

IRIDEX CORP  
Form 10-Q  
December 22, 2006

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

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

**For the quarterly period ended September 30, 2006**

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

**For the Transition period from to**

**Commission File Number: 0-27598**

**IRIDEX CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware

77-0210467

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. employer  
identification No.)

**1212 Terra Bella Avenue**

**Mountain View, California 94043-1824**

(Address of principal executive offices, including zip code)

**(650) 940-4700**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐  
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. (See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act).

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☒

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

**APPLICABLE TO CORPORATE ISSUERS:**

The number of shares of common stock, \$.01 par value, issued and outstanding as of December 15, 2006 was 7,829,948.

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

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,439	\$ 12,655
Available-for-sale securities	17,651	8,779
Accounts receivable, net	6,373	6,589
Inventories	8,529	8,594
Prepays and other current assets	639	885
Current deferred income taxes	1,415	1,415
Total current assets	39,046	38,917
Property and equipment, net	1,082	1,114
Deferred income taxes and other long term assets	1,179	1,073
Total assets	\$ 41,307	\$ 41,104
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,093	\$ 1,094
Accrued expenses	3,700	4,421
Deferred revenue	1,328	1,072
Total liabilities	6,121	6,587
Contingencies (Note 5)		
Stockholders' equity:		
Common stock	79	76
Additional paid-in capital	28,955	26,334
Accumulated other comprehensive loss	(2)	(27)
Treasury stock	(430)	(430)
Retained earnings	6,584	8,564
Total stockholders' equity	35,186	34,517
Total liabilities and stockholders' equity	\$ 41,307	\$ 41,104

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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	October 1, 2005	September 30, 2006	October 1, 2005
Sales	\$ 9,222	\$ 9,081	\$ 26,869	\$ 26,613
Cost of sales	4,350	4,202	13,076	13,511
Gross profit	4,872	4,879	13,793	13,102
Operating expenses:				
Research and development	1,506	1,172	3,955	3,133
Sales, general and administrative	4,854	2,990	12,651	8,852
Total operating expenses	6,360	4,162	16,606	11,985
Income (loss) from operations	(1,488)	717	(2,813)	1,117
Interest and other income, net	184	157	540	413
Income (loss) before income taxes	(1,304)	874	(2,273)	1,530
Benefit from (provision for) income taxes	161	5	293	(241)
Net income (loss)	\$ (1,143)	\$ 879	\$ (1,980)	\$ 1,289
Net income (loss) per common share basic	(\$0.15)	\$ 0.12	(\$0.26)	\$ 0.17
Net income (loss) per common share diluted	(\$0.15)	\$ 0.11	(\$0.26)	\$ 0.16
Shares used in per common share basic calculations	7,758	7,441	7,680	7,373
Shares used in per common share diluted calculations	7,758	8,102	7,680	7,885

(A) Results for the three and nine months ended September 30, 2006 and October 1, 2005 include stock-based compensation expense as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2006	October 1, 2005	September 30, 2006	October 1, 2005
	(In thousands)			
Cost of sales	\$ 28	\$	\$ 95	\$

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Research and development	67	188
Selling, general and administrative	331	1,077

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

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September</b>	<b>October</b>	<b>September</b>	<b>October</b>
	<b>30,</b>	<b>1,</b>	<b>30,</b>	<b>1,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net income (loss)	\$ (1,143)	\$ 879	\$ (1,980)	\$ 1,289
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities, net of tax	2	4	16	(9)
Comprehensive income (loss)	\$ (1,141)	\$ 883	\$ (1,964)	\$ 1,280

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

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	<b>October 1,</b>
	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net income (loss)	\$ (1,980)	\$ 1,289
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	390	320
Warrants issued for services		87
Stock-based compensation	1,360	
Provision for doubtful accounts	108	38
Provision for excess and obsolete inventories	51	167
Changes in operating assets and liabilities:		
Accounts receivable	108	509
Inventories	14	(572)
Prepays and other current assets	246	51
Other long term assets	(106)	
Accounts payable	(1)	(45)
Accrued expenses	(721)	(469)
Deferred revenue	256	332
Net cash provided by (used in) operating activities	(275)	1,707
Cash flows from investing activities:		
Purchases of available-for-sale securities	(17,651)	(5,592)
Proceeds from maturity of available-for-sale securities	8,804	4,222
Acquisition of property and equipment	(358)	(327)
Net cash used in investing activities	(9,205)	(1,697)
Cash flows from financing activities:		
Issuance of common stock	1,264	664
Net cash provided by financing activities	1,264	664
Net increase (decrease) in cash and cash equivalents	(8,216)	674
Cash and cash equivalents at beginning of period	12,655	10,381
Cash and cash equivalents at end of period	\$ 4,439	\$ 11,055



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

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**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 statement 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 and nine months period ended September 30, 2006 are not necessarily indicative of the results for the year ending December 30, 2006 or any future interim period.

**2. Restatement of Financial Results for the Quarter Ended April 1, 2006**

As disclosed in the Company's Current Report on Form 8-K dated August 21, 2006, in August 2006 the Audit Committee of the Board of Directors engaged outside counsel and initiated an independent review of the Company's revenue recognition practices. This review was initiated in response to an allegation made by a former employee that the Company had recognized revenues prematurely in its fourth fiscal quarter of 2004. The investigation concluded that the Company had prematurely recognized revenue in 2004, but the error did not arise from any wrongful intent to impact the Company's financial reporting. In the course of this review, other errors, unrelated to the allegation, were identified from the period beginning in the fourth quarter of 2003 through the first quarter of 2006. As it relates to the errors identified in the first quarter of 2006, the Company determined that it was necessary to restate its financial results for the quarter ended April 1, 2006 to reflect adjustments to the previously reported financial information. While the review identified errors relating to the periods from the fourth quarter of 2003 through December 31, 2005, the Audit Committee of the Board of Directors concluded that these errors were not material to the previously issued financial statements. The nine month results of 2006 includes adjustments to reduce revenue, cost of sales and operating expenses by \$81,000, \$43,000 and \$5,000, respectively, related to the correction of immaterial errors related to prior periods.

**3. 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 the adoption of Statement of Financial Accounting Standards No. 123(R), (SFAS 123(R)), the Company adopted on January 1, 2006, the Company's significant accounting policies have not materially changed as of September 30, 2006.

*Revenue Recognition*

Our revenues arise from the sale of laser consoles, delivery devices, disposables and service and support activities. Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided that no significant obligations remain and collection of the receivables is reasonably assured. Shipments are generally made with Free-On-Board (FOB) shipping point terms, whereby title passes upon shipment from our dock. Any shipments with FOB receiving point terms are recorded as revenue when the shipment arrives at the receiving point. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments. Revenue relating to extended warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. We recognize repair service revenue upon completion of the work. Cost is recognized as product sales revenue is recognized. The Company's sales may include post-sale obligations for training or other deliverables. When these obligations are fulfilled after product shipment, the Company recognizes revenue in accordance with the multiple element accounting guidance set forth in Emerging Issues Task Force No. 00-21, Revenue Arrangements with Multiple Deliverables. When the Company has objective and reliable evidence of fair value of the undelivered elements, it defers revenue attributable to the post-sale obligations and recognizes such revenue when the obligation is

fulfilled. Otherwise, the Company defers all revenue related to the transaction until all elements are delivered.

*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 nine months ending September 30, 2006 and October 1, 2005 follows (in thousands):

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	Nine Months Ended	
	September 30, 2006	October 1, 2005
Balance, beginning of period	\$ 1,072	\$ 910
Additions to deferred revenue	1,256	1,135
Revenue recognized	(1,000)	(803)
Balance, end of period	\$ 1,328	\$ 1,242

***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 nine months ending September 30, 2006 and October 1, 2005 follows (in thousands):

	Nine Months Ended	
	September 30, 2006	October 1, 2005
Balance, beginning of period	\$ 1,128	\$ 933
Accruals for warranties issued during the period	586	955
Settlements made in kind during the period	(868)	(789)
Balance, end of period	\$ 846	\$ 1,099

**4. Inventories**

Inventories are stated at the lower of cost or market. Cost is being determined under a standard cost method, which approximates a first in, first out basis. The components of inventories consist of the following (in thousands):

	September 30, 2006	December 31, 2005
Raw materials and work in progress	\$ 3,781	\$ 5,191
Finished goods	4,748	3,403
Total inventories	\$ 8,529	\$ 8,594

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In October 2005, the Company filed a suit against Synergetics USA, Inc. ( Synergetics USA ). The suit is entitled *IRIDEX Corporation v. Synergetics USA, Inc.*, Case No. 4:05CV1916CDP in the United States District Court for the Eastern District of Missouri, Eastern Division, St. Louis for infringement of our patent No. 5,085,492. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics USA answered our complaint in November 2005, denied liability for patent infringement, and filed counterclaims seeking a declaratory judgment that it did not infringe our patent. Synergetics USA 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.

On July 7, 2006, the United States District Court for the Eastern District of Missouri, Eastern Division, St. Louis issued a Claim Construction Ruling, interpreting 14 disputed phrases within the Company's patent No. 5,085,492. The court adopted the Company's position with respect to 13 of the 14 patent terms, and adopted a position between the Company's and Synergetics' positions with respect to the 14th term. On November 2, 2006, the Company amended its complaint to add patent infringement claims against Synergetics USA's wholly owned subsidiary, Synergetics Inc. On November 10, 2006, Synergetics Inc. and Synergetics USA, answered the amended complaint, denying liability for patent infringement and filing counterclaims seeking a declaratory judgment that they did not infringe the Company's patent. Synergetics Inc. also re-filed the three additional counterclaims relating to disparagement, thereby substituting Synergetics Inc. for Synergetics USA as the plaintiff on those counterclaims. Discovery is scheduled to end on December 22, 2006, and trial is scheduled to begin on April 16, 2007. The Company is confident that its patent claims have merit, and if the parties do not reach a settlement, the Company intends to vigorously pursue its claims to judgment.

The Company is involved in another suit with Synergetics Inc., entitled *Synergetics, Inc. v. Peregrine Surgical, Ltd., Innovatech Surgical, Inc., and IRIDEX Corporation*, Case No. 06-CV-107 in the United States District Court for the Eastern District of Pennsylvania. Synergetics Inc. filed suit against the Company on April 25, 2006, by adding the Company as a defendant to a then-existing lawsuit against the other two defendants. Synergetics Inc. alleges that the Company infringes its patent and seeks injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On June 29, 2006, the Company filed its response to Synergetics Inc.'s pleading, denying Synergetics Inc.'s claims and asserting counterclaims seeking a declaratory judgment that it does not infringe Synergetics Inc.'s patent. Synergetics Inc.'s responded to the Company's counterclaims on July 24, 2006, denying them. On August 10, 2006, the case was reassigned to District Judge Thomas Golden.

On July 19, 2006, Synergetics Inc. filed suit in the United States District Court for the Eastern District of Missouri against the Company, seeking a declaratory judgment that a laser probe connector system that it announced on July 10, 2006 does not infringe the Company's patent No. 5,085,492, and seeking a declaratory judgment that the Company's patent is invalid and unenforceable. This suit is entitled *Synergetics, Inc. v. IRIDEX Corporation*, Case No. 4:06CV1104CDP. On August 15, 2006, the Company answered the Synergetics Inc. complaint, denying that Synergetics Inc. was entitled to any relief, and filed crossclaims against Synergetics USA Inc. and counterclaims against Synergetics Inc., alleging that they infringe the Company's patent No. 5,085,492 and seeking injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On November 20, 2006, the Court ordered that this case (No. 4:06CV1104CDP) be consolidated for all purposes with the case against Synergetics USA, pending in the same court (No. 4:05CV1916CDP), that the amended pleadings in the earlier case shall be the operative pleadings, and that this case be administratively closed.

Management believes that liabilities resulting from the proceedings described above (collectively referred to hereafter in this Quarterly Report on Form 10-Q as the Synergetics Litigation Matters), 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 and are adequately covered by the Company's liability insurance. However, it is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more

of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

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**6. Computations of Net Income (Loss) Per Common Share**

Basic and diluted net income (loss) per share are computed by dividing net income (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 and a warrant to purchase common stock.

During the three months ended October 1, 2005, options to purchase 306,196 shares of common stock at a weighted average exercise price of \$9.17 per share were outstanding but were not included in the computations of diluted net income per common share because the exercise price of the related options exceeded the average market price of the common shares. During the nine months ended October 1, 2005, options to purchase 488,832 shares at a weighted average exercise price of \$8.32 were outstanding, but were not included in the computations of diluted net income per share because the exercise price of the related options exceeded the average market price of the common shares. During the three and nine months ended September 30, 2006, options to purchase 2,183,013 shares of common stock at a weighted average exercise price of \$5.98 per share as well as a warrant to purchase 25,000 shares at a weighted average exercise price of \$6.07 were outstanding, but were not included in the computations of diluted net loss per share because their effect was antidilutive. These options and warrant could dilute earnings per share in future periods.

**7. 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 and nine months ended September 30, 2006 and October 1, 2005 is as follows (in thousands):

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	Three Months Ended September 30, 2006			Three Months Ended October 1, 2005		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
Sales	\$ 7,954	\$ 1,268	\$ 9,222	\$ 7,883	\$ 1,198	\$ 9,081
Direct cost of goods sold	2,444	560	3,004	2,461	465	2,926
Direct gross margin	5,510	708	6,218	5,422	733	6,155
Total unallocated costs			( 7,522)			(5,281)
Pre-tax income (loss)			(1,304)			874

  

	Nine Months Ended September 30, 2006			Nine Months Ended October 1, 2005		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
Sales	23,175	\$ 3,694	\$ 26,869	\$ 21,764	\$ 4,849	\$ 26,613
Direct cost of goods sold	7,186	1,718	8,904	7,219	2,393	9,612
Direct gross margin	15,989	1,976	17,965	14,545	2,456	17,001
Total unallocated costs			(20,238)			(15,471)
Pre-tax income (loss)			(2,273)			1,530

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

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

**8. 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.



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**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 1998 Plan is administered by the Company's Board of Directors (the "Administrator"). 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 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 the Company 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 the Company is the original price paid by the purchaser. As of September 30, 2006 and October 1, 2005, 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 were 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 of Directors for at least the preceding six months. The options granted had exercise prices equal to the 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. Directors are now granted options under the 1998 Plan.

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***Stand-Alone Options and Warrants***

In July 2005, in connection with the employment of Barry G. Caldwell as 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 July 2005, 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 of 0 percent, contractual life of 3 years, risk free rates of 4.04 percent and volatility of 83 percent. At September 30, 2006, the warrant remained 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 Deborah Tomasco, the Company's 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 nine months ended September 30, 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 nine months ended September 30, 2006 was \$1.4 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 nine months ended October 1, 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 multiple award (graded vesting) method 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:

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	Employee Stock Option Plan		Employee Stock Purchase Plan Three Months Ended		Employee Stock Option Plan		Employee Stock Purchase Plan Nine Months Ended	
	Three Months Ended September	October	September	October	September	October	September	October
	30, 2006	1, 2005	30, 2006	1, 2005	30, 2006	1, 2005	30, 2006	1, 2005
Average risk free interest rate	4.80%	4.04%	4.99%	3.68%	4.80%	4.13%	4.99%	3.25%
Expected life (in years)	3.8	3.0	0.5	0.5	3.8	3.0	0.5	0.5
Dividend yield								
Average volatility	65.0%	84.0%	42.0%	83.0%	65.0%	84.0%	42.0%	84.0%

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 an 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 and does not anticipate issuing any dividends in the future.

The following table shows stock-based compensation expense included in the condensed consolidated statements of operations for the three and nine months ended September 30, 2006 (in thousands):

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Cost of sales	\$ 28	\$ 95
Research and development	67	188
Sales, general and administrative	331	1,077
	\$ 426	\$ 1,360

Stock-based compensation capitalized as part of inventory for the three and nine months ended September 30, 2006 was insignificant.

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 income (loss) and net income (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 the methodology prescribed under SFAS 123, the Company's pro forma net income and net income per common share under SFAS 123 for the nine months ended October 1, 2005 would have been as follows (in thousands except per share data).



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	Three Months Ended October 1, 2005	Nine Months Ended October 1, 2005
Net income, as reported for prior periods	\$ 879	\$ 1,289
Stock-based compensation expense related to employee stock options and employee stock purchases	(205)	(537)
Pro forma net income	\$ 674	\$ 752
Basic net income per share:		
As reported	\$ 0.12	\$ 0.17
Pro forma	\$ 0.09	\$ 0.10
Diluted net income per share:		
As reported	\$ 0.11	\$ 0.16
Pro forma	\$ 0.08	\$ 0.10

Pro Forma disclosures for the three and nine months ended September 30, 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 are set forth below (in thousands except 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	297,650	8.45	88
Options exercised	(215,626)	4.48	(920)
Options forfeited/cancelled/expired	(28,014)	6.73	(56)
Outstanding at September 30, 2006	2,208,013	\$ 5.98	\$ 13,630

The weighted average grant date fair value of options granted during the nine months ended September 30, 2006 was \$8.45 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 third 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 September 30, 2006. This amount changes based on the fair market value of the Company's stock. Total intrinsic value of options exercised for the nine months ended September 30, 2006 was \$0.9 million. Total fair value of options vested and expensed was \$1.1 million, net of tax, for the nine months ended September 30, 2006.

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As a result of adopting the fair value recognition provisions of SFAS 123(R), the impact to the condensed consolidated financial statements for the nine months ended September 30, 2006 from stock-based compensation is as follows (in thousands, except per share data):

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Stock-based compensation expense by award type:		
Employee stock options granted	\$ 418	\$ 1,336
Employee stock purchase plan	8	24
Total stock-based compensation	426	1,360
Total effect on stock-based compensation at the Company's marginal tax rate	(76)	(238)
Effect on net income (loss)	\$ 350	\$ 1,122
Effect on net income (loss) per share:		
Basic and diluted	\$ (0.04)	\$ (0.14)

A summary of the status of the Company's non-vested options as of September 30, 2006 and changes during the period ended September 30, 2006 is presented below (in thousands, except per share amounts):

	Number of Shares	Weighted Average Grant Dated Fair Value
Non-vested at December 31, 2005	893,119	\$ 5.72
Granted	297,650	8.45
Vested	(249,102)	5.17
Cancelled/forfeited	(28,014)	6.73
Non-vested at September 30, 2006	913,653	6.66

As of September 30, 2006, there were \$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 three years.

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The following table summarizes information with respect to stock options outstanding at September 30, 2006:

Range of Exercise Prices	Options Outstanding			Options Vested and Exercisable		
	Number of Shares Outstanding at September 30,	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares Exercisable at September 30,	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
\$2.94 \$3.50	242,617	6.44	\$ 3.36	210,622	\$ 3.37	6.40
\$3.52 \$4.00	300,170	3.20	\$ 3.86	287,095	\$ 3.87	3.04
\$4.01 \$5.08	309,999	5.88	\$ 4.64	220,459	\$ 4.53	4.89
\$5.13 \$5.69	228,627	6.01	\$ 5.47	121,342	\$ 5.48	4.47
\$6.00 \$6.00	7,437	8.67	\$ 6.00	770	\$ 6.00	8.67
\$6.07 \$6.07	325,000	8.76	\$ 6.07	112,502	\$ 6.07	8.16
\$6.19 \$7.84	317,063	6.65	\$ 7.16	117,083	\$ 6.97	5.12
\$7.98 \$8.75	248,300	7.08	\$ 8.35	39,267	\$ 8.47	3.81
\$8.88 \$12.19	221,300	3.64	\$ 9.47	177,720	\$ 9.28	2.87
\$12.75 \$12.75	7,500	3.76	\$ 12.75	7,500	\$ 12.75	3.76
\$2.94 \$12.75	2,208,013	6.01	\$ 5.98	1,294,360	\$ 5.45	

As of September 30, 2006, the aggregate intrinsic value of fully vested and exercisable options was \$4.2 million.

**9. Subsequent Event**

On November 30, 2006 the Company signed a definitive agreement with American Medical Systems, Inc. and Laserscope, a wholly owned subsidiary of American Medical Systems, Inc., (AMS) under which we intend to acquire the laser aesthetics business of Laserscope. Under the terms of the definitive agreement, we will acquire certain assets and liabilities of Laserscope for approximately \$26 million in cash and \$2 million in unregistered shares of IRIDEX common stock, subject to post closing adjustments. AMS will be supplying aesthetics laser products to the Company for a period of up to nine months. At the end of this period, the Company will purchase from AMS any remaining raw material, work in process and finished goods inventory for no more than \$9.0 million. The Company plans to use a combination of cash and bank financing to finance the transaction. The Board of Directors for IRIDEX has unanimously approved the terms of the transaction, which is expected to close by early January 2007, subject to certain closing conditions.

**10. Recent Accounting Pronouncements**

In September 2006, the SEC issued SAB No. 108 regarding the process of quantifying financial statement misstatements. SAB No. 108 states that registrants should use both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. The interpretations in SAB No. 108 contain guidance on correcting errors under the dual approach as well as provide transition guidance for correcting errors. This interpretation does not change the requirements within SFAS No. 154, Accounting Changes and Error Corrections a replacement of APB No. 20 and Financial Accounting Standards Board ( FASB ) Statement No. 3, for the correction of an error on financial statements. SAB No. 108 is effective for annual financial statements covering the first fiscal years ending after November 15, 2006. The Company will be required to adopt this interpretation by December 31, 2006. Management is currently evaluating the requirements of SAB No. 108 and the impact this interpretation may have on the consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157,, Fair Value Measurements. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of



America, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurements. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS No. 157 in the first quarter of fiscal year 2008. Management is currently evaluating the requirements of SFAS No. 157 and has not yet determined the impact on the consolidated financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* effective for fiscal years beginning after December 15, 2006. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. The Company will decide on its policy for interest and penalty classification by the end of 2006 and adopt the Interpretation beginning with the fiscal year ending 2007. Upon adoption, it is not expected that the Interpretation will have a material effect on the Company's financial position or results of operation.

**Table of Contents****Item 2.****MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This Quarterly Report on Form 10-Q contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results, 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 age-related macular degeneration (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.*

**Restatement of Financial Results for the Quarter Ended April 1, 2006**

As disclosed in the Company's Current Report on Form 8-K dated August 21, 2006, in August 2006 the Audit Committee of the Board of Directors engaged outside counsel and initiated an independent review of the Company's revenue recognition practices. This review was initiated in response to an allegation made by a former employee that the Company had recognized revenues prematurely in its fourth fiscal quarter of 2004. The investigation concluded that the Company had prematurely recognized revenue in 2004, but the error did not arise from any wrongful intent to impact the Company's financial reporting. In the course of this review, other errors, unrelated to the allegation, were identified from the period beginning in the fourth quarter of 2003 through the first quarter of 2006. As it relates to the errors identified in the first quarter of 2006, the Company determined that it was necessary to restate its financial results for the quarter ended April 1, 2006 to reflect adjustment to the previously reported financial information. While the review identified errors relating to the periods from the fourth quarter of 2003 through December 31, 2005, the Audit Committee of the Board of Directors concluded that these errors were not material to the previously issued financial statements. The nine month results of 2006 includes adjustments to reduce revenue, cost of sales and operating expenses by \$81,000, \$43,000 and \$5,000, respectively, related to the correction of immaterial errors related to prior periods.

**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 69 independent distributors into 107 countries. Our revenues arise primarily from the sale of our OcuLight Systems, IQ810 lasers, VariLite, DioLite 532 systems, delivery devices, disposables and 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 the 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</b>		<b>Nine Months Ended</b>	
	<b>September</b>	<b>October</b>	<b>September</b>	<b>October</b>
	<b>30,</b>	<b>1,</b>	<b>30,</b>	<b>1,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Sales	100.0%	100.0%	100.0%	100.0%
Cost of sales	47.2%	46.3%	48.7%	50.8%
Gross profit	52.8%	53.7%	51.3%	49.2%
Operating expenses:				
Research and development	16.3%	12.9%	14.7%	11.8%
Sales, general and administrative	52.7%	32.9%	47.1%	33.2%
Total operating expenses	69.0%	45.8%	61.8%	45.0%
Income (loss) from operations	(16.1)%	7.9%	(10.5)%	4.2%
Interest and other income, net	2.0%	1.7%	2.0%	1.5%
Income (loss) before income taxes	(14.1)%	9.6%	(8.5)%	5.7%
Benefit from (provision for) income taxes	1.7%	0.0%	1.1%	(0.9)%
Net income (loss)	(12.4)%	9.6%	(7.4)%	4.8%

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>Nine Months Ended</b>			
	<b>September 30,</b>		<b>October 1, 2005</b>		<b>September 30, 2006</b>		<b>October 1, 2005</b>	
	<b>2006</b>							
	<b>Amount</b>	<b>Percentage of total sales</b>	<b>Amount</b>	<b>Percentage of total sales</b>	<b>Amount</b>	<b>Percentage of total sales</b>	<b>Amount</b>	<b>Percentage of total sales</b>
Domestic	\$ 5,699	61.8%	\$ 5,787	63.7%	\$ 16,126	60.0%	\$ 16,438	61.8%
International	3,523	38.2%	3,294	36.30%	10,743	40.0%	10,175	38.2%
Total	9,222	100.0%	9,081	100.0%	26,869	100.0%	26,613	100.0%
Ophthalmology:								
Domestic	4,803	52.1%	4,733	52.1%	13,441	50.0%	12,481	46.9%
International	3,151	34.2%	3,150	34.7%	9,734	36.2%	9,283	34.9%

Total	7,954	86.3%	7,883	86.8%	23,175	86.2%	21,764	81.8%
Dermatology:								
Domestic	896	9.7%	1,054	11.6%	2,685	10.0%	3,957	14.9%
International	372	4.0%	144	1.6%	1,009	3.8%	892	3.3%
Total	\$ 1,268	13.7%	\$ 1,198	13.2%	\$ 3,694	13.8%	\$ 4,849	18.2%
Total recurring revenue	\$ 3,732	40.5%	\$ 3,223	35.5%	\$ 11,443	42.6%	\$ 9,653	36.3%
Total non-recurring revenue	\$ 5,490	59.5%	\$ 5,858	64.5%	\$ 15,426	57.4%	\$ 16,960	63.7%

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### *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 and repair, servicing and extended warranty protection for our laser systems). Within the dermatology segment we review overall 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 1.6% to \$9.2 million for the three months ended September 30, 2006 from \$9.1 million for the three months ended October 1, 2005. Domestic sales which represented 61.8% of total sales, decreased by 1.5% to \$5.7 million from \$5.8 million. The decrease in domestic sales was a result of a \$0.1 million decrease in domestic dermatology sales. The decrease in domestic dermatology sales was driven primarily by unfilled dermatology sales positions for most of the third quarter of 2006. International sales, which were 38.2% of total sales, increased by 7.0% to \$3.5 million from \$3.3 million. The increase in international sales was a result of a \$0.1 million increase in international ophthalmology revenue and a \$0.1 million increase in international dermatology revenue.

For the nine months ended September 30, 2006, total sales increased 1.0% to \$26.9 million for the nine months ended September 30, 2006 from \$26.6 million for the nine months ended October 1, 2005. Domestic sales, which were 60.0% of total sales, decreased by 1.9% to \$16.1 million for the nine months ended September 30, 2006 from \$16.4 million for the nine months ended October 1, 2005. The decrease in domestic sales was a result of a \$1.2 million decrease in domestic dermatology sales offset by a \$0.9 million increase in domestic ophthalmology revenue. The decrease in domestic dermatology sales was mainly due to unfilled sales positions during most of the third quarter of 2006. International sales, which represented 40.0% of total sales, increased by 5.6% to \$10.7 million for the nine months ended September 30, 2006 from \$10.2 million for the nine months ended October 1, 2005. The increase in international sales was a result of a \$0.4 million increase in international ophthalmology sales and a \$0.1 million increase in international dermatology revenue.

### *Ophthalmology Sales*

Ophthalmology sales increased 0.9% to \$8.0 million for the three months ended September 30, 2006 from \$7.9 million for the three months ended October 1, 2005. Domestic ophthalmology sales increased 1.5% to \$4.8 million for the three months ended September 30, 2006 from \$4.7 million for the three months ended October 1, 2005. The increase in domestic ophthalmology sales was due, in large part, to increased sales of disposable products, including new disposables introduced in the last 18 months. International ophthalmology sales remained constant at \$3.2 million for the three months ended September 30, 2006 and October 1, 2005. No overall change in international ophthalmology sales occurred as increased international sales of disposable products were offset by decreased sales of ophthalmology equipment.

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For the nine months ended September 30, 2006, ophthalmology sales increased 6.5% to \$23.2 million from \$21.8 million for the nine months ended October 1, 2005. Domestic ophthalmology sales increased 7.7% for the nine months ended September 30, 2006 to \$13.4 million from \$12.5 million for the nine months ended October 1, 2005. For the nine months ended September 30, 2006, international ophthalmology sales increased 4.9% to \$9.7 million from \$9.3 million for the nine months ended October 1, 2005. The increases in sales for domestic and international ophthalmology for the nine month period ended September 30, 2006 was due mainly to increased sales of disposable products.

We anticipate that with the continued focus on our direct ophthalmic business that the disposable business will continue to grow at greater than historical rates. The second half of the year is historically the highest revenue period with the fourth quarter being the highest.

***Dermatology Sales***

Dermatology sales remained relatively constant at \$1.2 million for the three months ended September 30, 2006 and October 1, 2005. Domestic dermatology sales decreased 15.0% to \$0.9 million for the three month period ended September 30, 2006 from \$1.1 million for the comparable period in 2005. The decrease in domestic dermatology sales was driven primarily by unfilled dermatology sales positions. International dermatology sales increased 158.3% to \$0.4 million for the three months ended September 30, 2006 from \$0.1 million for the three months ended October 1, 2005.

For the nine months ended September 30, 2006 dermatology sales decreased 23.8% to \$3.7 million from \$4.8 million for the nine months ended October 1, 2005. Domestic dermatology sales decreased 32.1% to \$2.7 million for the nine months ended September 30, 2006 from \$4.0 million for the nine months ended October 1, 2005. The decrease in domestic dermatology sales was driven mainly by unfilled sales positions on the dermatology sales team in the second quarter of 2006. We have since hired an additional dermatology sales representative and have revised our marketing programs. International dermatology sales increased 13.1% to \$1.0 million for the nine months ended September 30, 2006 from \$0.9 million for the comparable period in 2005.

The company has restructured the domestic sales distribution network in order to increase productivity levels. The company believes that these changes will enhance the level of dermatology revenues during the fourth quarter of 2006.

***Gross Margin***

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September</b>		<b>September</b>	
	<b>30</b>	<b>October 1,</b>	<b>30</b>	<b>October 1,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Sales	100.0%	100.0%	100.0%	100.0%
Cost of sales	47.2%	46.3%	48.7%	50.8%
Gross profit	52.8%	53.7%	51.3%	49.2%

Our gross profit remained constant at \$4.9 million for the three month periods ended September 30, 2006 and October 1, 2005. Gross profit as a percentage of sales for the three months ended September 30, 2006 decreased to 52.8% from 53.7% for the comparable prior year three month period. The total 0.9% decrease in gross profit as a percentage of sales during this period included a decrease of 2.2% relating to higher product costs including product mix, the change in inventory reserves and warranty charges, and a 0.5% decrease due to reduced average selling prices offset by an increase of 1.8% related to lower overhead costs.

For the nine months ended September 30, 2006, gross profit increased by \$0.7 million to \$13.8 million from \$13.1 million for the nine months ended October 1, 2005. Gross profit as a percentage of sales for the nine months ended September 30, 2006 increased to 51.3% from 49.2%. The total 2.1% increase in gross

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profit as a percentage of sales during this period included an increase of 3.5% relating to lower product costs including product mix, the change in inventory reserves and warranty charges and an increase of 0.8% related to lower overhead costs offset by a 2.2% decrease due to reduced average selling prices.

Although increasing competition has continued to result in a downward trend in average selling prices for some products, 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. 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. See -Factors That May Affect Future Results If We Cannot Increase Our Sales Volumes, Reduce Our Costs or Introduce Higher Margin Products to Offset Anticipated Reductions in the Average Unit Selling Price of our Products, Our Operating Results May Suffer. We expect our gross profit margins to continue to fluctuate due to changes in the relative proportions of domestic and international sales, mix of sales of existing products, pricing, product costs 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>Nine Months Ended</b>	
	<b>September 30, 2006</b>	<b>October 1, 2005</b>	<b>September 30, 2006</b>	<b>October 1, 2005</b>
Research and development expense as a percentage of total revenue	16.3%	12.9%	14.7%	11.8%

Our research and development expenses increased by 28.5% to \$1.5 million for the three months ended September 30, 2006 from \$1.2 million for the three months ended October 1, 2005. Research and development expenses increased as a percentage of sales to 16.3% for the three months ended September 30, 2006 from 12.9% for the comparable prior year three-month period. The increase in research and development expenses in absolute dollars and as a percentage of sales for the three month period ended September 30, 2006 was due to \$0.3 million in increased project spending for new development projects, \$0.1 million in stock compensation expense offset by decreased consulting expense of \$0.1 million.

For the nine months ended September 30, 2006 research and development expenses increased 26.2% to \$4.0 million from \$3.1 million for the nine months ended October 1, 2005. As a percentage of sales, research and development expense increased to 14.7% for the nine months Ended September 30, 2006 from 11.8% for the nine months ended October 1, 2005. The increase in research and development expense in absolute dollars and as a percentage of sales for the nine month period ended September 30, 2006 was due primarily to a \$0.4 million in increased project spending, \$0.2 million in stock compensation expense, \$0.2 million in increased salaries, benefits and recruiting and relocation expenses associated with new hires in 2006, and a \$0.1 million in other research and development expense.

The company's research and development expenses have been higher than normal levels as two major laser consoles and several new disposable products are in development.



**Table of Contents***Selling, General and Administrative*

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September</b>	<b>October 1,</b>	<b>September</b>	<b>October 1,</b>
	<b>30,</b>	<b>2005</b>	<b>30,</b>	<b>2005</b>
	<b>2006</b>		<b>2006</b>	
Selling, general and administrative expense as a percentage of total revenue	52.7%	32.9%	47.1%	33.3%

Our sales, general and administrative expenses increased by 62.3% to \$4.9 million for the three months ended September 30, 2006 from \$3.0 million for the three months ended October 1, 2005. As a percentage of sales, sales, general and administrative expenses increased to 52.7% for the three months ended September 30, 2006 from 32.9% 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 September 30, 2006 as compared to the three month period ended October 1, 2005 was due primarily to \$1.1 million in increased legal spending associated mainly with litigation, \$0.3 million in stock compensation expense, increased bad debt expense of \$0.2 million, \$0.1 million in increased salaries, benefits, recruiting expenses for new marketing personnel, \$0.1 million in increased selling expenses and \$0.1 million in other general and administrative increases.

For the nine months ended September 30, 2006 sales, general and administrative expense increased 42.9% to \$12.7 million from \$8.9 million for the nine months ended October 1, 2005. As a percentage of sales, sales, general and administrative expense increased to 47.1% for the nine months ended September 30, 2006 from 33.3% for the nine months ended October 1, 2005. The increase in sales, general and administrative expense in absolute dollars and as a percentage of sales for the nine month period ended September 30, 2006 was due primarily to \$1.63 million in increased legal spending associated mainly with litigation, \$1.0 million in stock compensation expense, \$0.6 million in increased selling expenses related to increased headcount and activity, \$0.4 million in increased marketing spending related to salaries, benefits and recruiting for new hires as well as increased marketing activity and , \$0.3 million in spending associated with an investigation of our revenue recognition practices,\$0.1 million in increased business development spending, and a \$0.1 million increase in other general and administrative spending. The company's selling, general and administrative expenses have been running at higher than historical levels throughout 2006 and, in particular, in the second and third quarters of 2006. This has been due to some unusual expenses particularly relating to legal expenses and new hire expenses. The company expects these unusual expenses to decline and return back to historical levels. Spending associated with the Synergetics litigation is not expected to continue beyond the second quarter of 2007 as a trial date of April 2007 has been established.

*Interest and Other Income, net.* For the three months ended September 30, 2006 we recorded net other income of \$184,000 as compared with net other income of \$157,000 for the three months ended October 1, 2005. For the nine months ended September 30, 2006, net other income was \$540,000 as compared with \$414,000 for the nine months ended October 1, 2005. The change in net other income for both the three and nine month periods was due primarily to increased interest rates and to increased cash, cash equivalents and available for sale securities.

*Income Taxes.* The effective income tax rate for the three month period ending September 30, 2006 was 12.3% as compared with 0.6% for the three month period ending October 1, 2005. For the nine month period ending September 30, 2006 the effective income tax rate was 12.9% as compared with 15.8% for the nine month period ending October 1, 2005. The change in the effective tax rate was driven primarily by the accounting for certain tax benefits associated with stock compensation expense commencing in 2006.

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### **Liquidity and Capital Resources**

At September 30, 2006, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of \$22.1 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 2007. As of September 30, 2006, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2007, assuming that the terms continue to be acceptable.

During the nine months ended September 30, 2006, operating activities used \$0.3 million of cash. The primary uses of cash from operating activities included a net loss of \$2.0 million and, a decrease in accrued expenses of \$0.7 million, offset by sources of cash which included stock compensation expense of \$1.4 million, depreciation of \$0.4 million, an increase in deferred revenue of \$0.3 million, a decrease in net accounts receivable of \$0.1 million and an increase in other miscellaneous sources of \$0.1 million. The decrease in accrued expenses related primarily to a \$0.9 million decrease in accrued salaries associated with payment of the 2005 bonus and commission as well as the timing of payroll, \$0.3 million in decreased warranty reserves due to decreased coverage periods, a \$0.3 million decrease in tax payable offset by a \$0.7 million increase in accrued legal and accounting fees associated mainly with litigation and \$0.1 million in other miscellaneous uses. Net accounts receivable decreased by \$0.2 million as a result of continued focus on collection efforts.

Investing activities used \$9.2 million in cash and cash equivalents during the nine months ended September 30, 2006, primarily due to purchases of available for sale securities of \$8.8 million, net of maturities and purchases of fixed assets of \$0.4 million.

Net cash provided by financing activities during the nine months ended September 30, 2006 was \$1.3 million which consisted of the issuance of common stock under employee option plans and the employee stock purchase plan.

As noted in Note 9 to the condensed and consolidated financial statements, on November 30, 2006, we signed a definitive agreement with American Medical Systems, Inc, and Laserscope, a wholly-owned subsidiary of American Medical Systems (AMS) under which we intend to acquire the laser aesthetics business of Laserscope. Under the terms of the definitive agreement, we will acquire certain assets and liabilities of Laserscope for approximately \$26 million in cash and \$2 million in unregistered shares of IRIDEX common stock, subject to post closing adjustments. AMS will be supplying aesthetic laser products to the Company for a period of up to nine months. At the end of this period, the Company will purchase from AMS any remaining raw materials, work in process and finished goods inventory for no more than \$9 million. The Company plans to use a combination of cash and bank financing to finance the transaction. Our Board of Directors has unanimously approved the terms of the transaction, which is expected to close by early January 2007 subject to certain closing conditions.

We believe that, based on current estimates, our cash, cash equivalents and available-for-sale securities together with cash generated from operations and the bank financing to be obtained in connection with our acquisition of the laser aesthetics business of Laserscope will be sufficient to meet our anticipated cash requirements for the 12 months following the acquisition which is expected to close by early January 2007. 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 well as the increased working capital requirements of our business following completion of our pending acquisition of the Laserscope laser aesthetics business. 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.

**Table of Contents****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; however, they have been updated below to reflect the adoption of SFAS 123(R) on January 1, 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 nine months ended September 30, 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 nine months ended September 30, 2006 was \$1.4 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 nine months ended October 1, 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 multiple award (graded vesting) method to the straight-line single option method.

**Recent Accounting Pronouncements**

In September 2006, the SEC issued SAB No. 108 regarding the process of quantifying financial statement misstatements. SAB No. 108 states that registrants should use both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. The interpretations in SAB No. 108 contain guidance on correcting errors under the dual approach as well as provide transition guidance for correcting errors. This interpretation does not change the requirements within SFAS No. 154, Accounting Changes and Error Corrections—a replacement of APB No. 20 and Financial Accounting Standards Board (FASB) Statement No. 3, for the correction of an error on financial statements. SAB No. 108 is effective for annual financial statements covering the first fiscal years ending after November 15, 2006. The Company will be required to adopt this interpretation by December 31, 2006. Management is currently evaluating the requirements of SAB No. 108 and the impact this interpretation may have on the consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurements. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS No. 157 in the first quarter of fiscal year 2008. Management is currently evaluating the requirements of SFAS No. 157 and has not yet determined the impact on the consolidated financial statements.

In July 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes—effective for fiscal years beginning after December 15, 2006. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. The Company will decide on its policy for interest and penalty classification by the end of 2006 and adopt the Interpretation beginning with the fiscal year ending 2007. Upon adoption, it is not expected that the Interpretation will have a material effect on the Company's financial position or results of operation.

**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 September 30, 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:

the fall in value of available-for-sale securities if market interest rates increase; and

the impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

Our exposure to interest rate risk at September 30, 2006 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of high quality corporate issuers, asset-backed securities and variable-rate municipal bonds. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 12 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments. As of September 30, 2006, the carrying value of these investments approximates fair market value. We do not believe any of our investments are other than temporarily impaired at September 30, 2006.

Management evaluates our financial position on an ongoing basis.

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*Currency Rate Risk.* As all of our sales transactions and the majority of our expenses 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 our disclosure controls and procedures (as defined in Rule 13A-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934 (the "34 Act"), as of the end of the period covered by this report.

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

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

A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management determined that the following control deficiencies constitute a material weakness in our internal control over financial reporting at September 30, 2006.

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. Specifically, the material weakness identified by our independent accountants relates to a failure to maintain adequate period-end review procedures to ensure the completeness and accuracy of certain journal entries impacting general ledger accounts. As a result, an error in a system generated custom inventory report and errors in two key spreadsheets related to warranty and deferred revenue resulted in incorrect entries being recorded to the financial statements which were not identified and corrected by management in a timely manner.

In addition, as disclosed in our Current Report on Form 8-K dated August 21, 2006, in August 2006, the Audit Committee of the Board of Directors engaged outside counsel and initiated an independent review of our revenue recognition practices. This review was initiated in response to an allegation made by a former employee. In the course of this review, errors in revenue recognition were identified from the period beginning in 2003 through the first quarter of 2006. As a result of these errors, the Audit Committee of the Board of Directors determined that it was necessary to restate our financial results for the quarter ended April 1, 2006 to reflect adjustments to the previously reported financial information. While errors were identified in prior years, we concluded that the errors were not material to the previously issued financial statements.

During the course of its review, management, with the participation of the CEO and CFO, determined the Company did not maintain effective controls over the accounting for revenue because of the following material weakness.

The Company did not maintain effective controls over the completeness and accuracy of the revenue recognition process. Specifically, effective controls were not designed and in place to ensure that all terms and conditions relating

to revenue agreements, including verbal and written side arrangements, non standard terms and multiple element arrangements, were identified to ensure revenue was accurately recorded in accordance with generally accepted accounting principles. Additionally, effective controls were not designed and in place to ensure that sales personnel did not enter into unauthorized side arrangements with customers, including rights of return. This control deficiency resulted in restatements of the Company's consolidated financial statements for the first quarter of 2006 and adjustments to the second quarter of 2006, affecting revenue, cost of goods sold, operating expenses and inventory. These control deficiencies could result in the misstatement of the aforementioned accounts that would result in a material misstatement of the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, management has determined that these control deficiencies constitute a material weakness at September 30, 2006.

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*Plan for remediation of material weaknesses*

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

Related to our period-end review procedures:

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

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

correction of a system generated custom report to include additional information necessary to prepare accurate financial information;

implementation of additional review procedures; and

enhancement of the current capabilities of the finance function.

Related to our revenue recognition practices:

reassignment of responsibilities for oversight of the sales function and responsibilities for internal control over sales transactions;

provision of additional training on a recurring basis for all domestic sales personnel on revenue recognition policies and procedures;

establishment of annual formal training for our customer service group on revenue recognition policies and procedures;

establishment of a checklist for use by our customer service group in processing revenue transactions to verify proper recognition and establishment of a policy by which this checklist is signed off by the preparer and at least one reviewer;

establishment of internal audit procedures over all domestic laser sale transactions; and

formalization over our sales returns process to include more thorough documentation, review and approval for all returns.

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

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

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

We have implemented most of the corrective actions related to the material weaknesses related to our period-end review procedures identified above in the three-month period covered by this Quarterly Report on Form 10-Q. We continue to implement automated general ledger reports to replace key spreadsheets where possible and we are in the

process of enhancing the current capabilities of the finance function. No other change has occurred in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the 34 Act) during the quarter ended September 30, 2006, that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting. As discussed in (a) above, management has designed a plan for remediation and is implementing changes in our internal control over financial reporting to remediate the material weaknesses identified above.



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

In October 2005, the Company filed a suit against Synergetics USA, Inc. ( Synergetics USA ). The suit is entitled *IRIDEX Corporation v. Synergetics USA, Inc.*, Case No. 4:05CV1916CDP in the United States District Court for the Eastern District of Missouri, Eastern Division, St. Louis for infringement of our patent No. 5,085,492. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics USA answered our complaint in November 2005, denied liability for patent infringement, and filed 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.

On July 7, 2006, the United States District Court for the Eastern District of Missouri, Eastern Division, St. Louis issued a Claim Construction Ruling, interpreting 14 disputed phrases within the Company's patent No. 5,085,492. The Court adopted the Company's position with respect to 13 of the 14 patent terms, and adopted a position between the Company's and Synergetics' positions with respect to the 14th term. On November 2, 2006, the Company amended its complaint to add patent infringement claims against Synergetics USA's wholly owned subsidiary, Synergetics Inc. On November 10, 2006, Synergetics Inc. and Synergetics USA, Inc. answered the amended complaint, denying liability for patent infringement and filing counterclaims seeking a declaratory judgment that they did not infringe the Company's patent. Synergetics Inc. also re-filed the three additional counterclaims relating to disparagement, thereby substituting Synergetics Inc. for Synergetics USA as the plaintiff on those counterclaims. Discovery is scheduled to end on December 22, 2006, and trial is scheduled to begin on April 16, 2007. The Company is confident that its patent claims have merit, and if the parties do not reach a settlement, the Company intends to vigorously pursue its claims to judgment.

The Company is involved in another suit with Synergetics Inc., entitled *Synergetics, Inc. v. Peregrine Surgical, Ltd., Innovatech Surgical, Inc., and IRIDEX Corporation*, Case No. 06-CV-107 in the United States District Court for the Eastern District of Pennsylvania. Synergetics filed suit against the Company on April 25, 2006, by adding the Company as a defendant to a then-existing lawsuit against the other two defendants. Synergetics alleges that the Company infringes its patent and seeks injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On June 29, 2006, the Company filed its response to Synergetics' pleading, denying Synergetics' claims and asserting counterclaims seeking a declaratory judgment that it does not infringe Synergetics' patent. Synergetics responded to the Company's counterclaims on July 24, 2006, denying them. On August 10, 2006, the case was reassigned to District Judge Thomas Golden.

On July 19, 2006, Synergetics Inc. (a wholly owned subsidiary of Synergetics USA, Inc.) filed suit in the United States District Court for the Eastern District of Missouri against the Company, seeking a declaratory judgment that a laser probe connector system that it announced on July 10, 2006 does not infringe the Company's patent No. 5,085,492, and seeking a declaratory judgment that the Company's patent is invalid and unenforceable. This suit is entitled *Synergetics, Inc. v. IRIDEX Corporation*, Case No. 4:06CV1104CDP. On August 15, 2006, the Company answered the Synergetics Inc. complaint, denying that Synergetics Inc. was entitled to any relief, and filed crossclaims against Synergetics USA Inc. and counterclaims against Synergetics Inc., alleging that they infringe the Company's patent No. 5,085,492 and seeking injunctive relief, monetary damages, treble damages, costs and attorneys' fees. On November 20, 2006, the Court ordered that this case (No. 4:06CV1104CDP) be consolidated for all purposes with the earlier case pending in the same court (No. 4:05CV1916CDP), that the amended pleadings in the earlier case shall be the operative pleadings, and that this case be administratively closed.

Management believes that liabilities resulting from the proceedings described above (collectively referred to hereafter in this Quarterly Report on Form 10-Q as the Synergetics Litigation Matters), 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 and are adequately covered by the Company's liability insurance. However, it is possible that cash flows or

results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

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**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:

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

acceptance of the company's new marketing programs;

recommendations and opinions by ophthalmologists, dermatologists, other clinicians, plastic surgeons and their associated opinion leaders, including study outcomes;

price of our products and prices of competing products and technologies;

availability of competing products, technologies and alternative treatments; and

level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales from recurring revenues including disposable laser probes, EndoProbes and service. Our ability to increase recurring revenues from the sale of EndoProbes will depend primarily upon the features of our current products and product innovation, ease of use and prices of our products, including the relationship to prices of competing delivery devices. The level of service revenues will depend on our quality of care, responsiveness and the willingness of our customers to request 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.

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

*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 (which was recently acquired by American Medical Systems, Inc.). On November 30, 2006, we signed a definitive agreement with American Medical Systems, Inc. and Laserscope under which we intend to acquire the laser aesthetics business of 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.

*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 September 30, 2006, our ophthalmology sales were \$8.0 million or 86.3% of total sales. For the nine months ended September 30, 2006, our ophthalmology sales were \$23.2 million or 86.2% 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.



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*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 September 30, 2006, our international sales were \$3.5 million or 38.2% of total sales. For the nine months ended September 30, 2006, our international sales were \$10.7 million or 40.0% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues, particularly ophthalmology, in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies. 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:

- impact of recessions in economies outside of the United States;
- performance of our international channel of distributors;
- foreign certification requirements, including continued ability to use the CE mark in Europe;
- reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- longer accounts receivable collection periods;
- potentially adverse tax consequences; and

multiple protectionist, adverse and changing foreign governmental laws and regulations.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations.

*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 21 employees and we maintain relationships with 69 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 distributionship 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.

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*Failure to Remediate the Material Weaknesses in Our Disclosure Controls and Procedures in a Timely Manner, or At All, Could Harm Our Operating Results or Cause Us to Fail to Meet Our Regulatory or Reporting Obligations.* We evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report and, based on this evaluation, management concluded that our disclosure controls and procedures were not effective because of the material weaknesses detailed in 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 and in Item 4 of this Quarterly Report on Form 10-Q.

In particular, the material weaknesses identified related to the Company's period-end review procedures and revenue recognition practices. We are taking a number of remedial actions designed to remedy the material weaknesses summarized above. However, if despite our efforts, we fail to remediate our material weaknesses, we could be subject to regulatory scrutiny and a loss of public confidence in our disclosure controls and procedures. These remediation efforts will likely increase our general and administrative expenses and could, therefore, have an adverse effect on our reported net income.

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

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

*If We Fail to Accurately Forecast Demand For Our Product and Component Requirements For the Manufacture of Our Product, We Could Incur Additional Costs or Experience Manufacturing Delays and May Experience Lost Sales or Significant Inventory Carrying Costs.* We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. 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

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on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent manufacturers, including the following:

unavailability of, shortages or limitations on the ability to obtain supplies of components in the quantities that we require;

delays in delivery or failure of suppliers to deliver critical components on the dates we require;

failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and

inability to obtain components at acceptable prices.

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

*We Face Risks Associated with our Collaborative and OEM Relationships.* Our collaborators may not pursue further development and commercialization of products resulting from collaborations with us or may not devote sufficient resources to the marketing and sale of such products. For example, in 2005 we developed and sold a laser system on an OEM basis for a third party which positively impacted the revenues and gross margins during the second half of 2005. We cannot provide assurance that these types of relationships will continue over a longer period. Our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. If a collaborator elects to terminate its agreement with us, our ability to develop, introduce, market and sell the product may be significantly impaired and we may be forced to discontinue altogether the product resulting from the collaboration. We may not be able to negotiate alternative collaboration agreements on acceptable terms, if at all. The failure of any current or future collaboration efforts could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

*We Face Manufacturing Risks.* The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and all of our final products at our facility in Mountain View, California. We may experience manufacturing difficulties, quality control issues or assembly constraints, particularly with regard to new products that we may introduce. We may 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.



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*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.

*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.

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

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

*We entered into a definitive asset purchase agreement with American Medical Systems, Inc. and Laserscope, a wholly owned subsidiary of American Medical Systems, Inc. on November 30, 2006 and we may experience unexpected difficulties closing this transaction or integrating the aesthetics business which we agreed to purchase in this transaction.* On November 30, 2006, we signed a definitive agreement with American Medical Systems, Inc. and Laserscope, a wholly-owned subsidiary of American Medical Systems, Inc., under which we intend to acquire the laser aesthetics business of Laserscope. Under the terms of the definitive agreement, we will acquire certain assets and liabilities of Laserscope, for approximately \$26 million in cash and \$2 million in unregistered shares of our common stock, subject to post closing adjustments. We intend to use a combination of cash and bank financing to finance the transaction. Our Board of Directors has unanimously approved the terms of the transaction, which is expected to close by early January 2007, subject to certain closing conditions. However, there can be no assurance that the transaction will close on a timely basis, or at all.

Integrating the aesthetics business of Laserscope may be expensive and time-consuming and we may not be able to successfully do so. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and can prove to be more difficult or expensive than predicted. The diversion of our management's attention and any delay or difficulties encountered in connection with the pending acquisition of the aesthetics business of Laserscope could result in the disruption of our on-going business or inconsistencies in standards, controls, procedures and policies that could negatively affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. [Moreover, we may need to raise additional funds through public or private debt or equity financing to cover the costs of this transaction, which may result in dilution for stockholders or the incurrence of indebtedness]. If our efforts to close the transactions contemplated by the definitive agreement or to integrate the aesthetics business are unsuccessful or are more difficult, time consuming or expensive than originally planned, we may incur unexpected disruptions to our on-going business. These disruptions could harm our operating results. Further, the following specific factors may adversely affect our ability to integrate the aesthetics business of Laserscope:

we may experience unexpected losses of employees or customers we expected to gain in connection with this transaction;

we may not achieve expected levels of revenue growth;

we may not be able to coordinate our current product development efforts with those of the aesthetics business of Laserscope in a way which permits us to bring future new products to the market in a timely and cost-effective manner; and

we may discover that liabilities that we assumed are greater than anticipated.

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



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*Our Stock Price Has Been and May Continue to be Volatile and an Investment in Our Common Stock Could Suffer a Decline in Value.* The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. 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. 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.

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

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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 Rely on Patents and Proprietary Rights to Protect our Intellectual Property and Business.* Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued fifteen United States patents and five foreign patents on the technologies related to our products and processes. We have approximately five pending patent applications in the United States and six foreign pending patent applications that have been filed. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

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

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

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop noninfringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition. Management believes that liabilities resulting from the Synergetics Litigation Matters described in Part II, Item 4, or other claims which are pending or known to be threatened, will not have a material adverse effect on the Company's financial position or results of operations. However, it is possible that cash flows or results or operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

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*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 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.

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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.

*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 Product Liability Claims are Successfully Asserted Against Us, We may Incur Substantial Liabilities That May Adversely Affect Our Business or Results of Operations.* We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue and skin conditions on and near a patient's face. Although we maintain product liability insurance with coverage limits of \$10.0 million per occurrence and an annual aggregate maximum of \$10.0 million, our coverage from our insurance policies may not be adequate. Product liability insurance is expensive. We might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

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





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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.

*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.

*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, bank financing associated with our acquisition of Laserscope 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 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.

*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.

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

None.

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

None.

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

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

31.1 Certification of Chief Executive Officer pursuant to 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, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, MicroPulse, ScanLite, ColdTip (Handpiece), VariSpot (Handpiece), TruView and EasyFit product names are our trademarks. All other trademarks or trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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**SIGNATURE**

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

IRIDEX Corporation  
(Registrant)

Date: December 22, 2006

By: /s/ Larry Tannenbaum

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

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**Exhibit Index**

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