

IRIDEX CORP
Form 10-Q
July 09, 2007

Table of Contents

**SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

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

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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer

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

APPLICABLE TO CORPORATE ISSUERS:

The number of shares of common stock, \$.01 par value, issued and outstanding as of June 26, 2007 was 8,211,562

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Operations</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	4
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	21
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	45
<u>Item 3. Defaults Upon Senior Securities</u>	45
<u>Item 5. Other Information</u>	46
<u>Item 6. Exhibits</u>	46
<u>Signature</u>	47
<u>EXHIBIT 10.1</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (unaudted)****IRIDEX Corporation****Condensed Consolidated Balance Sheets****(in thousands)**

	March 31, 2007 (1)	December 30, 2006(2)
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,568	\$ 21,051
Accounts receivable, net	9,688	6,052
Inventories	13,244	9,499
Prepays and other current assets	2,218	1,264
Total current assets	\$ 34,718	\$ 37,866
Property and equipment, net	1,789	1,087
Goodwill	11,751	
Other intangible assets, net	15,841	
Other long term assets	324	1,224
Total assets	\$ 64,423	\$ 40,177
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 5,460	\$ 1,830
Short term debt	5,236	
Accrued compensation	1,849	1,517
Accrued expenses	9,686	2,392
Accrued warranty	2,336	866
Deferred revenue	3,685	1,415
Current portion of long term debt	5,901	
Total liabilities	\$ 34,153	\$ 8,020
Stockholders equity:		
Common stock	83	79
Additional paid-in capital	32,735	29,697
Accumulated other comprehensive loss	(9)	
Treasury stock	(430)	(430)
Retained earnings (accumulated deficit)	(2,109)	2,811
Total stockholders equity	30,270	32,157
Total liabilities and stockholders equity	\$ 64,423	\$ 40,177

- (1) Unaudited
- (2) Derived from the consolidated audited financial statements included in our report filed on Form 10-K with the SEC for the year ended December 30, 2006.

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)

	Three Months Ended	
	March 31, 2007	April 1, 2006
Sales	\$ 12,566	\$ 8,843
Cost of sales	7,357	4,581
Gross profit	5,209	4,262
Operating expenses:		
Research and development	1,729	1,121
Selling, general and administrative	8,274	3,932
Total operating expenses	10,003	5,053
Loss from operations	(4,794)	(791)
Interest and other income (expense), net	(126)	179
Loss before income taxes	(4,920)	(612)
Benefit from income taxes		309
Net loss	\$ (4,920)	\$ (303)
Net loss per share basic and diluted	\$ (0.61)	\$ (0.04)
Shares used in computing net loss per share basic and diluted	8,080	7,587

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

Table of Contents

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

	Three Months Ended	
	March	April 1,
	31,	2006
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (4,920)	\$ (303)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	802	133
Non-cash stock-based compensation	356	457
Tax benefit from stock option exercises		249
Excess tax benefit related to stock-based compensation expense		(124)
Provision for (recoveries of) doubtful accounts		(4)
Provision for inventories	285	67
Changes in operating assets and liabilities, net of assets and liabilities acquired:		
Accounts receivable	1,687	495
Inventories	(1,327)	(257)
Prepays and other current assets	36	(205)
Other long term assets	(71)	
Accounts payable	3,602	15
Accrued warranty	(543)	
Accrued expenses	880	(1,153)
Deferred revenue	393	(59)
Net cash provided by (used in) operating activities	\$ 1,180	\$ (689)
Cash flows from investing activities:		
Purchases of available-for-sale securities	\$	\$ (15,512)
Proceeds from maturity of available-for-sale securities		6,142
Purchases of property and equipment	(217)	(69)
Cash received from acquisition	5,246	
Cash acquired in acquisition paid to seller	(1,261)	
Acquisition of business	(28,151)	
Net cash used in investing activities	\$ (24,383)	\$ (9,439)
Cash flows from financing activities:		
Proceeds from issuance of common stock	\$ 672	\$ 605
Excess tax benefit related to stock-based compensation expense		124
Proceeds of credit facility, net of issuance costs	11,900	
Repayment of credit facility	(863)	
Net cash provided by financing activities	\$ 11,709	\$ 729

Effect of foreign exchange rate changes	\$ 11	\$
Net decrease in cash and cash equivalents	(11,483)	(9,399)
Cash and cash equivalents at beginning of period	\$ 21,051	\$ 12,655
Cash and cash equivalents at end of period	\$ 9,568	\$ 3,256

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

-3-

Table of Contents

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

	Three Months Ended	
	March	April 1,
	31,	2006
	2007	2006
Net loss	\$ (4,920)	\$ (303)
Other comprehensive loss:		
Change in unrealized loss on available for sale securities, net of tax		9
Foreign currency translation adjustments	(9)	
Comprehensive loss	\$ (4,929)	\$ (294)

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

-4-

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 March 30, 2007. The results of operations for the three month period ended March 31, 2007 are not necessarily indicative of the results for the year ending December 29, 2007 or any future interim period.

The Company does not expect that current cash and cash equivalents, revenue expected to be generated from operations and available credit facilities, if any, will be sufficient to meet the Company s planned operating requirements for the next 12 months. These planned requirements include amounts owing to American Medical Systems, Inc. (AMS) due to the acquisition of the assets of the aesthetics business of Laserscope (Laserscope), a subsidiary of AMS, including the return of cash to AMS obtained through the acquisition of Laserscope s foreign subsidiaries and payments for inventory under the product supply agreement (the Product Supply Agreement) the Company entered into with Laserscope in connection with the asset acquisition (see Note10 below). In addition, for the second fiscal quarter ending June 30, 2007 the Company was not able to satisfy certain restrictive financial covenants contained in its credit facilities with Mid-Peninsula Bank and the Export-Import Bank (the Lenders) as well as an affirmative covenant regarding the preparation and delivery of quarterly financial statements within 45 days of quarter end (see Note 4). The Company has received a one-time waiver from Mid-Peninsula Bank with respect to its expected inability to satisfy the financial covenants contained in its loan agreements with the Lenders for the period ended June 30, 2007, but can provide no assurance that the Lenders will grant any additional future waivers if requested. The Company was also not in compliance with its debt covenants at the end of its first quarter but it was successful in obtaining a waiver of default for that period. In the event of noncompliance the Lenders would be entitled to exercise their remedies, under these facilities, which include declaring all obligations immediately due and payable and disposing of the collateral if obligations were not paid. The Company has modified planned operations in order to increase cash flows from operations, and intends to raise additional capital through equity or debt financing in order to enhance liquidity. However, there can be no assurances that the Company will be successful in these efforts or that any additional capital raised through debt or equity financings will be available on favorable terms or at all. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty

2. Summary of Significant Accounting Policies

The Company s significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended December 30, 2006 which was filed with the Securities and Exchange Commission on March 30, 2007. During the quarter ended March 31, 2007 the Company has implemented an accounting policy for the valuation of goodwill and intangible assets.

Table of Contents*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. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments. Revenue relating to extended warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. We recognize repair service revenue upon completion of the work. Cost is recognized as product sales revenue is recognized. The Company's sales may include post-sales obligations for training or other deliverables. 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.

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

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, other 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. If assumptions and estimates used to allocate the purchase price prove to be different based on actual results, future asset impairment charges could be required.

Goodwill and intangible assets determined to have indefinite lives are not amortized, but are subject to an annual impairment test. We intend to conduct an annual goodwill impairment test in the fourth quarter of our fiscal year. 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. We have identified the aesthetics medical device segment as the appropriate reporting unit for this analysis. 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 market value. The Company assesses the recoverability of its long-lived and intangible assets by determining whether the unamortized balances can be recovered through undiscounted future net cash flows of the related assets. The amount of impairment, if any, is measured based on projected discounted future net cash flows.

Table of Contents

Goodwill and purchased intangible assets were initially recorded in the first three months of 2007 in conjunction with the acquisition of the aesthetics business of Laserscope (Note 3). Changes in the estimated fair values of these assets in the future could result in significant impairment charges or changes to our expected amortization.

Deferred Revenue

Deferred revenue related to warranty contracts is recognized on a straight line basis over the period of the applicable contract. Cost is recognized as incurred. A reconciliation of changes in the Company's deferred revenue balances for the three months ending March 31, 2007 and April 1, 2006 follows:

	Three Months Ended	
	March 31, 2007	April 1, 2006
(in thousands)		
Balance, beginning of period	\$ 1,415	\$ 1,072
Additions to deferral through acquisition	1,870	
Additions to deferral	1,976	281
Revenue recognized	(1,576)	(340)
Balance, end of period	\$ 3,685	\$ 1,013

Warranty

The Company accrues for an estimated warranty cost upon shipment of products in accordance with Statement of Financial Accounting Standards (SFAS) No. 5, Accounting for Contingencies. Actual warranty costs incurred have not materially differed from those accrued. The Company's warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications. Warranty costs are reflected in the statement of operations as a cost of sales. A reconciliation of the changes in the Company's warranty liability for the three months ending March 31, 2007 and April 1, 2006 follows:

	Three Months Ended	
	March 31, 2007	April 1, 2006
(in thousands)		
Balance, beginning of period	\$ 866	\$ 1,128
Warranty accrual acquired through acquisition	1,771	
Accruals for warranties issued during the period	356	222
Settlements made in kind during the period	(657)	(344)
Balance, end of period	\$ 2,336	\$ 1,006

Accounting for Uncertainty in Income Taxes

Effective January 1, 2007, the Company adopted Financial Accounting Standards Interpretation, or FIN, No. 48, Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109. FIN No. 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN No. 48 utilizes a two-step approach for evaluating uncertain tax positions accounted for in accordance with SFAS No. 109, Accounting for Income Taxes (SFAS No. 109). Step one, recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, measurement, is based on the largest amount of benefit, which is more likely than not to be realized on ultimate settlement. The cumulative effect of adopting FIN

Table of Contents

No. 48 on January 1, 2007 is recognized as a change in accounting principle, recorded as an adjustment to the opening balance of retained earnings on the adoption date. As a result of the implementation of FIN No. 48, the Company recognized no change in the liability for unrecognized tax benefits related to tax positions taken in prior periods. Upon adoption of FIN No. 48, the Company's policy to include interest and penalties related to unrecognized tax benefits within the Company's provision for (benefit from) income taxes did not change. The Company's total amount of unrecognized tax benefits as of January 1, 2007 (adoption date) was \$517,733. Of this amount, none would affect the Company's effective tax rate if recognized.

3. Business Combination

On January 16, 2007, the Company completed the acquisition of the aesthetics business from American Medical Systems, Inc. (AMS) and Laserscope, a wholly owned subsidiary of AMS pursuant to the terms of the Asset Purchase Agreement dated November 30, 2006 between AMS, Laserscope, and Iridex Corporation. These financial statements include the results of operations for the acquired business from the acquisition date.

Iridex purchased the aesthetics business of former Laserscope from AMS due to its complementary fit with the existing Iridex laser business. Under the terms of the Asset Purchase Agreement, Iridex Corporation purchased the aesthetics business for the following consideration:

Cash paid on closing	\$ 26,000
Issuance of common stock	2,014
Post Closing adjustment to purchase price	(675)
Acquisition costs	2,976
Total preliminary purchase price	 \$ 30,315

Issuance of common stock included 213,435 shares of common stock valued at \$9.43 per share.

Acquisition costs include investment banking, legal and accounting fees, and other external costs directly related to the acquisition.

The preliminary allocation of the purchase price to tangible and identifiable intangible assets acquired and liabilities assumed was based on their estimated fair values at the date of acquisition as determined by management. These estimates are subject to further review by management upon completion of the audit of the aesthetics business of Laserscope for the year ended December 31, 2006. Independent valuation experts assisted the Company in determining the valuation of the intangible assets acquired. Further adjustments to these estimates may be included in the final allocation of the purchase price, if the adjustment is determined within the purchase allocation period (up to twelve months of the closing date). The excess of the purchase price over the tangible and identifiable assets acquired and liabilities assumed has been allocated to goodwill. The preliminary purchase price has been allocated as follows (in thousands):

Accounts Receivable	\$ 5,309
Finished Goods Inventory	\$ 2,691
Other current assets	\$ 311
Property and equipment	\$ 681
Intangible assets	\$ 16,447
Deferred Revenue	\$ (1,870)
Accrued Warranty	\$ (1,771)
Accrued Liabilities	\$ (3,234)
Fair value of net assets acquired	\$ 18,564
Goodwill	\$ 11,751
Total preliminary purchase price	 \$ 30,315

Table of Contents

In addition, the Asset Purchase Agreement signed with AMS calls for a post-close adjustment mechanism which in effect allows for an adjustment to the final purchase price based upon the parties' agreement to the final closing balance sheet and several other items. The Company has recorded \$675,000 as due from AMS as an adjustment to the purchase price as determined under the terms of the asset purchase agreement. The Company has not reached an agreement with AMS regarding this post close adjustment, therefore, we expect there to be future adjustments to the balance sheet primarily associated with the amount owed to AMS and the amount of residual goodwill recorded related to this transaction. Included in our cash balance at March 31, 2007 is \$3.9 million of cash owed to Laserscope for cash obtained through the acquisition of the foreign subsidiaries, but not included in the asset purchase agreement. This cash will be paid to Laserscope or netted against payments owed to the Company upon settlement of the post close balance sheet adjustment.

The components of the Company's intangible assets are as follows (in thousands):

Intangible Asset Acquired	Useful Lives	Annual Amortization	Gross Carrying Value	Accumulated Amortization	Net, Carrying Value
Gemini Handset Core Technology	10 Years	\$ 299	\$ 2,995	\$ 61	\$ 2,934
Gemini Current Technology	4 Years	1,282	5,129	260	4,869
Other Products Current Technology	1 Year	341	341	69	272
Accessories Current Technology	4 Years	15	62	3	59
Services Contractual Customer Relationships	10 Years	532	5,318	108	5,210
Contractual Distribution Agreement	5 Years	370	1,848	75	1,773
Trade Name	5 Years	151	754	30	724
		\$ 2,990	\$ 16,447	\$ 606	\$ 15,841

Amortization for the technology related intangibles is being recorded in cost of goods sold and amortization for marketing related intangibles is being recorded in selling, general and administrative expense.

Through this acquisition, the Company plans to increase its sales into the aesthetic laser market and augment its core ophthalmic business with enhanced revenue and marketing opportunities. These factors primarily contributed to a purchase price which resulted in the recording of goodwill. Goodwill of \$11.8 million represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. In accordance with Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, goodwill will not be amortized but will instead be tested for impairment annually or more frequently if certain indicators are present.

Estimated future amortization expense for purchased intangible assets from the acquisition is as follows:

2007	\$ 2,849
2008	\$ 2,666
2009	\$ 2,649
2010	\$ 2,649
2011	\$ 1,413
Thereafter	\$ 4,221

Total

\$ 16,447

-9-

Table of Contents

The Company has agreed under a Product Supply Agreement with Laserscope to purchase at the end of such agreement, quantities of work-in-process, raw and packaging materials, or spare and replacement parts that have an aggregate book value determined in accordance with GAAP not to exceed \$9.0 million. Pursuant to the Product Supply Agreement this ending inventory will be non-obsolete at the time of purchase and of a quality useable in manufacturing. The Company believes this commitment as defined will result in the acquisition of material useable in its ordinary course of business through the sale or servicing of aesthetic laser products. (Note 10)

Supplemental pro forma information that discloses the results of operations for the current interim period and the prior year comparable period as though the business combination had been completed as of the beginning of the period being reported on is not available because the preparation of the financial statements of the acquired business are not complete.

4. Bank Borrowings

On January 16, 2007, the Company entered into a Business Loan and Security Agreement with Mid-Peninsula Bank, part of Greater Bay Bank N.A. and Exim Bank. The Credit Agreement provides for an asset-based revolving line of credit of up to \$6 million (the Revolving Loans) and a \$6.0 million term loan (the Term Loan). Of the Revolving Loans, up to \$3.0 million principal amount will be guaranteed by Exim Bank. The Company's obligations under the Term Loans and the Revolving Loans are secured by a lien on substantially all of the Company's assets. Interest on the Term Loan and the Revolving Loans is the prime rate as published in the Wall Street Journal, minus 0.5%. Indebtedness outstanding under the Term Loan and the Revolving Loan was \$5.9 million and \$5.2 million respectively at March 31, 2007. These facilities contain certain financial and other covenants, including the requirement for Iridex to maintain profitability on a quarterly basis, tangible net worth of \$15.5 million, maintain unrestricted cash/marketable securities of \$3 million and maintain a debt service ratio of 1.75 to 1.00 on an annual basis. At March 31, 2007, the Company was not in compliance with certain of the financial covenants contained in these agreements.

On April 19, 2007, the Company and Mid-Peninsula Bank entered into amendments to each of the loan agreements. Pursuant to the Amendments, the Company agreed to deposit and maintain \$3.8 million in cash in a segregated deposit account with Lender as collateral in support of the Term Loan and to restrict up to \$2.2 million of the combined borrowing base from the Line of Credit in support of the Term Loan. The parties agreed to eliminate the requirement that the Company maintain a minimum of \$3.0 million in aggregate domestic unrestricted cash or marketable securities. In addition, Lender increased the credit extended by Lender to the Company under the Exim Agreement from \$3.0 to \$5.0 million; however this increase only resulted in a potential increase in a guarantee by Exim Bank and did not impact the total borrowing availability under the line. In connection with the Amendments, Lender also agreed to a one-time waiver of certain financial covenants contained in the loan agreements for the quarter ended March 31, 2007. The Company does not expect to be in compliance with certain financial covenants contained in the amended loan agreements at the end of its second fiscal quarter ending June 30, 2007. In addition the Company is in violation of an affirmative covenant regarding the preparation and delivery of quarterly financial statements within 45 days of quarter end. In anticipation of this violation Mid-Peninsula Bank and Export-Import Bank on June 19, 2007 waived the default from our expected non-compliance at June 30, 2007 of the tangible net worth covenant, the minimum debt service ratio and the minimum income covenant. This waiver related only to the breach of financial covenants expected on June 30, 2007 and does not cover any subsequent breach, should one occur, of the financial covenants contained within the loan agreements.

Table of Contents

In the accompanying balance sheet, all debt under the five year term loan is classified as current portion of long-term debt due to the fact that a covenant violation has occurred at the balance sheet date or would have occurred absent a loan modification and it is probable that the Company will not be able to cure the default (comply with the covenant) at measurement dates that are within the next 12 months.

In conjunction with the issuance of this debt, the Company incurred \$0.1 million of debt issuance costs which have been capitalized and will be amortized on an effective interest basis over the term of the debt which is sixty months.

5. Inventories

Inventories are stated at the lower of cost or market and include on-hand inventory, sales evaluation inventory and service loaner inventory. The Company includes evaluation units held for sales within inventories. The Company carries the evaluation units at cost less amortization over their estimated economic life of four years. Amortization related to evaluation units is recorded in cost of sales and reflects the physical deterioration, usage and obsolescence of the products. Proceeds from the sale of evaluation units are recorded as revenue and all costs incurred to refurbish a system prior to sale are charged to cost of sales.

Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (FIFO) method. Lower of cost or market is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory and are charged to cost of goods sold. Factors influencing these adjustments include changes in demand, product life cycle and development plans, component cost trends, product pricing, physical deterioration and quality issues. Revisions to these adjustments would be required if these factors differ from our estimates. The components of inventories consist of the following:

	March 31, 2007	December 30, 2006
Raw materials and work in progress	\$ 5,455	\$ 4,000
Finished goods	7,789	5,499
Total inventories	\$ 13,244	\$ 9,499

6. Contingencies

Patent Litigation On October 19, 2005, the Company filed a suit in the United States District Court for the Eastern District of Missouri against Synergetics, USA, Inc. for infringement of a patent. The Company later amended its complaint to assert infringement claims against Synergetics, Inc.; Synergetics USA, Inc. was dismissed from the suit. The Company alleged that Synergetics infringed the Company's patent by making and selling infringing products, including its Quick Disconnect laser probes and its Quick Disconnect Laser Probe Adapter, and sought injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On April 25, 2006, Synergetics added the Company as a defendant to a then existing lawsuit in the US District Court for the Eastern District of Pennsylvania. In that litigation, Synergetics alleged that the Company infringed its patent on a disposable laser probe design.

Trial in the Missouri litigation was scheduled to begin on April 16, 2007, however on April 6, 2007 the parties reached settlement on the claims. Under the terms of the settlement agreement, the parties agreed to terminate all legal proceedings between the parties and to a fully paid-up, royalty free, worldwide cross licensing of various patents between the two companies. In consideration of these licenses Synergetics agreed to pay the Company \$6.5 million over a period of five years. The first payment of \$2.5 million by Synergetics was received on April 16, 2007, followed with annual payments of \$0.8 million on each April 16th until 2012.

Table of Contents

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.

7. Computations of Net Loss Per Common Share

Basic and diluted net loss per share are computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share includes the dilutive effect of potentially dilutive common stock provided the inclusion of such potential common stock is not antidilutive. Potentially dilutive common stock consists of incremental common shares issuable upon the exercise of stock options and a warrant to purchase common shares.

During the three months ended March 31, 2007 and April 1, 2006 options to purchase 2,306,529 and 2,131,304 shares of common stock at weighted average exercise prices of \$6.55 and \$5.70 per share, respectively, were not included in the computations of diluted net loss per common share because their effect was antidilutive. Additionally, for the three months ended March 31, 2007 and April 1, 2006 warrants to purchase 25,000 shares of common stock at an average exercise price of \$6.07 were outstanding. These options and the warrants could dilute earnings per share in future periods.

8. Business Segments

The Company operates in two reportable segments: the ophthalmology medical device segment and the aesthetics medical device segment. In each segment the Company develops, manufactures, markets and services 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 months ended March 31, 2007 and April 1, 2006 is as follows (in thousands):

	Three Months Ended March 31, 2007			Three Months Ended April 1, 2006		
	Ophthalmology Medical Devices	Aesthetics Medical Devices	Total	Ophthalmology Medical Devices	Aesthetics Medical Devices	Total
Sales	\$ 7,189	\$ 5,377	\$ 12,566	\$ 7,540	\$ 1,303	\$ 8,843
Direct cost of goods sold	2,144	2,835	4,979	2,529	683	3,212
Direct gross margin	5,045	2,542	7,587	5,011	620	5,631
Total unallocated indirect costs			(12,507)			(6,243)
Pre-tax income (loss)			\$ (4,920)			\$ (612)

Indirect costs of manufacturing, research and development, and selling, general and administrative costs are not allocated to the segments.

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**9. Stock-based Compensation***Stand-Alone Options*

In February 2007, the Compensation Committee of the Company's Board of Directors approved the grant of 235,000 non-qualified stock options, outside of the Company's existing stock plans, to a total of 54 new employees, both domestic and international, hired in connection with the Company's recently completed acquisition of the assets of the aesthetics business of Laserscope. These options were granted as of February 28, 2007 at an exercise price of \$10.06 per share.

The following table shows the pre-tax stock-based compensation expense recognized during the quarter and included in the Consolidated Statements of Operations for the three month periods ended March 31, 2007 and April 1, 2006 (in thousands):

	Quarter Ended	
	March 31, 2007	December 30, 2006
Cost of sales	\$ 26	\$ 36
Research and development	62	48
Sales, general and administrative	268	373
	\$ 356	\$ 457

10. Subsequent Events

On April 6, 2007, the Company reached settlement on the claims against Synergetics under a patent infringement action. This settlement resulted in the Company receiving payment from Synergetics of \$2.5 million in April 2007 and subsequent annual payments of \$0.8 million per year for the next five years.

On May 23, 2007 Laserscope provided the Company with notice of material breach of the Product Supply Agreement as a result of the Company's failure to timely pay invoices of approximately \$2.7 million for finished goods inventory delivered by Laserscope to the Company under the Product Supply Agreement. As of June 27, 2007 the unpaid amount was equal to approximately \$3.5 million, which consisted of amounts due under outstanding invoices plus accrued interest. As a result of this nonpayment, Laserscope is currently only selling product to the Company on a prepaid basis. Until the Company is able to bring Laserscope current on its payments under this Product Supply Agreement, Laserscope has the right to terminate the agreement which would result in all payments immediately becoming due and payable.

On June 27, 2007, the Company entered into a letter agreement (the "Letter Agreement") with Laserscope pursuant to which the parties agreed that beginning with the week of July 2, 2007, the Company will pay \$400,000 per week to Laserscope against invoices outstanding under the Product Supply Agreement, plus accrued interest thereon and that the Company will pay all outstanding invoices in full, plus accrued interest, upon the earlier of (a) two (2) business days following the closing of an equity financing or (b) July 31, 2007. The parties further agreed that upon payment in full of all outstanding invoices, plus accrued interest in accordance with the Letter Agreement the Company will have cured the breach under the Product Supply Agreement. As long as the Company complies with its obligation to make payments to Laserscope in accordance with the Letter Agreement, Laserscope will ship service parts and products to the Company on a cash in advance or confirmed letter of credit basis. In exchange for the payment schedule outlined above, Laserscope has agreed that it will not exercise its right to terminate the Product Supply Agreement as a result of the material breach described in the May 23, 2007 letter from Laserscope to the Company. If the Company fails to comply in any respect with its obligation to make timely payments to

Table of Contents

Laserscope in accordance with the Letter Agreement, Laserscope has the right to terminate the Product Supply Agreement immediately upon written notice to the Company with no additional notice period or opportunity to cure.

11. Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not believe that the adoption of the provisions of SFAS 159 will materially impact our consolidated financial position and results of operations.

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; 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 newly 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 the use of contractors and consultants and a reduction in legal fees; expectations of revenue from the settlement of litigation; levels of interest income and expense; general economic conditions; levels of international sales and our current liquidity, ability to obtain additional financing and impact of concern regarding our ability to continue as a going concern and effects of recent accounting pronouncements on our financial position. In some cases, forward-looking statements can be identified by terminology, such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, intends, potential, continue, or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements, including as a result of the factors set forth under Factors That May Affect Future Operating Results and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2007 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. Our products are sold in the United States predominantly through a direct sales force and internationally through 95 independent distributors into 107 countries.

Our revenues arise from the sale of our IRIS Medical OcuLight Systems, IQ810 lasers, VariLite, DioLite 532 systems, delivery devices, disposables and revenues from service and support activities. Our current family of OcuLight systems includes the IRIS Medical OcuLight Symphony, OcuLight SL, OcuLight SLx, OcuLight TX, OcuLight GL and OcuLight GLx laser photocoagulation systems as well as the IQ810 laser. We also produce the Millennium Endolase module which is sold exclusively to Bausch & Lomb and incorporated into their Millennium Microsurgical System.

In January 2007, the Company acquired Laserscope's aesthetics business including its subsidiaries in France and the United Kingdom (UK) from American Medical Systems Holdings (AMS). Laserscope aesthetic treatments encompass minimally invasive surgical treatments for hair removal, leg vein treatments, wrinkle removal, acne damage, sun damage and skin rejuvenation. These procedures are usually not performed in an operating room and are therefore paid for by patients without the assistance of any insurance or Medicare reimbursement. Laserscope's aesthetic products include the Gemini Laser System, Venus-i Laser Systems, Lyra-i Laser System, Aura-i Laser System featuring StarPulse and Solis IPL System. Laserscope's delivery devices VersaStat i SmartScan Plus, SmartScan, CoolSpot, Dermastats and MicronSpot Dermastats.

Table of Contents

We believe that our future growth in revenue will be based upon the successful implementation of our strategy in these areas: 1) leveraging our core business and increasing recurring revenues, 2) broadening our product lines through product innovation, and 3) successfully integrating the newly acquired aesthetics business into our core Iridex laser business.

Results of Operations

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

	Three Months Ended	
	March	April 1,
	31,	2006
	2007	2006
Sales	100.0%	100.0%
Cost of Sales	58.5%	51.8%
Gross Profit	41.5%	48.2%
Operating Expenses:		
Research and development	13.8%	12.7%
Sales, general and administrative	65.8%	44.4%
Total operating expenses	79.6%	57.1%
Loss from operations	(38.1)%	(8.9)%
Interest and other expense, net	(1.0)%	2.0%
Loss before income taxes	(39.1)%	(6.9)%
Benefit from income taxes	0.0%	3.5%
Net loss	(39.1)%	(3.4)%

The following table sets forth for the periods indicated the amount of sales for our operating segments and sales as a percentage of total sales of medical devices for the ophthalmology and aesthetics segments.

	Three Months Ended			
	March 31, 2007		April 1, 2006	
	Amount	Percentage	Amount	Percentage
		of		of
		total sales		total sales
Domestic	\$ 6,675	53.1%	\$ 5,130	58.0%
International	5,891	46.9%	3,713	42.0%
Total	12,566	100.0%	8,843	100.0%
Ophthalmology:				
Domestic	4,007	31.9%	4,094	46.3%
International	3,182	25.3%	3,446	39.0%
Total	7,189	57.2%	7,540	85.3%

Aesthetics:				
Domestic	2,668	21.2%	1,036	11.7%
International	2,709	21.6%	267	3.0%
Total	\$ 5,377	42.8%	\$ 1,303	14.7%

Ophthalmology and Aesthetics Sales Overview:

We manage and evaluate our business in two segments – ophthalmology medical devices and aesthetic medical devices. We further break down these segments by geography – Domestic (United States) and International (the rest of the world). In addition, within ophthalmology, we review trends by laser system sales (laser boxes and delivery devices) and recurring sales (single use disposable probes, EndoProbes.) The newly acquired Laserscope aesthetics business is included in the aesthetic segments.

Table of Contents

Total sales increased by 42.1% to \$12.6 million for the three months ended March 31, 2007 from \$8.8 million for the three months ended April 1, 2006. Domestic sales, which represented 53.1% of total sales, increased 30.1% to \$6.7 million for the three month period ended March 31, 2007 from \$5.1 million for the three months ended April 1, 2006. The increase in domestic sales was the result of a \$0.7 million increase in domestic aesthetic revenue and a \$1.1 million increase in domestic service revenue largely attributable to the newly acquired Laserscope business offset by a \$0.2 million decrease in domestic ophthalmology revenue. International sales, which represented 46.9% of total sales, increased 58.7% to \$5.9 million for the three month period ended March 31, 2007 from \$3.7 million for the three months ended April 1, 2006. The increase in international sales was the result of a \$2.4 million increase in international aesthetic revenue and a \$0.1 million increase in international service revenue largely attributable to the newly acquired Laserscope aesthetics business offset by a \$0.3 million decrease in international ophthalmology revenue.

Ophthalmology Sales

Ophthalmology sales decreased 4.6% to \$7.2 million for the three month period ended March 31, 2007 from \$7.5 million for the three months ended April 1, 2006. For the three month period ended March 31, 2007, domestic ophthalmology sales decreased 2.1% to \$4.0 million from \$4.1 million for the three months ended April 1, 2006, primarily as a result of a \$0.3 million decrease in OEM business. International ophthalmology sales for the three month period ended March 31, 2007 decreased 7.7% to \$3.2 million, from \$3.4 million for the three months ended April 1, 2006. The decrease in international ophthalmology sales during the period was due to a \$0.3 million decrease in laser console sales offset by a \$0.1 million increase in sales of recurring disposable probes.

Aesthetic Sales

Aesthetic sales increased \$4.1 million from \$1.3 million for the three month period ended April 1, 2006 to \$5.4 million for the three month period ended March 31, 2007. Domestic aesthetic sales increased to \$2.7 million for the three month period ended March 31, 2007 from \$1.0 million for the three month period ended April 1, 2006. International aesthetic sales increased \$2.4 million from \$0.3 million for the three month period ended April 1, 2006 to \$2.8 million for the three month period ended March 31, 2007. The increase in aesthetic revenue was due to the addition of the newly acquired Laserscope business.

Gross Margin

Gross profit increased by \$0.9 million to \$5.2 million for the three months ended March 31, 2007 compared to \$4.3 million for the three months ended April 1, 2006. Gross profit as a percentage of sales for the three months ended March 31, 2007 decreased to 41.5% from 48.2% for the comparable prior year three month period. The total 6.7% decrease in gross profit as a percentage of sales during this period resulted from a 3.3% increase in overhead spending combined with a 3.7% increase in direct costs which included amortization expense of recently acquired intangible assets related to product technology. The overhead spending was primarily the result of increased expenses for the newly acquired field service organization, and increased spending related to manufacturing integration activities. Direct cost margins were unfavorably impacted by the higher mix of international aesthetic sales which typically generate lower average selling prices. Margins for our ophthalmic Iridex products improved slightly compared to prior year levels.

Our immediate margin improvement efforts are focused on achieving planned manufacturing cost efficiencies from integration of the Laserscope products with existing manufacturing capacity. Integration is

Table of Contents

expected to be completed by the end of the current fiscal year. In addition we are working to streamline the structure and efficiency of the newly acquired field service business. Overall, gross margins as a percentage of sales will continue to fluctuate due to the product mix of sales, costs associated with future product introductions, changes in the relative proportions of domestic and international sales, and a variety of other factors. See 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 includes the cost of research and product innovation efforts. Research and product innovation expenses increased by 54.2% to \$1.7 million, or 13.7% of net sales, in the first quarter of 2007 from \$1.1 million, or 12.7% of net sales, in the first quarter of 2006. The increase in spending in the first quarter of 2007 in comparison to the first quarter of 2006 related to \$0.4 million in increased salary expense associated with increased headcount and increased consultant and project spending of \$0.2 million associated with increased development efforts. R&D spending is targeted to approximate 9.0% of net sales in our planned business model.

Selling, General and Administrative

Selling, general and administrative expense increased in the first quarter of 2007 by \$4.3 million to \$8.3 million or 65.8% of net sales from \$3.9 million or 44.4% of net sales in the first quarter of 2006. The increase related primarily to higher salary due to increased headcount and associated selling expenses of \$0.8 million, \$0.7 million for increased marketing headcount and aesthetics related marketing programs and \$0.8 million of expense incurred in the two acquired Laserscope entities in the France and the United Kingdom. In addition general and administrative expense increased \$1.6 million due to an increase in legal fees of \$0.8 million in support of litigation, increased accounting fees of \$0.3 million and increased spending on consultants and contractors of \$0.3 million hired in support of the Laserscope integration activities, and \$0.2 million of amortization expense associated with marketing intangibles. We are planning to reduce the overall level of selling, general and administrative spending in future quarters through reduced spending programs, a reduction in the use of consultants and contractors and a reduction in legal expense due to the settlement of the Synergetics litigation.

Amortization of purchased intangibles

In the first quarter of 2007, we completed the acquisition of the aesthetics business from Laserscope. Amortization of intangible assets acquired from Laserscope was \$0.6 million recorded in the first quarter of 2007. \$0.4 million of this total was allocated to cost of goods sold since it relates to product technology intangibles. The remaining \$0.2 million of marketing amortization expense is recorded in selling, general and administrative expenses. We expect quarterly amortization expense of \$0.5 million to be recorded in cost of goods sold and \$0.3 million of amortization expense to be recorded in selling, general and administrative expenses for each of the remaining three quarters in 2007.

Interest and Other (expense) income, net.

For the three months ended March 30, 2007 amounts included in Interest and Other Expense, net consisted of interest expense of \$0.1 million on newly acquired debt. For the three months ended April 1, 2006 other income was \$0.2 million and consisted of interest income on available for sale securities. We do not expect to earn interest income in the near future and instead expect to incur interest expense related to our new credit facility.

Table of Contents*Income Taxes*

Significant components affecting the effective tax rate include pre-tax net income or 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. The effective income tax rate for the three month period ending April 1, 2006 was 50.5%. The change in the effective tax rate was driven primarily by the accounting for certain benefits associated with stock compensation expense commencing in 2006. In 2007 we do not anticipate recording a tax provision until we determine it is appropriate to revise the valuation allowance.

Liquidity and Capital Resources

The Company does not expect that current cash and cash equivalents, cash flow expected to be generated from operations and available credit facilities, if any, will be sufficient to meet the Company's planned operating requirements for the next twelve months.

Generally, the Company's principal sources of liquidity are cash from operations and borrowings under our credit facility. As of March 31, 2007 we had \$9.5 million of cash and cash equivalents. Our cash and cash equivalents decreased by \$11.5 million during the three months ended March 31, 2007. This decrease is due to acquisition related payments, partially offset by financing activities. In the first three months of 2007, cash provided by operations was \$1.2 million. Significant changes in working capital accounts, net of amounts related to the acquisition were:

a \$1.7 million decrease in accounts receivable;

a \$1.3 million increase in inventory;

a \$3.6 million increase in accounts payable, and

a \$0.9 million increase in accrued expenses.

The Company generated positive cash flow from operations despite the \$4.9 million loss for the quarter due to non-cash charges of approximately \$1.15 million and increases in accounts payable and accruals of \$4.9 million. In future periods as accounts payable and accruals are reduced, cash flow from operations will be reduced.

In the first three months of 2007, cash flow used in investing activities was \$24.4 million primarily related to the acquisition of the aesthetics business of Laserscope. In the first three months of 2007, cash flows from financing activities included proceeds from the issuance of common stock under our equity based stock compensation plans of \$0.7 million and \$11.9 million of cash from the draw-down of our current credit facility. Included in our cash balance at March 31, 2007 is \$4.0 million of cash owed to Laserscope for cash obtained through the acquisition of the foreign subsidiaries, but not included in the asset purchase agreement. This cash will be paid to Laserscope or netted against payments owed to the Company upon settlement of the post close balance sheet adjustment.

The Company has agreed under a product supply agreement (the "Product Supply Agreement") with Laserscope to purchase at the end of such agreement, quantities of work-in-process, raw and packaging materials, or spare and replacement parts that have an aggregate book value determined in accordance with GAAP not to exceed \$9.0 million. Pursuant to the Product Supply Agreement this ending inventory will be non-obsolete and of a quality useable in manufacturing. The Company believes this commitment as defined will result in the acquisition of material useable in its ordinary course of business through the sale or servicing of aesthetic laser products.

We are currently not able to make payments on all of our outstanding obligations as they come due, including obligations of approximately \$3.5 million, which consists of amounts due under outstanding invoices plus accrued interest owed to Laserscope pursuant to the Product Supply Agreement. On June 27, 2007, the Company entered into a letter agreement (the "Letter Agreement") with Laserscope pursuant to

Table of Contents

which the parties agreed that beginning with the week of July 2, 2007, the Company will pay \$400,000 per week to Laserscope against invoices outstanding under the Product Supply Agreement, plus accrued interest thereon and that the Company will pay all outstanding invoices in full, plus accrued interest, upon the earlier of (a) two business days following the close of a equity financing or (b) July 31, 2007. The parties further agreed that upon payment in full of all outstanding invoices, plus accrued interest in accordance with the Letter Agreement, the Company will have cured the breach under the Product Supply Agreement. As long as the Company complies with its obligation to make payments to Laserscope in accordance with the Letter Agreement, Laserscope will ship service parts and products to the Company on a cash in advance or confirmed letter of credit basis. In exchange for the payment schedule outlined above Laserscope has agreed it will not exercise its right to terminate the Product Supply Agreement as a result of the material breach described in the May 23, 2007 letter from Laserscope to the Company. If the Company fails to comply in any respect with its obligation to make timely payments to Laserscope in accordance with the Letter Agreement, Laserscope has the right to terminate the Product Supply Agreement immediately upon written notice to the Company with no additional notice period or opportunity to cure.

In April 2007, we received \$2.5 million from Synergetics in settlement of a patent infringement claim and expect to receive subsequent annual payments of \$0.8 million per year for the next five years.

The Company expects that for the second fiscal quarter ending June 30, 2007 the Company will not be able to satisfy certain restrictive financial covenants contained in its credit facilities with Mid-Peninsula Bank and Exim Bank. In anticipation of this violation Mid-Peninsula Bank and Export-Import Bank on June 19, 2007 waived the default from our expected non-compliance at June 30, 2007 of the tangible net worth covenant, the minimum debt service ratio and the minimum income covenant. This waiver relates only to the breach of financial covenants expected on June 30, 2007 and does not cover any subsequent breach, should one occur, of the financial covenants contained within the loan agreements. The Company has modified planned operations in order to increase cash flows from operations, and intends to raise additional capital through equity or debt financing in order to enhance liquidity. However, there can be no assurances that the Company will be successful in these efforts or that any additional capital raised through debt or equity financings will be available on favorable terms or at all.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not believe that the adoption of the provisions of SFAS 159 will materially impact our consolidated financial position and results of operations.

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

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities or our debt instruments. We have no holdings of derivative or commodity instruments.

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, our current credit facility and any future financing requirements.

Table of Contents

Qualitative Disclosures

Interest Rate Risk.

Our primary interest rate risk exposures for the periods covered by this report relate to the impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

Currency Rate Risk.

Historically, we have denominated our sales both domestically and internationally in US dollars. With the acquisition of the Laserscope aesthetics business we have acquired two foreign subsidiaries that make sales and incur the majority of their expenses in their local currencies. These subsidiaries operate in France and the United Kingdom and their currencies are the Euro and Pounds Sterling respectively. Monthly income and expense from these operations are translated using average rates and balance sheets are translated using month end rates. Differences are recorded within stockholders' equity as a component of accumulated other comprehensive income (loss) or to the statement of operations, as applicable. As our revenues denominated in currencies other than the dollar increase, we have an increased exposure to foreign currency rate risk. Based on our overall exposure for foreign currency at March 31, 2007, a hypothetical 10% change in foreign currency rates would not have a material impact on our net sales and operating expenses. We may elect to mitigate this rate risk, in part or in whole, through the purchase of forward currency contracts.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Our management evaluated, with the participation of our 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. 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.

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, our assets are safeguarded against unauthorized or improper use and its transactions are properly recorded and reported, 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 control over financial reporting are included within our disclosure controls and procedures, they are included in the scope of our quarterly controls evaluation.

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 following control deficiencies constitute a material weakness in our internal control over financial reporting as of March 31, 2007.

Table of Contents

In connection with the annual audit of our financial statements as of December 30, 2006, our independent registered public accounting firm communicated to our management and the Audit Committee of the Board of Directors that they had identified a control deficiency that existed in the design or operation of our internal controls over financial reporting that they considered to be a material weakness, because the control deficiency resulted in more than a remote likelihood that a material misstatement could occur in our annual financial statements and not be prevented or detected. Specifically, the material weakness identified by our independent accountants relates to a failure to maintain adequate period-end review procedures to ensure the completeness and accuracy of certain journal entries impacting general ledger accounts. As a result, an error in a system generated custom inventory report and errors in two key spreadsheets related to warranty and deferred revenue resulted in incorrect entries being recorded to the financial statements which were not identified and corrected by management in a timely manner.

Plan for remediation of material weaknesses

To address the material weaknesses in our internal control over financial reporting identified above, management has designed a remediation plan which will supplement the existing controls of the Company. The remediation plan addresses the following corrective actions:

implementation of additional controls over the preparation and review of key spreadsheets;

implementation of automated general ledger reports to replace existing key spreadsheets where possible;

implementation of additional review procedures; and

enhancement of the current capabilities of the finance function.

We began implementing certain corrective actions relating to our period-end review procedures subsequent to the three month period covered by this Quarterly Report on Form 10-Q. We believe that once all of these corrective actions are implemented, including the enhancement of the capabilities of the finance function, the material weaknesses that were identified will be mitigated.

Even if we are to successfully remediate each of the material weaknesses 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.

(b) Changes in Internal Controls

There were 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. These changes relate to the acquisition of two foreign subsidiaries operating in the countries of France and the United Kingdom. We are in the process of integrating these foreign subsidiaries which have internal control and disclosure procedures that were not designed or maintained for public company reporting. We will focus our efforts on improving their internal control over financial reporting during the remainder of this year.

During February 2007, the Company enhanced the current capabilities of the Company's finance function by adding a new Chief Financial Officer.

Table of Contents**PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

Patent Litigation On October 19, 2005, the Company filed a suit in the United States District Court for the Eastern District of Missouri against Synergetics, USA, Inc. for infringement of a patent. The Company later amended its complaint to assert infringement claims against Synergetics, Inc.; Synergetics USA, Inc. was dismissed from the suit. The Company alleged that Synergetics infringed the Company's patent by making and selling infringing products, including its Quick Disconnect laser probes and its Quick Disconnect Laser Probe Adapter, and sought injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On April 25, 2006, Synergetics added the Company as a defendant to a then existing lawsuit in the US District Court for the Eastern District of Pennsylvania. In that litigation, Synergetics alleged that the Company infringed its patent on a disposable laser probe design.

Trial in the Missouri litigation was scheduled to begin on April 16, 2007, however on April 6, 2007 the parties reached settlement on the claims. Under the terms of the settlement agreement, the parties agreed to terminate all legal proceedings between the parties and to a fully paid-up, royalty free, worldwide cross licensing of various patents between the two companies. In consideration of these licenses Synergetics agreed to pay the Company \$6.5 million over a period of five years. The first payment of \$2.5 million by Synergetics was paid on April 16, 2007, followed with annual payments of \$0.8 million on each April 16th until 2012.

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 or results of operation. You should carefully consider the risks described below before making an investment decision.

We do not believe that our current liquidity and capital resources will be sufficient to meet our currently planned operating requirements for the next 12 months and we may not be able to comply with the restrictive covenants contained in our loan agreements with Mid-Peninsula Bank, part of Greater Bay Bank N.A., and the Export-Import Bank, despite recent amendments to such loan agreements.

We do not believe that our current liquidity and capital resources, cash expected to be generated from operations and our ability to draw-down on our credit facilities, if at all, will be sufficient to meet our currently planned operating requirements for the next 12 months. Our concerns about our ability to satisfy our liquidity requirements over the next 12 months are primarily a result of our current operating performance relative to plan, as well as our continuing losses, negative cash flows and current liquidity in relation to future obligations, including our obligations to make payments to Laserscope under the Product Supply Agreement

Table of Contents

including currently outstanding invoices of approximately \$3.5 million and up to \$9.0 million for raw material and work in process inventory payable upon termination of the Product Supply Agreement and our inability to satisfy certain covenants under our loan agreement with Mid-Peninsula Bank, part of Greater Bay Bank N.A., and the Export-Import Bank (the Lenders) as of June 30, 2007 and our potential inability to satisfy the covenants contained in these agreements, as amended, in the future.

Our recent and current operating performance has not met our expectations, primarily as a result of our inability to realize the full benefits of the acquisition of the aesthetics business of Laserscope in our previously anticipated time frame, as well as recent negative cash flows from operations. In particular, revenues from the aesthetics business have been below our expectations. Our ability to realize the potential benefits of the acquisition will depend, in part, on our ability to integrate the aesthetics business. As expected, our efforts towards integrating the aesthetics business of Laserscope has and will continue to take a significant amount of time and place a significant strain on our managerial, operational and financial resources, and may continue to be more difficult and expensive than originally anticipated. This continued diversion of our management's attention and any additional delays or difficulties encountered in connection with the integration of the aesthetics business could harm our operating results and increase the difficulty of our being able to satisfy our liquidity requirements.

In addition, as of March 31, 2007, we were not able to satisfy certain restrictive covenants contained in our credit facilities with the Lenders. On April 19, 2007, we entered into amendments with the Lenders pursuant to which, (i) we agreed to deposit and maintain \$3.8 million in cash in a segregated deposit account with the Lenders as collateral in support of our term loan and to restrict up to \$2.2 million of the combined borrowing base from our line of credit in support of the term loan, and (ii) the parties agreed to eliminate the requirement that we maintain a minimum of \$3.0 million in aggregate domestic unrestricted cash or marketable securities. The Lenders also agreed to increase the credit extended to the Company under the agreement with the Export-Import Bank from \$3.0 to \$5.0 million. In connection with these amendments, Mid-Peninsula Bank agreed to a one-time waiver of certain financial covenants contained in the loan agreements with the Mid-Peninsula Bank. This one-time waiver does not apply to any other potential future breaches of any of the financial covenants by the Company contained in the agreements with the Lenders. Compliance with the financial covenants for which such waiver was obtained is evaluated on a quarterly basis and the Lenders may not be willing to grant additional waivers if we fail to comply with restrictive covenants in the future.

If we default on these credit facilities and the Lenders exercise their remedies, this will further contribute to the difficulties we expect to face in meeting our liquidity requirements over the next 12 months. Our obligations under these credit facilities are secured by a lien on substantially all of the Company's assets. We currently have drawn down \$11.1 million under this credit facility which is the full amount currently available, and, given our current financial status, we currently do not expect to be able to satisfy the restrictive covenants relating to these facilities as of June 30, 2007. In the event of default by the Company with the covenants under these facilities, the Lenders would be entitled to exercise their remedies, which include declaring all obligations immediately due and payable and disposing of the collateral if obligations were not paid. Although we entered into amendments to the loan agreements with the Lenders in order to enhance our ability to comply with the restrictive covenants contained therein, we cannot assure you that we will be able to comply with these covenants in the future and do not expect to be in compliance as of the end of the fiscal quarter ending June 30, 2007. In anticipation of this violation Mid-Peninsula Bank and Export-Import Bank on June 19, 2007 waived the default from our expected non-compliance at June 30, 2007 of the tangible net worth covenant, the minimum debt service ratio and the minimum income covenant. This waiver related only to the breach of financial covenants expected on June 30, 2007 and does not cover any subsequent breach should one occur, of the financial covenants contained within the loan agreements. See Note 4 of Notes to Consolidated Financial Statements in Item 1 of Part I of this report for more information regarding these credit facilities.

Table of Contents

We are not currently able to make payments on all of our outstanding obligations as they come due, including obligations of approximately \$3.5 million currently owed to Laserscope as of June 27, 2007 pursuant to the Product Supply Agreement we entered into with Laserscope in connection with the acquisition of the aesthetics business of Laserscope. On May 23, 2007 Laserscope provided the Company with notice of material breach of the Product Supply Agreement as a result of the Company's failure to timely pay invoices of approximately \$2.7 million for finished goods inventory delivered to the company under the agreement. On June 27, 2007, the Company entered into a letter agreement (the Letter Agreement) with Laserscope pursuant to which the parties agreed that beginning with the week of July 2, 2007, the Company will pay \$400,000 per week to Laserscope against invoices outstanding under the Product Supply Agreement, plus accrued interest thereon and that the Company will pay all outstanding invoices in full, plus accrued interest, upon the earlier of (a) two (2) business days following the closing of an equity financing or (b) July 31, 2007. The parties further agreed that (i) upon payment in full of all outstanding invoices, plus accrued interest in accordance with the Letter Agreement the Company will have cured the breach under the Product Supply Agreement, (ii) for so long as the Company complies with its obligation to make payments to Laserscope in accordance with the Letter Agreement, Laserscope will ship service parts and products to the Company only on a cash in advance or confirmed letter of credit basis, and (iii) after the Company has paid in full all outstanding invoices, plus accrued interest, in accordance with the Letter Agreement, Laserscope will ship service parts and products to the Company under the Product Supply Agreement only on a cash in advance or confirmed letter of credit basis for the remaining term of the Product Supply Agreement. In exchange for the Company's agreements under the Letter Agreement, Laserscope agreed that for so long as the Company complies with its obligation to make payments to Laserscope in accordance with the Letter Agreement, Laserscope will not exercise its right to terminate the Product Supply Agreement as a result of the material breach described in the May 23, 2007 letter from Laserscope to the Company. If the Company fails to comply in any respect with its obligation to make timely payments to Laserscope in accordance with the Letter Agreement, Laserscope has the right to terminate the Product Supply Agreement immediately upon written notice to the Company with no additional notice period or opportunity to cure.

In order to address our liquidity issues, we plan to, among other things: (i) work towards integrating the aesthetics business as quickly and efficiently as possible and maximizing the potential benefits that may be realized from the acquisition, (ii) modify our planned operations in order to increase our cash flows from operations, (iii) seek to further restructure or replace our current credit facilities, and (iv) raise additional capital through equity or debt financing in order to enhance our liquidity.

We cannot assure you that we will be successful in these efforts or that any additional capital raised through debt or equity financings will be available on favorable terms or at all or that any additional capital raised will be sufficient to address our liquidity or capital resources needs. If we are unsuccessful in these efforts, we may have to suspend or cease operations or significantly dilute our stockholders' equity holdings.

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

In order to complete the acquisition, we entered into financing arrangements that provide for a \$6 million term loan and a revolving credit line of up to \$6 million. We had no debt outstanding at December 30, 2006. We had \$12 million outstanding on January 17, 2007 when the acquisition of the aesthetics business of Laserscope was consummated. We also used the majority of our liquid resources to finance the acquisition of the aesthetics business of Laserscope. Upon the transfer of the manufacturing of the Laserscope products from Laserscope to us, we are required to purchase up to \$9 million of raw materials

Table of Contents

inventory from Laserscope. As a result of the increase in debt, demands on our cash resources have increased following the completion of the acquisition. The increased levels of debt could, among other things:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our debt, thereby reducing funds available for working capital, capital expenditures, acquisitions and other purposes;
- making it more difficult for us to meet our payment and other obligations under our outstanding debt;
- increase our vulnerability to, and limit our flexibility in planning for, adverse economic and industry conditions;
- increase our sensitivity to interest rate increases on our indebtedness with variable interest rates;
- result in an event of default if we fail to comply with the financial and other restrictive covenants contained in our debt agreements, which event of default could result in all of our debt becoming immediately due and payable;
- affect our credit rating;
- limit our ability to obtain additional financing to fund future working capital, capital expenditures, additional acquisitions and other general corporate requirements;
- create competitive disadvantages compared to other companies with less indebtedness; and

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

As a result of the above, we are currently unable to satisfy certain restrictive financial covenants contained in our loan agreements and may not be able to do so in the future. In the event of default by the Company with the covenants under these facilities, the Lenders would be entitled to exercise their remedies which would include declaring all obligations immediately due and payable and disposing of the collateral if obligations were not paid.

Our Loan Agreements Contain Covenant Restrictions that May Limit Our Ability to Operate Our Business and To Service Our Indebtedness, We Will Require a Significant Amount of Cash. Our Ability to Generate Cash Flow Depends on Many Factors Beyond Our Control.

Our ability to meet our payment and other obligations under our debt depends on our ability to generate significant cash flows in the future. This, to some extent, is subject to general economic, financial, competitive, legislative and regulatory factors as well as other factors that are beyond our control. We cannot assure holders that our business will generate cash flow from operations, or that future borrowings will be available to us under our credit facilities or otherwise, in an amount sufficient to enable us to meet our payment obligations under our debt and to fund other liquidity needs. Our loan agreements contain covenant restrictions that may limit our ability to operate our business. As discussed above, we are currently unable to satisfy certain restrictive financial covenants contained in our loan agreements and may not be able to do so in the future. In the event of default by the Company with the covenants under these facilities, the Lenders would be entitled to exercise their remedies which would include declaring all obligations immediately due and payable and disposing of the collateral if obligations were not paid.

Table of Contents

Although We Expect that Our Acquisition of the Aesthetics Business of Laserscope Will Result in Benefits to the Company, the Company May Not Realize Those Benefits Because of Integration and Other Challenges.

On January 16, 2007, we completed our acquisition of the aesthetics business of Laserscope (the Aesthetics Business), a wholly-owned subsidiary of American Medical Systems Holdings, Inc. 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. Integrating the Aesthetics Business may be expensive and time-consuming and we may not be able to successfully do so. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and can prove to be more difficult or expensive than predicted. The diversion of our management's attention and any delay or difficulties encountered in connection with the pending acquisition of the Aesthetics Business could 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. Further, the following specific factors may adversely affect our ability to integrate the Aesthetics Business:

coordinating marketing functions;

transferring of the manufacturing of the Laserscope products to the Company;

unanticipated issues in integrating information, communications and other systems;

unanticipated incompatibility of purchasing, logistics, marketing and administration methods;

greater than anticipated liabilities;

retaining key employees, including members of our aesthetics sales force;

consolidating corporate and administrative infrastructures;

the diversion of management's attention from ongoing business concerns;

coordinating our current product and process development efforts with those of the Aesthetics Business in a way which permits us to bring future new products to the market in a timely and cost-effective manner; and

coordinating geographically separate organizations.

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

In addition, as part of our acquisition, we entered into agreements with Laserscope to obtain certain manufacturing support, administrative services and future intellectual property rights. In the event that Laserscope fails to provide this support and service, or provides such support and service at a level of quality and timeliness inconsistent with the historical delivery of such support and service, or fails to grant us the intellectual property rights we expected, our ability to integrate the Aesthetics Business will be hampered and our operating results may be harmed.

Table of Contents

As discussed above, we are currently in breach of our Product Supply Agreement with Laserscope and on June 27, 2007 we entered into a letter agreement with Laserscope relating to this breach. Pursuant to this letter agreement, Laserscope agreed to not terminated the Product Supply Agreement so long as we pay \$400,000 per week to Laserscope against invoices outstanding under the Product Supply Agreement, plus accrued interest thereon and pay all outstanding invoices in full, plus accrued interest, upon the earlier of (a) two (2) business days following the closing of an equity financing or (b) July 31, 2007. If we fail to make these scheduled payments and are unable to bring Laserscope current on the payments we owe to them under the Product Supply Agreement, Laserscope has the right to terminate the agreement which would result in all payments immediately becoming due and payable, including the final payment for raw material and work in process inventory, which could require us to pay up to \$9.0 million for such raw materials and work in process inventory in addition to any other outstanding amounts we owe to Laserscope.

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 4 of Part I of this Quarterly Report on Form 10-Q.

In particular, the material weaknesses identified related to the Company's period-end review procedures. We are taking a number of remedial actions designed to remedy the material weaknesses summarized above. 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.

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. Beginning with our fiscal year ending December 29, 2007 we will be required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act which will 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.

Table of Contents

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 light therapeutic-based photocoagulator 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;

acceptance of the company's new marketing programs;

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 EndoProbes 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 service revenues will depend on our quality of care, responsiveness and the willingness of our customers to request and utilize our products and services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices or services may have a material adverse effect on our business, results of operations and financial condition.

If There is Not Sufficient Demand for the 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 aesthetic procedures is a material assumption of our growth strategy. Most procedures performed using our products are elective procedures not reimbursable through government or private health insurance, and the costs of such procedures are borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including:

evolving customer needs;

the introduction of new products and technologies;

evolving surgical practices;

evolving industry standards;

Table of Contents

the cost of procedures performed using our products;

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;

the success of our sales and marketing efforts; and

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

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

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.

Our research and development process is expensive, prolonged, and entails considerable uncertainty. Because of the complexities and uncertainties associated with ophthalmic and aesthetic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products of current or future competitors. Therefore, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Table of Contents

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

The clinical trials required to obtain regulatory approvals for our products are complex and expensive and their outcomes are uncertain. We incur expense for, and devote 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 aesthetic 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, Carl Zeiss, Inc., Alcon, and Synergetics, Inc. Most of these companies currently offer a competitive semiconductor-based laser system in ophthalmology. Also within ophthalmology pharmaceutical alternative treatments for AMD such as Visudyne (Novartis), Macugen (OSI Pharmaceuticals) and Lucentis (Genentech) compete rigorously with traditional laser procedures. Our principal competitors in aesthetic are Palomar Technologies, Candela Corporation, Cutera Inc., Cynosure Inc. and Lumenis Ltd. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. 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. Medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

If 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.

We have experienced some declines in the average unit price of our products and expect to continue to suffer from declines in the future. 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 Depend on Sales of Our Ophthalmology Products for a Significant Portion of Our Operating Results.

We derive, and expect to continue to derive, a large portion of our revenue and profits from sales of our ophthalmology products. For the fiscal quarter ended March 31, 2007, our ophthalmology sales were \$7.2 million or 57.2% of total sales. We anticipate that sales of our ophthalmology products will continue to account for a significant portion of our revenues in the foreseeable future.

Table of Contents

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 revenue from international sales. For the fiscal quarter ended March 31, 2007, our international sales were \$5.9 million. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies. 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:

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 distribution channels;

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;

fluctuations in foreign currency exchange rates;

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 revenue and profitability.

Table of Contents

We Are Exposed to Risks Associated With Worldwide Economic Slowdowns and Related Uncertainties.

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. Unstable political, social and economic conditions make it difficult for our customers, our suppliers and us to accurately forecast and plan future business activities. In particular, it is difficult to develop and implement strategy, sustainable business models and efficient operations, as well as effectively manage supply chain relationships. If such conditions persist, our business, financial condition and results of operations could suffer.

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

Our ability to sell our products and generate revenue depends upon our direct sales force within the United States and primarily through relationships with independent distributors outside the United States. Currently our direct sales force consists of 41 employees and we maintain relationships with 77 independent distributors internationally selling our products into 107 countries through four direct Area Sales Managers. 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 primarily 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, 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 our company in the past and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. This competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, contributes to increases in the salaries we are required to pay in order to attract and retain qualified personnel, which may increase our operating expenses and, if we are unable to pay competitive

Table of Contents

salaries, hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

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

We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. Over the past several quarters, we have placed a high priority on our asset management efforts to, among other things, reduce overall inventory levels and increase our cash position. 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. We plan to assume responsibility for manufacturing the aesthetics product line that we acquired from Laserscope when the Product Supply Agreement we entered into with American Medical Systems Holdings in connection with the acquisition of the aesthetics business of Laserscope terminates. We expect this transition to occur on or before October 2007 and 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. 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

Table of Contents

regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to decline. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components in the quantity and quality desired and at the prices we have budgeted.

Pursuant to our Product Supply Agreement, we rely on AMS, through its Laserscope subsidiary to manufacture significant portions of our aesthetics products. On May 23, 2007 Laserscope provided us with notice of material breach of the Product Supply Agreement as a result of our failure to timely pay invoices of approximately \$2.7 million for finished goods inventory delivered by Laserscope to us under the Product Supply Agreement. As a result of this nonpayment, Laserscope is currently only selling product to us on a prepaid basis. On June 27, 2007 we entered into a letter agreement with Laserscope relating to this breach. Pursuant to this letter agreement, Laserscope agreed to not terminated the Product Supply Agreement so long as we pay \$400,000 per week to Laserscope against invoices outstanding under the Product Supply Agreement, plus accrued interest thereon and pay all outstanding invoices in full, plus accrued interest, upon the earlier of (a) two (2) business days following the closing of a \$5 million equity financing or (b) July 31, 2007. If we fail to make these scheduled payments and are unable to bring Laserscope current on the payments we owe to them under the Product Supply Agreement, Laserscope has the right to terminate the agreement which would result in all payments immediately becoming due and payable, including the final payment for raw material and work in process inventory, which could require us to pay up to \$9.0 million for such raw materials and work in process inventory in addition to any other outstanding amounts we owe to Laserscope.

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. We cannot provide assurance that these types of relationships will continue over a longer period. Our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. If a collaborator elects to terminate its agreement with us, our ability to develop, introduce, market and sell the product may be significantly impaired and we may be forced to discontinue altogether the product resulting from the collaboration. We may not be able to negotiate alternative collaboration agreements on acceptable terms, if at all. The failure of any current or future collaboration efforts could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

We Face Manufacturing Risks.

The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and 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. We may experience increased costs or delays and disruptions in manufacturing when we transition the production of the aesthetics product line that we acquired from Laserscope to our facilities upon the termination of the Product Supply

Table of Contents

Agreement we entered into with American Medical Systems Holdings in connection with the acquisition of the aesthetics business of Laserscope. We expect this transition to occur on or before October 2007 and we may not have sufficient resources to assume these manufacturing obligations without increased costs or delays and disruptions in manufacturing. 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.

We Depend on Collaborative Relationships to Produce, 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 American Medical Systems Holdings in connection with the acquisition of the aesthetics business of Laserscope, pursuant to which American Medical Systems Holdings currently manufactures a substantial portion of our aesthetics products. We expect to transition the manufacturing of these products to our facilities on or before October 2007, but we may not have sufficient resources to assume these manufacturing obligations without increased costs or delays and disruptions in manufacturing. We have also 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, 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 eye care professionals, hospitals, ambulatory surgical centers, corporate optometry chains 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.

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;

-37-

Table of Contents

the timing of the introduction and market acceptance of new products, product enhancements and new applications;

changes in demand for our existing line of aesthetic and ophthalmic products;

the cost and availability of components and subassemblies, including the ability of our sole or limited source suppliers to 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 aesthetic and ophthalmic products and foreign and domestic sales;

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

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

our long and highly variable sales cycle;

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

changes in customers or potential customers budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products; and

increased product innovation costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors.

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

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

The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. From time to time, we meet with investors and potential investors. In addition, we receive attention by securities analysts

Table of Contents

and present at analyst meetings when invited. 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.

Material Increases in Interest Rates May Harm Our Sales.

We currently sell our products primarily to health care providers in general practice. These health care providers often 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 continue to 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.

Table of Contents

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.

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 revenue 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.

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 fifteen United States patents and five foreign patents on the technologies related to our products and processes. We have approximately five pending patent applications in the United States and six foreign pending patent applications that have been filed. Our patent applications may not be approved. 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.

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

Table of Contents

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.

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 noninfringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition. Management believes that liabilities resulting from the matters described in Part II, Item 1, or other 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. 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.

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 allow us to sell 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.

Table of Contents

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 for each product line. 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.

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.

Table of Contents

If We Fail to Manage Growth Effectively, Our Business Could Be Disrupted Which Could Harm Our Operating Results.

We have experienced and may continue to 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.

Our Manufacturing Capacity May Not Be Adequate to Meet the Demands of Our Business.

If our sales increase substantially, including increases in the sales of our aesthetic 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. Any prolonged disruption in the operation of our manufacturing facilities could materially harm our business. We cannot assure you that if we choose to scale-up our manufacturing operations, we will have the resources necessary to do so, or that we will be able to obtain regulatory approvals in a timely fashion, which could affect our ability to meet product demand or result in additional costs.

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. Although we maintain product liability insurance with coverage limits of \$10.0 million per occurrence and an annual aggregate maximum of \$10.0 million, our coverage from our insurance policies may not be adequate. Product liability insurance is expensive. 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.

Our ophthalmology products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as governmental programs and private insurance plans, for the health care services provided to their patients. Third-party payers are increasingly scrutinizing and challenging the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our

Table of Contents

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.

The Successful Outcome of Clinical Trials and the Development of New Applications Using Certain of Our Products will Accelerate Future Revenue Growth Rates.

The Company's ability to generate incremental revenue growth will depend, in part, on the successful outcome of clinical trials that lead to the development of new applications using our products. Clinical trials are long, expensive and uncertain processes. If the future results of any of our clinical trials fail to demonstrate improved patient outcomes and/or the development of new product applications, our ability to generate incremental revenue growth would be adversely affected.

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 product innovation 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

Table of Contents

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.

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 Sudan and Syria under license through a distribution agreement with an independent distributor. In addition, certain of our products were distributed in Iran without United States governmental authorization. The aggregate revenue 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.

Table of Contents

Item 5. Other Information

None.

Item 6. Exhibits

- 10.1 Amended and Restated 1998 Stock Plan
- 31.1 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 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.
- 32.1 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, MicroPulse, ScanLite, ColdTip (Handpiece), VariSpot (Handpiece), TruView and EasyFit product names are our trademarks. All other trademarks or trade names appearing in the 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: July 6, 2007

By: /s/ MERYL RAINS

Meryl Rains
Chief Financial Officer and Vice President,
Administration
(Principal Financial Officer,
Chief Accounting Officer and Authorized
Signatory)

-47-

Table of Contents

Index

- 10.1 Amended and Restated 1998 Stock Plan
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.