a Timely Manner, or at All, 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 and based on this evaluation, management concluded that our disclosure controls and procedures were not effective because of the material weaknesses detailed in Item 4T of Part I of this Quarterly Report on Form 10-Q.

In particular, the material weaknesses identified related to the Company's staffing levels that impacted our ability to implement the remediation plan designed to address the material weakness identified in last year's Annual Report concerning period-end review procedures. We are taking a number of steps designed to remedy the material weaknesses summarized above, including hiring a Chief Financial Officer and other staff members of the finance function, including a financial controller. However, if despite our remediation efforts, we fail to remediate our material weaknesses, we could be subject to regulatory scrutiny and a loss of public confidence in our disclosure controls and procedures. These remediation efforts will likely increase our general and administrative expenses and could, therefore, have an adverse effect on our reported net income.

Even if we are to successfully remediate such material weaknesses, because of inherent limitations, our disclosure controls and procedures may not prevent or detect misstatements or material omissions. Projections of 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.

*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;

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 disposable laser probes, EndoProbes and service. Our ability to increase recurring revenues from the sale of laser probes 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.

---

## **Table of Contents**

### *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.

### *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 Lumenis Ltd., Nidek Co. Ltd, Carl Zeiss Meditec AG, Ellex Medical Lasers Ltd, Alcon Inc., and Synergetics. 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.

In aesthetics our principal competitors are Syneron, Candela Corporation, Palomar Technologies, Inc., Cutera, 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.





---

**Table of Contents**

*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.

*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 five 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 (disposable & non-disposable) 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 disposable laser probe products. Expiration of this patent may increase competition from our competitors for our disposable laser probe 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 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.

**Table of Contents**

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.

*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 September 27, 2008, our international sales were \$4.6 million or 38.6% 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 subsidiaries. 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:

fluctuations in foreign currency exchange rates;

differing local product preferences and product requirements;

cultural differences;

changes in foreign medical reimbursement and coverage policies and programs;

political and economic instability;

impact of recessions in economies outside of the United States;

difficulty in staffing and managing foreign operations;

performance of our international channel of distributors;

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;

longer accounts receivable collection periods;

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, especially following our acquisition of the aesthetics business of Laserscope, 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 are uncertain as to the withholding tax exposure relating to our overseas subsidiaries.*

Management has determined that there was a probable underpayment of withholding tax concerning its overseas subsidiaries relating to periods prior to the Company's acquisition of these subsidiaries. The range of the underpayment including penalties and interest is estimated by management to be \$644,000 to \$1,877,000. The acquisition of the overseas subsidiaries is governed by the Purchase Agreement which provides the Company with indemnification by AMS in certain situations, including situations relating to unpaid taxes, and management of the Company is of the opinion that this exposure will be indemnified by AMS.

We can not assure you that relevant taxing authorities will agree with management's estimate and therefore the ultimate tax exposure may differ significantly. There may be further withholding tax exposures of which management is unaware and the final resolution may not be covered by the indemnification offered by AMS in the Purchase Agreement.

---

**Table of Contents**

*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 24 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.

*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.

---

**Table of Contents**

*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. During the fourth quarter of 2007, we received \$3.7 million in additional aesthetics inventory from AMS in connection with the acquisition of the aesthetics business of Laserscope. At that time, with the exception of some aesthetics products which are not being transferred to the Company, we assumed primary responsibility for manufacturing the aesthetics product line that we acquired from Laserscope and we will be integrating this operation into our current facility and manufacturing organization. We may not have sufficient resources to assume these manufacturing obligations without increased costs or delays and disruptions in manufacturing. 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.

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. In order to address our current liquidity issues, we have delayed the time period in which we have made payments to our vendors that are the sources of our component supply without the permission of such vendors. 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. For example, in 2005 we developed and sold a laser system on an OEM basis for a third party which positively impacted the revenues and gross margins during the second half of 2005, but did not continue. We cannot provide assurance that these types of relationships will continue over a longer period. Our reliance on others for clinical development,

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

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.

---

**Table of Contents**

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

We depend on both clinical and commercial collaborative relationships. We entered into a Product Supply Agreement with AMS in connection with the acquisition of the aesthetics business of Laserscope, pursuant to which AMS currently manufactures several of our aesthetics products. With the exception of some service parts and the balance of finished goods ordered from AMS, we have transitioned the manufacturing for the majority of these products to our facilities during the fourth quarter of 2007, but we may not have sufficient resources to assume these manufacturing obligations without increased costs or delays and disruptions in manufacturing. We are party to a Manufacture and Supply Agreement with Synergetics, Inc. pursuant to which Synergetics will manufacture the Company's line of adjustable laser probes on a non-exclusive basis, which represents one model of our disposable laser probe offering. 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.

*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;

**Table of Contents**

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 current liquidity issues;

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 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 in each of the last six quarters ended starting with the quarter ended March 31, 2007 through the quarter ended September 27, 2008. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarter. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

*Our Stock Price Has Been and May Continue to be Volatile and an Investment in Our Common Stock Could Suffer a Decline in Value.*

The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. In addition, the trading price of our common stock has been significantly adversely affected by our recent operation performance and by liquidity issues. In the fiscal year ended December 29, 2007, the trading price of our common stock fluctuated from a high of \$10.70 per share to a low of \$2.20 per share. During the nine month period ending September 27, 2008, the trading price of our common stock fluctuated from a high of \$4.29 per share to a



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

low of \$1.49 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.

---

## **Table of Contents**

### *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 interest rates increase, these financing arrangements will be more expensive to our customers, which would effectively increase the overall cost of owning our products for our customers and thereby, 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 Regulation Which May Cause Us to Delay or Withdraw the Introduction of New Products or New Applications for Our Products.*

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

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

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

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

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

## **Table of Contents**

*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 pre-market approval. We may not be able to obtain additional 510(k) clearance or pre-market 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.

*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 sales may be required in future periods.

---

**Table of Contents**

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 business 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.

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

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

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.

---

## **Table of Contents**

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.

### *Our Export Controls May Not be Adequate to Ensure Compliance With United States Export Laws, Especially When We Sell Our Products to Distributors Over Which We Have Limited Control.*

The United States government has declared an embargo that restricts the export of products and services to a number of countries, including Iran, Syria, Sudan and Cuba, for a variety of reasons, including the support by these countries of terrorism. We sell our products through distributors in Europe, Asia and the Middle East, and in such circumstances the distributor is responsible for interacting with the end user of our products, including assisting in the set up of any products purchased by such end user. In order to comply with United States export laws, we have instituted export controls including training for our personnel in export restrictions and requirements, appointing an export control officer to oversee our export procedures, executing agreements with our distributors that include defining their territory for sale and requirements pertaining to United States export laws, obtaining end user information from our distributors and screening it to restricted party lists maintained by the United States government. While we believe that these procedures are adequate to prevent the export or re-export of our products into countries under embargo by the United States government, we cannot assure you that our products will not be exported or re-exported by our distributors into such restricted countries. In particular, our control over what our distributors do with our products is necessarily limited, and we cannot assure you that they will not sell our products to an end user in a country in violation of United States export laws. Any violation of United States export regulations could result in substantial legal, consulting and accounting costs, and significant fines and/or criminal penalties. In the event that our products are exported to countries under a United States trade embargo in violation of applicable United States export laws and regulations, such violations, costs and penalties or other actions that could be taken against us could adversely affect our reputation and/or have an adverse effect on our business, financial condition, prospects or results of operations.

## **Table of Contents**

We have sold and may continue to sell, with a license, our products into countries that are under embargo by the United States and as a result have incurred and may continue to incur significant legal, consulting and accounting fees and may place our Company's reputation at risk.

United States export laws permit the sale of medical products to certain countries under embargo by the United States government if the seller of such products obtains a license to do so, which requirements are in place because the United States has designated such countries as state sponsors of terrorism. Certain of our products have been sold in Iran, Sudan and Syria under license through distribution agreements with independent distributors. The aggregate revenues generated by sales of our products into Iran, Sudan and Syria have been immaterial to our business and results of operations.

We may continue to supply medical devices to Iran, Sudan and Syria and other countries that are under embargo by the United States government upon obtaining all necessary licenses. We do not believe, however, that our sales into such countries will be material to our business or results of operations. There are risks we face in selling to countries under United States embargo, including, but not limited to, possible damage to our reputation for sales to countries that are deemed to support terrorism, and failure of our export controls to limit sales strictly to the terms of the relevant license, which failure may result in civil and criminal penalties. In addition, we may incur significant legal, consulting and accounting costs in ensuring compliance with our export licenses to countries under embargo. Any damage to our reputation from such sales, failure to comply with the terms of our export licenses or the additional costs we incur in making such sales could have a material adverse impact on our business, financial condition, prospects or results of operations.

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

None.

### **Item 3. Defaults Upon Senior Securities**

None.

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

None.

### **Item 5. Other Information**

None.

### **Item 6. Exhibits**

- 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**

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

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, MicroPulse, OtoProbe, ScanLite, Symphony, VariLite and EasyFit product names are our trademarks. All other trademarks or trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.



**Table of Contents**

**SIGNATURE**

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

IRIDEX Corporation (Registrant)

Date: November 4, 2008

By: /s/ THEODORE A. BOUTACOFF

Name: Theodore A. Boutacoff

Title: President, Chief Executive Officer and Chairman

(Principal Executive Officer)

36

**Table of Contents**

**Exhibit Index**

- 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.