

IRIDEX CORP  
Form 10-Q  
May 16, 2006



**IRIDEX Corporation**  
**Table of Contents**

	Page
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements (unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets as of April 1, 2006 and December 31, 2005</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended April 1, 2006 and April 2, 2005</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the three months ended April 1, 2006 and April 2, 2005</u>	5
<u>Condensed Consolidated Statements of Comprehensive Income for the three months ended April 1, 2006 and April 2, 2005</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	14
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	19
<b><u>Item 4. Controls and Procedures</u></b>	19
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	21
<b><u>Item 1A. Risk Factors</u></b>	21
<b><u>Item 2. Changes in Securities and Use of Proceeds</u></b>	33
<b><u>Item 3. Defaults Upon Senior Securities</u></b>	33
<b><u>Item 4. Submission of Matters to Vote of Security Holders</u></b>	33
<b><u>Item 5. Other Information</u></b>	33
<b><u>Item 6. Exhibits and Reports on Form 8-K</u></b>	33
<b><u>Signature</u></b>	33

**Table of Contents****Part I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements**

**IRIDEX Corporation**  
**Condensed Consolidated Balance Sheets**  
(in thousands)  
(unaudited)

	<b>April 1, 2006</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,256	\$ 12,655
Available-for-sale securities	18,166	8,779
Accounts receivable, net	6,247	6,589
Inventories	8,687	8,594
Prepays and other current assets	1,090	885
Current deferred income taxes	1,415	1,415
Total current assets	38,861	38,917
Property and equipment, net	1,063	1,114
Deferred income taxes	1,073	1,073
Total assets	\$ 40,997	\$ 41,104
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,109	\$ 1,094
Accrued expenses	3,312	4,421
Deferred revenue	995	1,072
Total liabilities	5,416	6,587
Contingencies (Note 4)		
Stockholders' equity:		
Common stock	78	76
Additional paid-in capital	27,643	26,334
Accumulated other comprehensive loss	(10)	(27)
Treasury stock	(430)	(430)
Retained earnings	8,300	8,564
Total stockholders' equity	35,585	34,517
Total liabilities and stockholders' equity	\$ 40,997	\$ 41,104

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



**Table of Contents**

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

	<b>Three Months Ended</b>	
	<b>April</b>	
	<b>1,</b>	<b>April 2,</b>
	<b>2006</b>	<b>2005</b>
Sales	\$ 9,010	\$ 8,145
Cost of sales	4,665	4,467
Gross profit	4,345	3,678
Operating expenses:		
Research and development	1,121	1,039
Sales, general and administrative	3,941	2,797
Total operating expenses	5,062	3,836
Loss from operations	(717)	(158)
Interest and other income, net	179	126
Loss before income taxes	(538)	(32)
Benefit from income taxes	274	12
Net loss	\$ (264)	\$ (20)
Net loss per share – basic and diluted	( \$0.03)	( \$0.00)
Shares used in computing net loss per share – basic and diluted	7,587	7,317

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

**Table of Contents**

**IRIDEX Corporation**  
**Condensed Consolidated Statements of Cash Flows**  
(in thousands)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>April 1, 2006</b>	<b>April 2, 2005</b>
Cash flows from operating activities:		
Net loss	\$ (264)	\$ (20)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	133	113
Non-cash stock-based compensation	457	
Tax benefit from stock option exercises	249	
Excess tax benefit related to stock-based compensation expense	(124)	
Provision for doubtful accounts	(4)	(5)
Provision for inventories	67	57
Changes in operating assets and liabilities:		
Accounts receivable	346	561
Inventories	(173)	(646)
Prepays and other current assets	(205)	(264)
Accounts payable	15	(54)
Accrued expenses	(1,109)	(1,109)
Deferred revenue	(77)	52
Net cash used in operating activities	(689)	(1,315)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(15,512)	(7,151)
Proceeds from maturity of available-for-sale securities	6,142	4,331
Acquisition of property and equipment	(69)	(115)
Net cash used in investing activities	(9,439)	(2,935)
Cash flows from financing activities:		
Issuance of common stock	605	71
Excess tax benefit related to stock-based compensation expense	124	
Net cash provided by financing activities	729	71
Net decrease in cash and cash equivalents	(9,399)	(4,179)
Cash and cash equivalents at beginning of period	12,655	10,381
Cash and cash equivalents at end of period	\$ 3,256	\$ 6,202

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

5

---



Table of Contents

**IRIDEX Corporation**  
**Condensed Consolidated Statements of Comprehensive Loss**  
(in thousands)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>April</b>	
	<b>1,</b>	<b>April 2,</b>
	<b>2006</b>	<b>2005</b>
Net loss	\$ (264)	\$ (20)
Other comprehensive income (loss):		
Change in unrealized gain (loss) on available-for-sale securities, net of tax	9	(16)
Comprehensive loss	\$ (255)	\$ (36)

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

**Table of Contents**

**IRIDEX Corporation**  
**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

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

The condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto, together with management s discussion and analysis of financial condition and results of operations, contained in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on April 3, 2006. The results of operations for the three month period ended April 1, 2006 are not necessarily indicative of the results for the year ending December 30, 2006 or any future interim period.

**2. Summary of Significant Accounting Policies**

The Company s significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005 which was filed with the Securities and Exchange Commission on April 3, 2006. With the exception of Statement of Financial Accounting Standards No. 123 (R), ( SFAS 123(R) ), which the Company adopted on January 1, 2006, the Company s significant accounting policies have not materially changed as of April 1, 2006.

**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 ended April 1, 2006 and April 2, 2005 follows (in thousands):

	Three Months Ended	
	April 1, 2006	April 2, 2005
Balance, beginning of period	\$ 1,072	\$ 910
Additions to deferral	263	397
Revenue recognized	(340)	(345)
Balance, end of period	\$ 995	\$ 962

**Table of Contents****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 ended April 1, 2006 and April 2, 2005 follows (in thousands):

	Three Months Ended	
	April 1, 2006	April 2, 2005
Balance, beginning of period	\$ 1,128	\$ 933
Accruals for warranties issued during the period	222	167
Settlements made in kind during the period	(344)	(144)
Balance, end of period	\$ 1,006	\$ 956

**3. Inventories**

Inventories are stated at the lower of cost or market. Cost is based on actual sales computed on a first in, first out basis. The components of inventories consist of the following (in thousands):

	<b>April 1, 2006</b>	<b>December 31, 2005</b>
Raw materials and work in progress	\$ 5,832	\$ 5,191
Finished goods	2,855	3,403
Total inventories	\$ 8,687	\$ 8,594

**4. Contingencies**

From time to time, the Company may be engaged in certain administrative proceedings, incidental to its normal business activities. Management believes that liabilities resulting from such proceedings, or claims which are pending or known to be threatened, are adequately covered by liability insurance and will not have a material adverse effect on the Company s financial position or results of operations.

In October 2005, the Company filed a suit against Synergetics, USA, Inc. for infringement of a patent. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys fees. Synergetics answered our complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe our patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that we had raised safety issues involving Synergetics product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys fees. Our response to these counterclaims was a denial of any wrongdoing and a reference to the expiration of the statute of limitations on those claims. Management believes that liabilities resulting from such proceedings, or 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.

In late April, 2006, Synergetics USA added IRIDEX as a named co-defendant in a lawsuit previously filed against Innovatech Surgical, Inc and Peregrine Surgical Ltd in Pennsylvania. The lawsuit involves the alleged infringement of U.S. patent number 6,984,230 issued to Synergetics, Inc. on January 10, 2006 and entitled Directional Laser Probe. Because the adjustable probe that Peregrine manufactures for IRIDEX is accused by Synergetics of infringing its patent, IRIDEX had already been defending this matter, and it is not surprising that Synergetics added IRIDEX as a co-defendant. Management believes that liabilities resulting from such proceedings, or 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.

**Table of Contents****5. 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 income per share includes the dilutive effect of potentially dilutive common stock provided the inclusion of such potential common stock is not antidilutive. Potential common stock consists of incremental common shares issuable upon the exercise of stock options.

During the three months ended April 1, 2006 and April 2, 2005 options to purchase 2,131,304 and 1,898,249 shares of common stock at weighted average exercise prices of \$5.70 and \$5.33 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 April 1, 2006 a warrant to purchase 25,000 shares of common stock at an average exercise price of \$6.07 was outstanding. There were no warrants outstanding for the three month period ended April 2, 2005. These options and the warrant could dilute earnings per share in future periods.

**6. Business Segments**

We operate in two reportable segments: the ophthalmology medical device segment and the dermatology medical device segment. In both segments, we develop, manufacture and market 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 April 1, 2006 and April 2, 2005 is as follows (in thousands):

	Three Months Ended April 1, 2006			Three Months Ended April 2, 2005		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
Sales	\$ 7,588	\$ 1,422	\$ 9,010	\$ 6,193	\$ 1,952	\$ 8,145
Direct cost of goods sold	2,548	747	3,295	2,099	996	3,095
Direct gross margin	5,040	675	5,715	4,094	956	5,050
Total unallocated costs			(6,253)			(5,082)
Pre-tax loss			\$ (538)			\$ (32)

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

**Table of Contents**

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

**7. Stock-based Compensation**

**Employee Stock Purchase Plan**

The IRIDEX 2005 Stock Purchase Plan (the "Purchase Plan") permits eligible employees (including officers) to purchase Common Stock through payroll deductions, which may not exceed 10% of an employee's compensation. No employee may purchase more than \$25,000 worth of stock in any calendar year or more than 2,000 shares of Common Stock in any twelve-month period. The price of shares purchased under the Purchase Plan is 85% of the lower of the fair market value of the Common Stock at the beginning of the offering period or the end of the offering period.

**Stock Option Plans**

***Amended and Restated 1989 Incentive Stock Plan***

The Amended and Restated 1989 Plan (the "1989 Plan") provided for the grant of options and stock purchase rights to purchase shares of our Common Stock to employees and consultants. The terms of the 1989 Plan, which expired in August 1999, are substantially the same as the 1998 Plan described below.

***1998 Stock Plan***

The 1998 Stock Plan (the "1998 Plan"), as amended, provides for the granting to employees (including officers and employee directors) of incentive stock options and for the granting to employees (including officers and employee directors) and consultants of nonstatutory stock options, stock purchase rights ("SPRs"), restricted stock, restricted stock units, performance shares, performance units and stock appreciation rights. The exercise price of incentive stock options and stock appreciation rights granted under the 1998 Plan must be at least equal to the fair market value of the shares at the time of grant. With respect to any recipient who owns stock possessing more than 10% of the voting power of our outstanding capital stock, the exercise price of any option or SPR granted must be at least equal to 110% of the fair market value at the time of grant. Options granted under the 1998 Plan are exercisable at such times and under such conditions as determined by the Administrator; generally over a four year period. The maximum term of incentive stock options granted to any recipient must not exceed ten years; provided, however, that the maximum term of an incentive stock option granted to any recipient possessing more than

**Table of Contents**

10% of the voting power of our outstanding capital stock must not exceed five years. In the case of SPRs, unless the Administrator determines otherwise, the Company has a repurchase option exercisable upon the voluntary or involuntary termination of the purchaser's employment with us for any reason (including death or disability). Such repurchase option lapses at a rate determined by the Administrator. The purchase price for shares repurchased by us is the original price paid by the purchaser. As of April 1, 2006, no shares were subject to repurchase. The form of consideration for exercising an option or stock purchase right, including the method of payment, is determined by the Administrator. The 1998 Plan expires in June 2008.

***1995 Director Option Plan***

In October 1995, the Company adopted the 1995 Director Option Plan (the "Director Plan"), under which members of the Board of Directors are granted options to purchase 11,250 shares upon the first to occur of their appointment or the adoption of the Director Plan ("First Option") and an option to purchase 3,750 shares ("Subsequent Option") on July 1 of each year thereafter provided that he or she has served on the Board for at least the preceding six months. The options granted are at fair market value on the date of grant. The First Option becomes exercisable as to one-twelfth (1/12) of the shares subject to the First Option for each quarter over a three-year period. Each Subsequent Option becomes exercisable as to one-fourth (1/4) of the shares subject to the Subsequent Option for each quarter, commencing one quarter after the First Option and any previously granted Subsequent Options have become fully exercisable. Options granted under the Director Plan have a term of 10 years.

In the event of our merger with or into another corporation, resulting in a change of control, or the sale of substantially all of our assets, each Director Plan options become exercisable in full and shall be exercisable for 30 days after written notice to the holder of the event causing the change in control.

The Director Plan terminated in 2005.

***Stand-Alone Options***

In July 2005, in connection with the employment of the Company's Chief Executive Officer, the Company's Board of Directors granted a stand alone option, outside of the Company's existing stock plans, to the Chief Executive Officer. The option entitles Mr. Caldwell to purchase up to 234,104 shares of the Company's common stock at an exercise price of \$6.07 per share. In conjunction with the employment of the Company's Chief Executive Officer, in consideration of services performed under a recruiting contract, the Company issued a warrant to purchase 25,000 shares of the Company's common stock at an exercise price of \$6.07 per share. The warrant is exercisable at any time and expires on July 5, 2008. The fair value of the warrants of \$87,000 was recorded as an expense for the twelve month period ended December 31, 2005. The fair value of the warrant was calculated using the Black-Scholes pricing model with the following assumptions: dividend yield 0 percent, contractual life of 3 years, risk free rates of 4.04 percent and volatility of 83 percent. At April 1, 2006, the warrant remains outstanding.

In March 2006, in connection with the employment of the Company's Vice President of Product Innovation, the Company's Board of Directors granted a stand alone option, outside of the Company's existing stock plans, to the Vice President of Product Innovation. The option entitles Ms. Tomasco to purchase up to 50,000 shares of the Company's common stock at an exercise price of \$8.26 per share.

***Stock-Based Compensation***

The Company adopted SFAS 123(R) using the modified prospective method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year. The Company's financial statements as of and for the three months ended April 1, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective method, the Company's financial statements for prior periods have not been restated to reflect, and do not include the impact of SFAS 123(R). Stock-based

**Table of Contents**

compensation expense recognized under SFAS 123(R) for the three months ended April 1, 2006 was \$0.5 million, which consisted of stock-based compensation expense related to stock options and employee stock purchases. There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized during the three months ended April 2, 2005.

We estimate the fair value of stock options granted using the Black-Scholes option-pricing formula. In conjunction with the adoption of SFAS 123(R) on January 1, 2006, the Company changed its method of attributing the value of stock-based compensation from the accelerated multiple-option approach to the straight-line single option method for options granted following the adoption of SFAS 123(R).

The determination of fair value of all options granted by the Company is computed based on the Black-Scholes option-pricing model with the following weighted average assumptions:

	Employee Stock Option Plan		Employee Stock Purchase Plan	
	Three Months Ended April 1, 2006	Three Months Ended April 2, 2005	Three Months Ended April 1, 2006	Three Months Ended April 2, 2005
Average risk free interest rate	4.50%	3.38%	4.60%	2.50%
Expected life (in years)	3.6	3	0.5	0.5

Dividend yield

Average volatility	50.0%	86.0%	45.0%	85.0%
--------------------	-------	-------	-------	-------

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of the Company's stock price history over a period commensurate with the expected term of the options, trading volume of the Company's stock, look-back volatilities and Company specific events that affected volatility in a prior period. The expected term of options granted is based on analysis of historical exercise and post-vesting employment termination behavior. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. No dividend yield is included as the Company has not issued any dividends.

The following table shows stock-based compensation expense included in the Condensed Consolidated Statements of Operations for the three months ended April 1, 2006 (in thousands):

Cost of sales	\$ 36
Research and development	48
Sales, general and administrative	373
	\$ 457

Stock-based compensation capitalized as part of inventory for the three months ended April 1, 2006 was immaterial.

The modified prospective transition method of SFAS 123(R) requires the presentation of pro-forma information for periods presented prior to the adoption of SFAS 123(R) regarding net loss and net loss per share as if the Company had accounted for the Company's stock options under the fair value method of SFAS 123. If compensation expense had been determined based upon the fair value at grant date for employee compensation arrangements, consistent with



Edgar Filing: IRIDEX CORP - Form 10-Q

the methodology prescribed under SFAS 123, the Company's pro forma net loss and net loss per common share under SFAS 123 for the three months ended April 2, 2005 is as follows (in thousands except per share data).

	Three Months Ended April 2, 2005	
Net loss, as reported for prior periods	\$	(20)
Stock-based compensation expense related to employee stock options and employee stock purchases		(125)
Pro forma net loss	\$	(145)
Basic and diluted net loss per share:		
As reported	\$	(0.00)
Pro forma	\$	(0.02)

**Table of Contents**

Pro Forma disclosures for the three months ended April 1, 2006 are not presented because stock-based employee compensation was accounted for under SFAS 123(R)'s fair value method during this period.

Information with respect to activity under these option plans is set forth below (in thousand except per share and per share data):

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2005	2,154,003	\$ 5.50	\$ 14,518
Options granted	102,500	8.18	416
Options exercised	(115,590)	4.19	(930)
Options forfeited/cancelled/expired	(9,609)	6.04	(59)
Outstanding at April 1, 2006	2,131,304	\$ 5.70	\$ 13,945

The weighted average grant date fair value of options granted during the three months ended April 1, 2006 was \$3.89 per share.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the first quarter of fiscal 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on April 1, 2006. This amount changes based on the fair market value of the Company's stock. Total intrinsic value of options exercised for the three months ended April 1, 2006 was \$1.0 million. Total fair value of options vested and expensed was \$0.3 million, net of tax, for the three months ended April 1, 2006.

As a result of adopting the fair value recognition provisions of SFAS 123(R), the impact to the Condensed Consolidated Financial Statements for the three months ended April 1, 2006 from stock-based compensation is as follows (in thousands, except per share data):

	Three Months Ended April 1, 2006
Stock-based compensation expense by award type:	
Employee stock options granted	\$ 447
Employee stock purchase plan	10
Total stock-based compensation	457
Total effect on stock-based compensation at the Company's marginal tax rate	(183)
Effect on net loss	\$ 274
Effect on net loss per share:	
Basic and diluted	\$ (0.04)

A summary of the status of the Company's non-vested shares as of April 1, 2006 and changes during the period ended April 1, 2006 is presented below (amount in thousands, except per share amounts):

Weighted  
Average

	Number of Shares	Grant Dated Fair Value
Non-vested at December 31, 2005	893,119	\$ 5.72
Granted	102,500	8.18
Vested	(56,515)	4.60
Cancelled/forfeited	(9,609)	6.04
Non-vested at April 1, 2006	929,495	\$ 6.06

As of April 1, 2006, there was \$2.4 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements under both of the plans. The cost is expected to be recognized over a weighted average period of 3 years.

The following table summarizes information with respect to stock options outstanding at April 1, 2006:

Range of Exercise Prices	Options Outstanding			Options Vested and Exercisable		
	Number of Shares Outstanding at April 1, 2006	Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares Exercisable at April 1, 2006	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)
\$2.94 - \$3.50	260,530	6.93	\$ 3.36	189,314	\$ 3.38	6.81
\$3.52 - \$4.00	352,796	3.51	\$ 3.87	333,453	\$ 3.88	4.36
\$4.01 - \$5.00	221,020	5.24	\$ 4.42	181,643	\$ 4.41	6.21
\$5.08 - \$5.50	224,709	6.79	\$ 5.24	87,375	\$ 5.27	6.22
\$5.56 - \$6.00	118,750	8.36	\$ 5.64	45,705	\$ 5.61	8.60
\$6.07 - \$6.07	325,000	9.26	\$ 6.07	25,000	\$ 6.07	9.26
\$6.19 - \$7.63	228,799	6.77	\$ 6.84	111,508	\$ 7.05	7.79
\$7.98 - \$8.88	264,950	6.16	\$ 8.40	97,748	\$ 8.72	5.70
\$9.00 - \$12.75	131,000	4.34	\$ 9.65	126,313	\$ 9.68	4.04
\$14.88 - \$14.88	3,750	0.25	\$ 14.88	3,750	\$ 14.88	0.25
\$2.93 - \$14.88	2,131,304	6.29	\$ 5.70	1,201,809	\$ 5.41	

As of April 1, 2006, the aggregate intrinsic value of fully vested and exercisable options was \$8.2 million.

**Table of Contents****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, actual order rate and 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; the potential for production cost decreases and higher gross margins; our ability to develop and introduce new products through strategic alliances; favorable Center for Medicare and Medicaid coverage decisions regarding AMD procedures that use our products; results of clinical studies and risks associated with bringing new products to market; general economic conditions; and levels of international sales. In some cases, forward-looking statements can be identified by terminology, such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, intends, potential, continue, or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements, including as a result of the factors set forth under Factors That May Affect Future Operating Results and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 3, 2006 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 provider of therapeutic based laser systems and delivery devices used to treat eye diseases in ophthalmology and skin conditions in dermatology (aesthetics). Our products are sold in the United States predominantly through a direct sales force and internationally through 77 independent distributors into 107 countries. Our revenues arise primarily 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 business includes a recurring revenue component which includes the sale of our disposable single use laser probes, EndoProbes, combined with the repair, servicing and extended warranty protection for our laser systems. Cost of sales consists primarily of the cost of purchasing components and sub-systems, assembling, packaging, shipping and testing components at our facility, and the direct labor and associated overhead. Research and development expenses consist primarily of personnel costs, materials and research support provided to clinicians at medical institutions developing new applications which utilize our products. Research and development costs have been expensed as incurred. Sales, general and administrative expenses consist primarily of costs of personnel, sales commissions, travel expenses, advertising and promotional expenses, facilities, legal and accounting, insurance and other expenses which are not allocated to other departments.

Effective January 1, 2006, we adopted the provisions of SFAS No. 123(R), *Share-Based Payment*, which requires us to measure all employee stock-based compensation awards using a fair value method and record such expense in our consolidated financial statements. Prior to January 1, 2006, we had accounted for stock-based compensation awards in accordance with Accounting Principles Board (APB) Opinion No. 25. We have chosen to implement SFAS No. 123(R) using the modified prospective method. Under this method, periods prior to January 1, 2006 are not restated to reflect stock-based compensation using a fair value method.

**Table of Contents****Results of Operations**

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

	<b>Three Months Ended April 1, 2006</b>	<b>Three Months Ended April 2, 2005</b>
Sales	100.0%	100.0%
Loss from operations	(8.0)%	(1.9)%
Loss from operations excluding stock-based compensation expense	(2.9)%	(1.9)%
Net loss	(2.9)%	(0.3)%
Net loss excluding stock-based compensation expense	(0.5)%	(0.3)%

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.

		<b>Three Months Ended</b>		
	<b>Amount</b>	<b>April 1, 2006 Percentage of total sales</b>	<b>Amount</b>	<b>April 2, 2005 Percentage of total sales</b>
Domestic	\$ 5,297	58.8%	\$ 4,925	60.5%
International	3,713	41.2%	3,220	39.5%
Total	9,010	100.0%	8,145	100.0%
Ophthalmology:				
Domestic	4,142	46.0%	3,413	41.9%
International	3,446	38.2%	2,780	34.1%
Total	7,588	84.2%	6,193	76.0%
Dermatology:				
Domestic	1,155	12.8%	1,512	18.6%
International	267	3.0%	440	5.4%
Total	\$ 1,422	15.8%	\$ 1,952	24.0%
Total recurring revenue	\$ 3,780	42.0%	\$ 3,096	38.0%

Total non-recurring revenue	\$ 5,230	58.0%	\$ 5,049	62.0%
-----------------------------	----------	-------	----------	-------

*Ophthalmology and Dermatology Sales Overview*

We manage and evaluate our business in two segments — ophthalmology and dermatology. We then further break down these major 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, combined with the repair, servicing and extended warranty protection for our laser systems). Within the dermatology segment

**Table of Contents**

we primarily view macro trends surrounding our laser systems, which include our newly introduced DioLite XP and VariLite laser systems and the DioLite laser system.

Total sales increased by 10.6% to \$9.0 million for the three months ended April 1, 2006 from \$8.1 million for the three months ended April 2, 2005. Domestic sales, which represented 58.8% of total sales, increased by 7.6% to \$5.3 million for the three months ended April 1, 2006 from \$4.9 million for the three months ended April 2, 2005. The increase in domestic sales was a result of a \$0.7 million increase in domestic ophthalmology revenue offset by a \$0.3 million decrease in domestic dermatology revenue. International sales, which were 41.2% of total sales, increased by 15.3% to \$3.7 million for the three months ended April 1, 2006 from \$3.2 million for the three months ended April 2, 2005. The increase in international sales was a result of a \$0.6 million increase in international ophthalmology sales offset by a \$0.1 million decrease in international dermatology revenue.

*Ophthalmology Sales*

Ophthalmology sales increased 22.5% to \$7.6 million for the three months ended April 1, 2006 from \$6.2 million for the three months ended April 2, 2005. For the three month period ended April 1, 2006, domestic ophthalmology sales increased 21.3% to \$4.1 million from \$3.4 million for the three months ended April 2, 2005 primarily as a result of a \$0.5 million increase in recurring revenue and a \$0.2 million increase in unit sales of laser systems. International ophthalmology sales increased 24.0% to \$3.4 million for the three months ended April 1, 2006 from \$2.8 million for the three months ended April 2, 2005. The increase in international ophthalmology sales during this period was due to a \$0.4 million increase in unit sales of laser consoles and a \$0.2 million increase in recurring revenue. The increase in recurring revenue related to our focus on disposable laser probes and our increasing installed base.

*Dermatology Sales*

Dermatology sales decreased 27.2% to \$1.4 million for the three months ended April 1, 2006 from \$2.0 million for the three months ended April 2, 2005. Domestic dermatology sales decreased 23.6% to \$1.2 million for the three month period ended April 1, 2006 from \$1.5 million for the comparable prior year three month period due primarily to a \$0.4 million decrease in unit sales of laser consoles. The decrease in sales reflected to some degree the late timing of the American Academy of Dermatology (AAD) meeting from which sales leads are generated, but more importantly was also indicative of some sales inefficiencies that are being addressed. International dermatology sales decreased 39.3% to \$0.3 million for the three months ended April 1, 2006 from \$0.4 million for the three months ended April 2, 2005, primarily due to a \$0.1 million decrease in unit sales of our laser consoles.

*Gross Margin*

	<b>Three Months Ended</b>	
	<b>April 1, 2006</b>	<b>April 2, 2005</b>
Sales	100.0%	100.0%
Cost of sales	51.8%	54.8%
Gross profit	48.2%	45.2%
Gross profit excluding stock-based compensation expense	48.6%	45.2%

Our gross profit increased by \$0.6 million to \$4.3 million for the three month periods ended April 1, 2006 compared to \$3.7 million for the three months ended April 2, 2005. Gross profit as a percentage of sales for the three months ended April 1, 2006 increased to 48.2% from 45.2% for the comparable prior year three month period. The total 3% increase in gross profit as a percentage of sales during this period resulted from a 1.7% decrease in overhead spending combined with a 1.3% decrease in direct costs.

**Table of Contents**

We intend to continue our efforts to reduce the cost of components and manufacturing and thereby mitigate the impact of price reductions on our gross profit. We believe gross profit in dollars will increase as volumes increase and unit production costs will decrease as costs are engineered out of new products. In addition, as we evaluate gross margins on each of our product lines, we may choose to place greater focus on product lines with better margins. Overall, however, 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*

	<b>Three Months Ended</b>	
	<b>April 1, 2006</b>	<b>April 2, 2005</b>
Research and development expense as a percentage of total revenue	12.4%	12.8%
Research and development expense as a percentage of total revenue excluding stock-based compensation expense	11.9%	12.8%

Research and development expenses increased by 7.9% to \$1.1 million for the three months ended April 1, 2006 from \$1.0 million for the three months ended April 2, 2005. Research and development expenses decreased as a percentage of sales to 12.4% for the three months ended April 1, 2006 from 12.8% for the comparable prior year three-month period. The increase in research and development spending was driven by stock compensation expense and a minor increase in engineering project spending. The decrease in research and development expense as a percentage of sales for the three month period ended April 1, 2006 as compared to the three month period ended April 2, 2005 was due primarily to the level of increased research and development spending relative to the level of increased sales.

*Selling, General and Administrative*

	<b>Three Months Ended</b>	
	<b>April 1, 2006</b>	<b>April 2, 2005</b>
Selling, general and administrative expense as a percentage of total revenue	43.7%	34.3%
Selling, general and administrative expense as a percentage of total revenue excluding stock-based compensation expense	39.7%	34.3%

Our sales, general and administrative expenses increased by 40.9% to \$3.9 million for the three months ended April 1, 2006 from \$2.8 million for the three months ended April 2, 2005. As a percentage of revenues, sales, general and administrative expenses increased to 43.7% for the three months ended April 1, 2006 from 34.3% for the comparable prior year three-month period. The increase in sales, general and administrative expense in absolute dollars and as a percentage of sales for the three month period ended April 1, 2006 as compared to the three month period ended April 2, 2005 was due to a \$0.4 million charge for stock compensation expense as well as an increase of \$0.3 million in sales spending associated with increased revenues, an increase of \$0.2 million in marketing spending due mainly to increased headcount as well as increased spending on marketing programs and a \$0.2 million increase in general and administrative spending associated with increased headcount as well as legal fees.

*Interest and Other Income, net.* For the three months ended April 1, 2006 we had net other income of \$179,000 as compared with net other income of \$126,000 for the three months ended April 2, 2005. The change in net other income for the three month periods was due primarily to increased interest rates and to increased cash, cash equivalents and available-for-sale securities.



**Table of Contents**

*Income Taxes.* The effective income tax rates for the three month periods ending April 1, 2006 and April 2, 2005 were lower for periods where we had pre-tax income and higher for periods where we had pre-tax losses than the Federal and State combined statutory rate of 40% because of certain tax benefits associated with stock compensation expense.

**Liquidity and Capital Resources**

At April 1, 2006, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of \$21.4 million. In addition, we have available \$4 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in October 2006. As of April 1, 2006, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2006, assuming that the terms continue to be acceptable.

During the three months ended April 1, 2006, operating activities used \$0.7 million of cash. The primary uses of cash included a decrease in accrued liabilities of \$1.1 million, a net loss of \$0.3 million, an increase in prepaid expenses and other current assets of \$0.2 million, a \$0.1 million increase in net inventory and a \$0.1 million decrease in deferred revenue offset by sources of cash from operating activities which included stock compensation expense of \$0.5 million, the tax benefit from stock compensation expense of \$0.2 million, a decrease in net accounts receivable of \$0.3 million and depreciation of \$0.1 million. The decrease in accrued liabilities related primarily to a \$0.6 million reduction in accrued payroll related to payout of the fiscal 2005 bonus and to the timing of the salary accrual at December 31, 2005. Miscellaneous decreases in accrued liabilities comprised the remainder of the overall decrease in accrued liabilities. The decrease in net accounts receivable was due to increased collection efforts.

Investing activities used \$9.4 million in cash and cash equivalents during the three months ended April 1, 2006, primarily due to net purchases of available-for-sale securities of \$9.4 million and to purchases of fixed assets of \$0.1 million.

Net cash provided by financing activities during the three months ended April 1, 2006 was \$0.7 million, which consisted of the issuance of common stock under employee option plans and the employee stock purchase plan as well as the tax benefit from stock compensation expense of (\$0.1) million.

We believe that, based on current estimates, our cash, cash equivalents and available-for-sale securities together with cash generated from operations and our credit facility will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Our liquidity could be negatively affected by a decline in demand for our products, the need to invest in new product development or reductions in spending by our customers as a result of the continuing economic downturn or other factors. There can be no assurance that additional debt or equity financing will be available when required or, if available, can be secured on terms satisfactory to us. See *-Factors That May Affect Future Results We May Need Additional Capital, which May Not Be Available, and Our Ability to Grow May Be Limited as a Result.*

**Accounting Policies**

The Company's critical accounting policies are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005 which was filed with the Securities and Exchange Commission on April 3, 2006.

The Company adopted SFAS 123(R) using the modified prospective method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year. The Company's financial statements as of and for the three months ended April 1, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective method, the Company's financial statements for prior periods have not been restated to reflect, and do not include the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the three months ended April 1, 2006 was \$0.5 million, which consisted of stock-based compensation expense related to stock options and employee stock

**Table of Contents**

purchases. There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized during the three months ended April 2, 2005. See Note 7 for additional information.

We estimate the fair value of stock options granted using the Black-Scholes option-pricing formula. In conjunction with the adoption of SFAS 123(R) on January 1, 2006, the Company changed its method of attributing the value of stock-based compensation from the accelerated multiple-option approach to the straight-line single option method.

**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, available-for-sale marketable securities and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. We have no long-term debt as of April 1, 2006.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed a term of 12 to 14 months.

**Qualitative Disclosures**

*Interest Rate Risk.* Our primary interest rate risk exposures relate to:

- n The available-for-sale securities will fall in value if market interest rates increase.
  
- n The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity and therefore would not expect the operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on its short- and long-term marketable securities portfolio.

Management evaluates our financial position on an ongoing basis.

*Currency Rate Risk.* As all of our sales transactions are denominated in U.S. currency, we do not hedge any balance sheet exposures against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

**Item 4. Controls and Procedures**

**Evaluation of disclosure controls and procedures .**

*a) Evaluation of disclosure controls and procedures.*

Our management evaluated, with the participation of its Chief Executive Officer (CEO) and its Chief Financial Officer (CFO), the effectiveness of the design and operation of its disclosure controls and

**Table of Contents**

procedures (as defined in Rule 13A-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934 (the "34 Act") as of the end of the period covered by this report.

Disclosure controls and procedures are designed with the objective of ensuring that (i) information required to be disclosed in our reports filed under the 34 Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the CEO and CFO, is 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, its 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.

Based on that evaluation, the CEO and CFO concluded, due to the material weakness described below, that as of the end of the period covered by this report, the disclosure controls and procedures were ineffective in ensuring that all material information required to be disclosed in the reports we file and submit under the 34 Act has been made known to them on a timely basis and that such information has been properly recorded, processed, summarized and reported, as required. As discussed in (b) below, we are taking steps to remediate the material weakness.

In connection with the annual audit of our financial statements as of December 31, 2005, 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. The material weakness identified by our independent accountants relates to a failure to maintain adequate period-end review procedures over 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.

*b) Changes in internal control over financial reporting.*

In response to the deficiencies noted above, we have identified the following corrective actions necessary to address the material weakness described above, as follows:

Implement additional controls over the preparation and review of key spreadsheets

Implement automated general ledger reports to replace existing key spreadsheets where possible,

Correct a system generated custom report to include additional information necessary to prepare accurate financial information

Implement additional review procedures

Enhance the current capabilities of the finance function.

We have begun implementing these corrective actions and believe that these corrective actions, once implemented, will mitigate the material weakness that was identified.

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.

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

In October 2005, we filed a suit against Synergetics, USA, Inc. for infringement of a patent. We seek injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics answered our complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe our patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that we had raised safety issues involving Synergetics product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys' fees. Our response to these counterclaims was a denial of any wrongdoing and a reference to the expiration of the statute of limitations on those claims. Management believes that liabilities resulting from such proceedings, or claims which are pending or known to be threatened will not have a material adverse effect on our financial position or results of operations. While we believe it is not material to our operations, we expect significant dedication of management resources and legal costs in connection with this lawsuit.

In late April, 2006, Synergetics USA added IRIDEX as a named co-defendant in a lawsuit previously filed against Innovatech Surgical, Inc and Peregrine Surgical Ltd in Pennsylvania. The lawsuit involves the alleged infringement of U.S. patent number 6,984,230 issued to Synergetics, Inc. on January 10, 2006 and entitled Directional Laser Probe. Because the adjustable probe that Peregrine manufactures for IRIDEX is accused by Synergetics of infringing its patent, IRIDEX has already been defending Peregrine in this matter, and it is not surprising that Synergetics added IRIDEX as a co-defendant. Management believes that liabilities resulting from such proceedings, or 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.

**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 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 dermatology 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:

- n Acceptance of product performance, features, ease of use, scalability and durability;
- n Acceptance of the company's new marketing programs;
- n Recommendations and opinions by ophthalmologists, dermatologists, other clinicians, plastic surgeons and their associated opinion leaders, including study outcomes;
- n Price of our products and prices of competing products and technologies;
- n Availability of competing products, technologies and alternative treatments; and
- n 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 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 our services rather than purchase competing products or services. Any

significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices or services may have a material adverse effect on our business, results of operations and financial condition.

**Table of Contents**

*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 dermatology 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 dermatology are Palomar Technologies, Candela Corporation, Syneron, Lumenis Ltd. and Laserscope. 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. Some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

*Our 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.

*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 three months ended April 1, 2006, our ophthalmology sales were \$7.6 million or 84.2% 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 three months ended April 1, 2006, our international sales were \$3.7 million or 41.2% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues, particularly in ophthalmology, 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 including:

- n Impact of recessions in economies outside of the United States;
- n Performance of our international channel of distributors;
- n Foreign certification requirements, including continued ability to use the CE mark in Europe;
- n Reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- n Longer accounts receivable collection periods;
- n Potentially adverse tax consequences; and
- n 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. For additional discussion about our foreign currency risks, see Item 3, Quantitative and Qualitative Disclosures about Market Risk.

*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 relationships with independent distributors outside the United States. Currently our direct sales force consists of 18 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 entirely dependent on the efforts of these third parties. If any distributor breaches terms of its distribution agreement or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may limit our revenues and our ability to maintain market share. The loss of the services of these key personnel would harm our business. Similarly, our distributorship 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

**Table of Contents**

key management, technical, sales, and other critical personnel. Our officers and other key personnel are employees-at-will, and we cannot assure you that we will be able to retain them. Key personnel have left our company in the past and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

*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 not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations and, as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

*If 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. 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:

- n Unavailability of, shortages or limitations on the ability to obtain supplies of components in the quantities that we require;
- n Delays in delivery or failure of suppliers to deliver critical components on the dates we require;
- n Failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and
- n Inability to obtain components at acceptable prices.



**Table of Contents**

Our business and operating results may suffer from the lack of alternative sources of supply for critical sole and limited source components. The process of qualifying suppliers is complex, requires extensive testing with our products, and may be lengthy, particularly as new products are introduced. New suppliers would have to be educated in our production processes. In addition, the use of alternate components may require design alterations to our products and additional product testing under FDA and relevant foreign regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to decline. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. We do not currently intend to manufacture any of these components. 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.

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

General economic uncertainties and political concerns;

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

Changes in demand for our existing line of dermatology 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 dermatology 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.

**Table of Contents**

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 and present at analyst meetings when invited. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes. In addition, the stock market has experienced extreme volatility in the last few years that has often been unrelated to the performance of particular companies. These broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

*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.

**Table of Contents**

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.

*We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications.* We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and innovation and clinical testing of our products. Commercially, we currently 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.

*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 be assured 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.

*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 as of December 31, 2005, our disclosure controls and procedures were not effective because of the material weaknesses detailed in Part II (Controls and Procedures), Item 9A of our annual report on form 10-K for the year ended December 31, 2005, which was filed with the SEC on April 3, 2006. In particular, the material weaknesses identified related to a failure to maintain adequate period-end review procedures over 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. While we believe that the material weaknesses did not have a material effect on our reported results, they nevertheless constituted deficiencies in our disclosure controls and procedures. In addition, to remediate the material weaknesses summarized above, we may need to implement additional controls over the preparation and review of key spreadsheets, implement automated general ledger reports to replace existing key spreadsheets where possible, correct a system generated custom report to include additional information necessary to prepare accurate financial

information, implement additional review procedures and enhance the current capabilities of the finance function. If, despite our remediation efforts, we fail to ameliorate 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.

**Table of Contents**

*Our products could be subject to recalls even after receiving FDA approval or clearance. A recall would harm our reputation and adversely affect our operating results.* The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales.

If we modify one of our FDA approved or cleared devices, we may need to seek new approvals or clearances which, if not granted, would prevent us from selling our modified products.

**Table of Contents**

Any modifications to an FDA-approved or 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 PMA approval. We may not be able to obtain additional 510(k) clearances or PMA approvals for new products or for modifications to, or additional intended uses or indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices and the labeling of our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and stop marketing the modified devices, which could harm our operating results and require us to redesign or relabel 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 five 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 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

**Table of Contents**

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 such proceedings, or claims which are pending or known to be threatened, are adequately covered by liability coverage and will not have a material adverse effect on the Company's financial position or results of operation. In October 2005, the Company filed suit against Synergetics, USA, Inc. for infringement of a patent. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics answered the Company's complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe the Company's patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that the Company had raised safety issues involving Synergetics' product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys' fees. The Company's response to those counterclaims was a denial of wrongdoing and a reference to the expiration of the statute of limitations on those claims. While we believe its not material to the Company's operation, the company may incur significant dedication of management resources and legal costs in connection with this lawsuit.

*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. 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.

*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. In addition, third party payers may not initiate coverage of new procedures using our products for a significant period. In September 2000, the Center for Medicare and Medicaid Services, or CMS, advised that claims for reimbursement for certain age related macular degeneration, or AMD, procedures which use our OcuLight SLx laser system, could be submitted for reimbursement, with coverage and payment to be determined by the local medical carriers at their discretion. To date five carriers representing 17 states have written reimbursement coverage policies on Transpupillary Thermotherapy, or TTT. The states reimbursing for TTT are Alaska, Arizona, California, Colorado, Hawaii, Iowa, Idaho, Mississippi, North Carolina, North Dakota, Nevada, Oregon, Pennsylvania, South Dakota, Tennessee, Washington and Wyoming. Domestic sales of the OcuLight SLx laser system may continue to be limited until more local medical carriers reimburse for performing such AMD

**Table of Contents**

procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level. The clinical results of the TTT4CNV trial and other clinical trials may influence the individual state or CMS decision to reimburse for certain laser procedures. In November 2005, we filed a CPT (Current Procedural Terminology) Change Request Form seeking the extension of Category III (Emerging Technology) codes 0016T and 0017T for wet and dry forms of AMD. We learned in early May that the panel had voted to retain the Category III codes 0016T and 0017T on reporting Transpupillary Thermotherapy/Ablation of macular drusen for an extension of five years or until codes have been accepted for placement in the Category I section of CPT.

Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding reimbursement of medical procedures using our products and any healthcare reform measures. Further proposed legislation, regulation and policy changes affecting third party reimbursement are likely. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation may have on us. However, denial of coverage and reimbursement of our products would have a material adverse effect on our business, results of operations and financial condition.

*If 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.

*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. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product innovation and clinical trials for new applications and products. We must also be prepared to expand our work force and to train, motivate and manage additional employees as the need for additional personnel arises. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to effectively manage future growth could have a material adverse effect on our business, results of operations and financial condition.

*If 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.

*We May Need Additional Capital, which May Not Be Available, and Our Ability to Grow May be Limited as a Result.* We believe that our existing cash balances, available-for-sale securities, credit facilities and cash flow expected to be generated from future operations will be sufficient to meet our capital requirements at least through the next 12 months. However, we may be required, or could elect, to seek additional funding prior to that time. The development and marketing of new products and associated support personnel requires a significant commitment of resources. If cash from available sources is insufficient, we may need additional capital, which may not be available on favorable terms, if at all. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, take



**Table of Contents**

advantage of future opportunities, fund potential acquisitions or respond to competitive pressures or unanticipated requirements. Any inability to raise additional capital when we require it would seriously harm our business.

*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. We have supported several clinical trials, including, for example, the TTT4CNV and the PTAMD clinical trials.

**Table of Contents**

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Trademark Acknowledgments**

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, IQ810, VariLite, DioLite XP, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, MicroPulse, ScanLite Scanner, 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.

**SIGNATURE**

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

IRIDEX Corporation  
(Registrant)

Date: May 16, 2006

By: /s/ Larry Tannenbaum

Larry Tannenbaum  
Chief Financial Officer and Vice President, Administration  
(Principal Financial, Principal Accounting Officer  
and Authorized Signatory)

33

---

**Table of Contents**

**Exhibit Index**

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.