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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

OR

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

For the transition period _____ to _____ .

Commission file number: 000-50644

CUTERA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**77-0492262**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**

3240 Bayshore Blvd., Brisbane, California 94005
(Address of principal executive offices)

(415) 657-5500
(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 an accelerated filer (as defined in rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

The number of shares of Registrant's common stock issued and outstanding as of October 31, 2005 was 11,837,716.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CUTERA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 4,728	$ 7,070
Marketable investments	77,488	59,200
Accounts receivable, net	5,331	6,643
Inventory	5,000	3,004
Deferred tax asset	1,680	2,284
Other current assets	2,513	878
Total current assets	96,740	79,079
Property and equipment, net	1,044	1,071
Intangibles, net	502	399
Total assets	$ 98,286	$ 80,549
Liabilities and Stockholders' Equity		
Liabilities:		
Accounts payable	$ 1,625	$ 1,195
Accrued liabilities	8,553	8,194
Deferred revenue	1,427	1,171
Total current liabilities	11,605	10,560
Deferred rent	984	648
Deferred revenue, net of current portion	1,156	833
Non-current portion of deferred tax liability	60	52
Total liabilities	13,805	12,093
Contingencies (Note 8)		
Stockholders' equity:		
Common stock	12	11
Additional paid-in capital	71,002	62,738
Deferred stock-based compensation	(2,417)	(2,226)
Retained earnings	15,933	7,942
Other comprehensive loss	(49)	(9)
Total stockholders' equity	84,481	68,456
Total liabilities and stockholders' equity	$ 98,286	$ 80,549

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

CUTERA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net revenue	$18,950	$12,703	$51,667	$36,548
Cost of revenue[1]	4,746	3,408	13,642	10,454
Gross profit	14,204	9,295	38,025	26,094
Operating expenses:				
Sales and marketing	6,151	4,677	17,694	13,578
Research and development	1,275	979	3,692	2,985
General and administrative	1,621	2,171	5,819	6,151
Amortization of stock-based compensation[2]	433	317	1,100	954
Total operating expenses	9,480	8,144	28,305	23,668
Income from operations	4,724	1,151	9,720	2,426
Interest and other income, net	549	198	1,351	255
Income before income taxes	5,273	1,349	11,071	2,681
Provision for income taxes	(1,472)	(472)	(3,080)	(991)
Net income	$ 3,801	$ 877	$ 7,991	$ 1,690
Net income available to common stockholders used in basic earnings per share	$ 3,801	$ 877	$ 7,991	$ 1,394
Net income per share:				
Basic	$ 0.33	$ 0.08	$ 0.70	$ 0.18
Diluted	$ 0.27	$ 0.07	$ 0.58	$ 0.14
Weighted-average number of shares used in per share calculations:				
Basic	11,661	10,729	11,369	7,863
Diluted	13,924	13,085	13,681	11,922
(1) Cost of revenue includes amortization of stock-based compensation of:	$ 40	$ 39	$ 102	$ 129
(2) Amortization of stock-based compensation is attributable to the following operating expense categories:				
Sales and marketing	71	63	160	211
Research and development	59	105	240	309
General and administrative	303	149	700	434
	433	317	1,100	954
Total amortization of stock-based compensation	$ 473	$ 356	$ 1,202	$ 1,083

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

CUTERA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash flows from operating activities:		
Net income	$ 7,991	$ 1,690
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	503	380
Allowance for doubtful accounts	(296)	102
Change in reserve for excess and obsolete inventory	434	95
Stock-based compensation	1,202	1,083
Change in deferred tax asset/liability	612	(759)
Tax benefits related to employee stock options	3,125	182
Loss on disposal of assets	—	104
Changes in assets and liabilities:		
Accounts receivable	1,608	1,172
Inventory	(2,430)	(965)
Other current assets	(1,635)	(34)
Accounts payable	430	16
Accrued liabilities	359	985
Deferred rent	336	536
Deferred revenue	579	714
Net cash provided by operating activities	12,818	5,301
Cash flows from investing activities:		
Acquisition of property and equipment	(414)	(652)
Purchase of intangibles	(165)	—
Proceeds from sales of marketable investments	18,294	—
Proceeds from maturities of marketable investments	34,373	—
Purchase of short term investments, net	(70,995)	(6,055)
Change in restricted cash	—	250
Net cash used in investing activities	(18,907)	(6,457)
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	3,747	441
Proceeds from issuance of common stock, net	—	46,336
Net cash provided by financing activities	3,747	46,777
Net (decrease) / increase in cash and cash equivalents	(2,342)	45,621
Cash and cash equivalents at beginning of period	7,070	10,290
Cash and cash equivalents at end of period	$ 4,728	$ 55,911
Supplemental disclosure of non-cash information:		
Change in deferred stock based compensation, net of terminations	$ 1,393	$ (175)
Conversion of preferred stock to common stock	$ —	$ 7,372

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

CUTERA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Basis of Presentation

The condensed consolidated financial statements include the accounts of Cutera, Inc. (the "Company"), a Delaware corporation, and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

The financial information furnished is unaudited. The condensed consolidated financial statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that the Company considers necessary for the fair presentation of the results of operations for the interim periods covered and of the financial condition of the Company at the date of the interim balance sheet. The results for interim periods are not necessarily indicative of the results for the entire year. The condensed consolidated balance sheet at December 31, 2004 has been derived from the audited financial statements at that date. The condensed consolidated financial statements should be read in conjunction with the Company's financial statements and the notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2004 filed with the Securities and Exchanged Commission ("SEC") on March 25, 2005.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's annual report on Form 10-K for the year ended December 31, 2004 and have not changed significantly as of September 30, 2005.

Note 2. Accounting for Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements using the intrinsic value method and has adopted the disclosure-only provisions of Statement of Financial Accounting Standard ("SFAS") No. 123 "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure." The Company is required to disclose the pro forma effects on net income as if it had elected to use the fair value approach to account for all its stock-based employee compensation plans.

The following table illustrates the effect on net income if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation arrangements (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income, as reported	$ 3,801	$ 877	$ 7,991	$ 1,690
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	224	282	716	865
Less: Total stock-based employee compensation determined under fair-valued based method for all awards, net of related tax effects	(624)	(378)	(1,558)	(1,039)
Pro forma net income	$ 3,401	$ 781	$ 7,149	$ 1,516
Pro forma net income available to common stockholders, used in basic earnings per share:	$ 3,401	$ 781	$ 7,149	$ 1,251
Basic net income per share:				
As reported	$ 0.33	$ 0.08	$ 0.70	$ 0.18
Pro forma	$ 0.29	$ 0.07	$ 0.63	$ 0.16
Diluted net income per share:				
As reported	$ 0.27	$ 0.07	$ 0.58	$ 0.14
Pro forma	$ 0.25	$ 0.06	$ 0.53	$ 0.13

In computing these pro forma amounts, the Company has used the minimum value method for options granted prior to January 15, 2004 (the date of the first filing of the Company's Form S-1 in connection with its initial public offering) and the fair value method for options granted after this date.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Equity instruments issued to non-employees are recorded at their fair value on the measurement date. The compensation expense for non-employee option grants is recognized over the expected service period on a straight-line basis.

Stock-based compensation consists of amortization of deferred stock-based compensation related to restricted stock units and stock options to purchase common stock issued to employees; and the values of options to purchase common stock issued to non-employees. Amortization of deferred stock-based compensation totaled $473,000 and $356,000 for the three months ended September 30, 2005 and 2004, respectively. For the nine months ended September 30, 2005 and 2004, total deferred stock-based amortization was $1.2 million and $1.1 million, respectively.

Note 3. Net Income Per Share

Basic net income per share is computed by dividing net income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net income per share is computed by giving effect to all potential dilutive common stock, including options and restricted stock unit awards. The following table sets forth the computation of basic and diluted net income per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Numerator:				
Net income	$ 3,801	$ 877	$ 7,991	$ 1,690
Less: Amount allocated to participating preferred stockholders	—	—	—	(296)
Net income available to common stockholders –Basic	$ 3,801	$ 877	$ 7,991	$ 1,394
Net income available to common stockholders – Diluted	$ 3,801	$ 877	$ 7,991	$ 1,394
Denominator:				
Weighted-average number of common shares outstanding used in computing basic net income per share	11,661	10,729	11,369	7,863
Dilutive potential common shares used in computing diluted net income per share	2,263	2,356	2,312	4,059
Total weighted-average number of shares used in computing diluted net income per share	13,924	13,085	13,681	11,922

Anti-dilutive securities

The following restricted stock unit awards and outstanding options (prior to the application to the treasury stock method) were excluded from the computation of diluted net income per common share for the periods presented because including them would have had an antidilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Options to purchase common stock	—	758	53	508
Restricted stock units	—	—	17	—

Note 4. Inventory

Inventory consists of the following (in thousands):

	September 30, 2005	December 31, 2004
Raw materials	$ 2,472	$ 1,510
Finished goods	2,528	1,494
	$ 5,000	$ 3,004

Note 5. Warranty and Service Contracts

The Company has a direct field service organization in the United States, Canada, Switzerland and Japan that provides service for its products in these countries. The Company has third party service providers in all other locations. The Company generally provides a warranty with its products, depending on the type of product. After the warranty period, maintenance and support are offered on a service contract basis or on a time and materials basis.

Warranty reserve (in thousands):

	September 30, 2005	September 30, 2004
Balance at December 31, 2004 and 2003	$ 1,850	$ 1,700
Add: Accruals for warranties issued in 2005 and 2004	1,818	1,306
Less: Settlements made during the period	(1,832)	(1,156)
Balance at September 30, 2005 and 2004	$ 1,836	$ 1,850

Deferred service contract revenue (in thousands):

	September 30, 2005	September 30, 2004
Balance at December 31, 2004 and 2003	$ 1,906	$ 1,322
Add: Payments received	2,290	1,442
Less: Revenue recognized	(1,641)	(1,135)
Balance at September 30, 2005 and 2004	$ 2,555	$ 1,629

Service contract revenue is recognized on a straight-line basis over the period of the applicable service contract. Costs incurred under service contracts during the three months ended September 30, 2005 and 2004, amounted to $304,000 and $170,000, respectively. For the nine months ended September 30, 2005 and 2004, costs incurred under service contracts were $795,000 and $578,000, respectively. All service contract costs are recognized as incurred.

Note 6. Comprehensive Income

Comprehensive income generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gain / (loss) on marketable investments represents the only component of other comprehensive income that is excluded from net income. The changes in components of other comprehensive income for the periods presented are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income	$ 3,801	$ 877	$ 7,991	$ 1,690
Unrealized gain / (loss) on available-for-sale investments	(37)	(4)	(40)	(4)
Comprehensive income	$ 3,764	$ 873	$ 7,951	$ 1,686

Note 7. Income Tax

The interim effective income tax rate is based on management's best estimate of the annual effective income tax rate. The effective tax rate for the three months ended September 30, 2005 and 2004 was 28% and 35%, respectively. For the nine months ended September 30, 2005 and 2004, the year-to-date tax rate was 28% and

37%, respectively. These rates reflect applicable United States federal and state tax rates and the tax impact of foreign operations, offset by research and development tax credits, tax exempt interest income and deductions for disqualifying incentive stock option exercises.

Undistributed earnings of the Company's foreign subsidiaries of approximately $383,000 at September 30, 2005 are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to various foreign countries.

The American Jobs Creation Act of 2004, provides for a temporary 85% dividends received deduction on certain foreign earnings repatriated during a one-year period. The deduction would result in an approximate 5.25% federal tax rate on the repatriated earnings. To qualify for the deduction, the earnings must be reinvested in the United States pursuant to a domestic reinvestment plan established by a company's chief executive officer and approved by the Company's board of directors. Certain other criteria in the Jobs Act must be satisfied as well. The Company does not anticipate it will apply the above provision to qualifying earnings repatriations in fiscal year 2005, however, the Company will continue to analyze and assess whether such repatriation would be practical.

Note 8. Contingencies

In February 2002, Palomar Medical Technologies ("Palomar") filed a lawsuit against the Company in the United States District Court, District of Massachusetts. The plaintiff alleges that by making, using, selling or offering for sale the Company's CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, the Company is willfully and deliberately infringing U.S. Patent No. 5,735,844. This patent concerns a method and apparatus for removing hair with light energy. Massachusetts General Hospital ("MGH") later joined the lawsuit as an additional plaintiff, since Palomar is the exclusive licensee, and MGH is the owner, of the patent at issue in the lawsuit. Palomar and MGH are seeking to enjoin the Company from selling products found to infringe the patent, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. The Company is defending the action vigorously, claiming that its products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, the Company has filed a counterclaim alleging that the patent should be declared unenforceable because of inadequate disclosures made to the U.S. Patent and Trademark Office by the plaintiffs during that patent's prosecution with the U.S. Patent and Trademark Office. The litigation is active, although a trial date has not yet been set by the court. The court has heard the Company's summary judgment motion but has not yet issued a ruling. The outcome of this motion could accelerate the litigation's determination.

In April 2005, the plaintiffs filed a second lawsuit in this same court, alleging that by making, using, selling or offering for sale products using pulsed-light technology for hair removal, the Company is willfully and deliberately infringing U.S. Patent Nos. 5,735,844 and 5,595,568. The plaintiffs are seeking to enjoin the Company from selling products found to infringe those patents, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. The Company responded by filing a motion to dismiss this second lawsuit on the grounds of lack of jurisdiction, and by filing complaints for declaratory relief against these plaintiffs in California and Delaware. This motion is pending with the court.

The Company believes that it has meritorious defenses of non-infringement and invalidity in these actions. Since the outcome of this litigation is unpredictable, and since management believes that a significant adverse result for the Company is not probable, no expense has been recorded with respect to the contingent liability associated with this matter. If the Company does not prevail, it may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. The Company could also be ordered to stop selling any products that perform laser- or pulse-light based hair removal. Most of our products include an application for hair removal. See the section entitled "Factors That May Affect Future Results" relating to this litigation.

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Management does not believe the final disposition of these matters will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

Note 9. Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, “Inventory Costs, an amendment of Accounting Research Bulletin (“ARB”) No. 43, Chapter 4.” SFAS No. 151 amends ARB No. 43, Chapter 4, to clarify those abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to the cost of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 151 will be effective January 1, 2006 for the Company. The adoption of SFAS No. 151 is not expected to have a material impact on the Company’s consolidated financial statements.

In December 2004, the FASB originally issued SFAS No. 123(R). SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R), as amended, is effective for public companies for the first annual period beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 123(R) will be effective January 1, 2006 for the Company. In March 2005, the SEC issued Staff Accounting Bulletin (“SAB”) No. 107, “TOPIC 14: Share-based payment.” SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately. The adoption of SFAS No. 123(R) and SAB No. 107 will decrease the Company’s earnings.

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

The following discussion should be read in conjunction with the attached financial statements and notes thereto, and with our audited financial statements and notes thereto for the fiscal year ended December 31, 2004 as contained in our annual report on Form 10-K filed with the SEC on March 25, 2005. This quarterly report, including the following sections, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 *that involve risks and uncertainties. These statements include statements relating to our expectations as to future growth* of the Titan installed base and handpiece refill revenue, as well as our belief that it is unlikely that we would experience a significant adverse result *in our current litigation against Palomar Medical Technologies. Our actual results could differ materially from the forward-looking statements contained in this report as a result of a number of risk factors including, but not limited to, those set forth in the section entitled "Factors That May Affect Future Results" commencing on page 18 and elsewhere in this report. You should carefully consider these risks, in addition to the other information in this report and in our other filings with the SEC. All forward-looking statements and reasons why results may differ included in this report are made as of the date of this report, and we assume no obligation to update any such forward-looking statement or reason why such results might differ.*

Introduction

Management's discussion and analysis of financial condition and results of operations, or MD&A, is provided as a supplement to the accompanying condensed consolidated financial statements and footnotes contained in Item 1 of this report to provide an understanding of our results of operations, financial condition, and changes in financial condition. The MD&A is organized as follows:

- *Executive summary.* This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.
- *Results of operations*. This section provides our analysis and outlook for the significant line items on our consolidated statement of operations.
- *Liquidity and capital resources*. This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of September 30, 2005.
- *Recent accounting pronouncements*. This section describes the issuance and effects of new accounting pronouncements that are applicable to our Company.
- *Factors that may affect future results*. This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the MD&A captions discussed below and elsewhere in this report.

Executive Summary

Company Description. We are a global medical device company specializing in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetics system to the professional aesthetic market. Our easy-to-use families of products-CoolGlide, Xeo and Solera – enable dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners to perform safe, effective and non-invasive aesthetic procedures for their patients.

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research, regulatory, sales, marketing and administrative activities. Outside the United States, we operate direct sales and service facilities in Canada, Germany, Switzerland and Japan and have a direct sales presence in Australia, France, Spain and the United Kingdom. As of September 30, 2005, we had 59 direct sales and sales support employees worldwide, a global network of distributors located in more than 25 countries, and a distributor relationship in the United States with PSS World Medical, an organization of over 750 medical product sales consultants covering a wide range of medical specialties.

Products and Significant Business Trends. Our revenue is derived from the sale of products, product upgrades, service and handpiece refills. Product revenue represents the sale of a system console that incorporates a universal graphic user interface, a laser or other light-based module, control system software, high voltage electronics, and one or more handpieces. We offer our customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications as their practice grows. This enables customers to upgrade their systems whenever they want and provides us with a source of recurring revenue, which we classify as product upgrade revenue. Service revenue relates to amortization of pre-paid maintenance and support contract revenue and receipts for time and material spent for servicing customer products. Handpiece refill revenue is associated with our Titan handpiece, which requires a periodic "refilling" process after a set number of pulses has been performed.

During the first nine months of 2005, our business continued to experience significant growth. Net revenue in the first nine months of 2005 increased by $15.1 million, or 41%. For the nine months ended September 30, 2004, compared to the same period in 2003, our net revenue increased by $9.9 million, or 37%.

Our continuing revenue growth is primarily attributable to the following:

- Investments made in our global sales and marketing infrastructure to increase our market penetration in an expanding aesthetic laser market. We are continuing to expand our international organization to capitalize on the significant potential for our products outside the United States. We have a direct presence in the major international markets and have established two service and support hubs overseas- a Pacific Rim hub in Tokyo, Japan and since July, 2005 a hub in Zurich, Switzerland.
- Continuing introduction of new aesthetic products and applications. In 2004, we launched the Titan application as an upgrade to our CoolGlide Xeo platform and also on a new Solera platform that offers an entry level product for a more price-sensitive market. In 2005, we introduced Solera Opus, an economical compact platform for hair removal and skin rejuvenation.
- Marketing to physicians outside the core dermatologist and plastic surgeon specialties, including the fast-growing medi-spa market. The medi-spa market is comprised of physicians who offer aesthetic treatments in a spa environment. Our easy-to-use, innovative products are gaining popularity and traction in this growing market as global demand for light-based aesthetic procedures continues to increase. For physicians- including dermatologists, plastic surgeons and non-core specialties- these fee-for-service aesthetic procedures represent an attractive source of supplemental revenue over and above the typical fees earned from managed care providers.

With respect to the geographical sourcing of our revenue, for the nine months ended September 30, 2005, compared to the same period in 2004, our U.S. revenue increased by $12.3 million, or 51%, and our international revenue increased in that same period by $2.8 million, or 22%. For the nine months ended September 30, 2005, compared to the same period in 2004, revenue from U.S. customers represented 70% of our total revenue, versus 65% for the same period in 2004. This stronger U.S growth, versus international growth, was primarily attributable to our increased sales and marketing efforts and our higher concentration of direct sales employees in the United States. As we continue to invest in our direct international efforts and look for new distributors in countries where we have no representation, we expect our international revenue to increase, compared with the quarter ended September 30, 2005.

Significant Industry Factors. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances and compliance for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. Our industry is subject to extensive government regulation, including the regulation by the United States Food and Drug Administration ("FDA"). Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other risk factors is provided in the "Factors Affecting Future Operating Results" section below.

Results of Operations

The following table sets forth selected consolidated financial data for the three and nine month periods indicated, expressed as a percentage of total revenue.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Consolidated Statement of Operations:				
Revenue Mix By Geography:				
Revenue from United States customers	76%	67%	70%	65%
Revenue from International customers	24%	33%	30%	35%
	100%	**100%**	**100%**	**100%**
Revenue Mix By Product:				
Products	85%	72%	84%	82%
Product upgrades	7%	23%	9%	13%
Service	5%	5%	5%	5%
Handpiece refills	3%	0%	2%	0%
	100%	**100%**	**100%**	**100%**
Operating Ratios:				
Total gross profit	75%	73%	74%	71%
Operating expenses:				
Sales and marketing	32%	37%	34%	37%
Research and development	7%	8%	7%	8%
General and administrative	9%	17%	12%	17%
Amortization of stock-based compensation	2%	2%	2%	3%
Total operating expenses	**50%**	**64%**	**55%**	**65%**
Income from operations	**25%**	**9%**	**19%**	**6%**
Interest and other income, net	3%	2%	2%	1%
Income before income taxes	**28%**	**11%**	**21%**	**7%**
Provision for income taxes	8%	4%	6%	3%
Net income	**20%**	**7%**	**15%**	**4%**

Three months ended September 30, 2005 and September 30, 2004 and nine months ended September 30, 2005 and September 30, 2004.

Net Revenue.

Revenue is derived primarily from the sale of products, product upgrades, service and Titan handpiece refills. For the three months ended September 30, 2005, compared to the same period in 2004, total revenue increased by $6.2 million, or 49%. This was the result of a $7.0 million, or 77%, increase in product revenue; $439,000, or 72%, increase in service revenue; $481,000 increase in handpiece refill revenue associated with our Titan handpieces that require frequent refilling; which was offset by $1.7 million, or 56%, decrease in upgrade revenue. The geographical sourcing of the $6.2 million increase was approximately $6.0 million from U.S. revenue and $269,000 from international revenue. Our current quarter revenue growth was primarily attributable to higher revenue from our premium multi-application CoolGlide Xeo product; the strong market acceptance of our products in the expanding medi-spa market; and increased revenue from service and Titan refill business, due to the increased number of units installed at customer sites. Our product upgrade revenue decreased this quarter, compared to the same period last year, due primarily to the fact that during our third quarter of 2004, there was pent-up demand associated with the launch of our Titan product and several customers purchased Titan upgrades on the CoolGlide Xeo platform.

For the nine months ended September 30, 2005, compared to the same period in 2004, net revenue increased $15.1 million, or 41%. The $15.1 million increase was the result of a $12.8 million, or 43%, increase of product revenue; $1.3 million, or 50%, increase in service revenue; and $1.0 million increase in revenue from Titan handpiece refills. The geographical source of the $15.1 million increase was $12.3 million from higher U.S. revenue and $2.8 million from higher international revenue. The primary contributors to our revenue growth were the continued expansion of our direct sales force, higher revenue from our premium multi-application CoolGlide Xeo product, the introduction of our new Solera products; the strong market acceptance of our products in the expanding medi-spa market; and increased revenue from service and Titan refill business, due to the increased number of units installed at customer sites.

C***ost of Revenue.***

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the three months ended September 30, 2005, compared to the same period in 2004, cost of revenue increased $1.3 million, primarily due to the increase in revenue. Cost of revenue as a percentage of net revenue, for the three months ended September 30, 2005, compared to the same period in 2004, decreased by 2% to 25%.

For the nine months ended September 30, 2005, compared to the same period in 2004, cost of revenue increased $3.2 million, or 30%, while revenue increased by 41%. Cost of revenue as a percentage of net revenue, for the nine months ended September 30, 2005, compared to the same period in 2004, decreased by 3% to 26%.

Sales and Marketing.

Sales and marketing expenses consist primarily of personnel costs and expenses associated with customer-attended workshops, trade shows and advertising. For the three months ended September 30, 2005, compared to the same period in 2004, sales and marketing expenses increased $1.5 million, or 32%. Of this increase, $1.2 million was attributable to higher personnel expenses resulting from increased headcount and $350,000 was due to higher promotional expenses. For the three months ended September 30, 2005, compared to the same period in 2004, sales and marketing expenses as a percentage of net revenue decreased by 5% to 32%.

For the nine months ended September 30, 2005, compared to the same period in 2004, sales and marketing expenses increased $4.1 million, or 30%. This increase was primarily attributable to approximately $3.4 million of higher personnel expenses due to increased headcount, $572,000 of higher promotional expenses and $241,000 of higher travel expenses related to the higher headcount. Promotional efforts primarily include customer workshops and industry trade shows. For the nine months ended September 30, 2005, compared to the same period in 2004, sales and marketing expenses as a percentage of net revenue decreased by 3% to 34%.

Research and Development.

Research and development expenses consist primarily of personnel, clinical, regulatory and material costs. For the three months ended September 30, 2005, compared to the same period in 2004, research and development expenses increased $297,000, or 30%. This increase primarily resulted from higher personnel expenses in engineering. For the three months ended September 30, 2005, compared to the same period in 2004, research and development expenses as a percentage of net revenue decreased by 1% to 7%.

For the nine months ended September 30, 2005, compared to the same period in 2004, research and development expenses increased $707,000, or 24%. The increase was primarily attributable to $658,000 of higher personnel expense due to increased headcount and $53,000 of higher material and outside services associated with new product development. As a percentage of net revenue, for the nine months ended September 30, 2005, compared to the same period in 2004, research and development expenses decreased by 1% to 7%.

General and Administrative.

General and administrative expenses consist primarily of personnel costs, legal and accounting fees and other general administrative expenses. For the three months ended September 30, 2005, compared to the same period

in 2004, general and administrative expenses decreased by $550,000, or 25%. This decrease was primarily attributable to lower legal expenses of $724,000, due primarily to the timing of the Palomar litigation; partially offset by higher personnel expenses of $189,000. As a percentage of net revenue, general and administrative expenses in the quarter ended September 30, 2005, compared to the same period in 2004, decreased by 8% to 9% due primarily to higher revenue and lower legal expenses.

For the nine months ended September 30, 2005, compared to the same period in 2004, general and administrative expenses decreased $332,000, or 5%. This decrease was primarily attributable to lower legal expenses of $762,000, due primarily to the timing of our Palomar litigation; lower bad debt expenses of $399,000; and expenses incurred in the nine months ended September 30, 2004 but not in the same period in 2005, including costs associated with moving our facilities from Burlingame to Brisbane, California of $291,000 and a litigation settlement of $175,000. This was offset by $1.1 million of higher personnel expenses; $287,000 of increased accounting, tax and audit consulting fees, due primarily to the Sarbanes Oxley implementation in 2005; and $126,000 of higher travel expenses. As a percentage of net revenue, general and administrative expenses for the nine months ended September 30, 2005, compared to the same period in 2004, decreased by 5% to 12%, due primarily to higher revenue and reduced spending.

Interest and Other Income, Net.

For the three months ended September 30, 2005, compared to the same period in 2004, interest and other income, net, increased by $351,000. For the nine months ended September 30, 2005, compared to the same period in 2004, interest and other income increased $1.1 million. These increases were primarily attributable to higher tax-exempt interest income, resulting from higher investment balances and better yields in 2005, compared to the same periods in 2004.

Provision for Income Taxes.

Provision for income taxes for the three months ended September 30, 2005, compared to the same period in 2004, decreased by $1.0 million. The effective tax rate for the three months ended September 30, 2005 was 28%, compared to 35% for the same period in 2004. Provision for income taxes for the nine months ended September 30, 2005, compared to the same period in 2004, decreased by $2.1 million. For the nine months ended September 30, 2005 and 2004, the effective tax rates were 28% and 37%, respectively. The decreases in effective tax rates in 2005 periods, compared to the same periods in 2004, were primarily attributable to higher tax-exempt interest income; higher incentive stock options exercises that became tax deductible due to a disqualifying disposition by the option holders; and an adjustment associated with a release of tax reserves due to the settlement of a previously uncertain tax position.

Amortization of Stock-Based Compensation.

Stock-based compensation consists of amortization of deferred stock-based compensation related to restricted stock units awarded to employees; stock options to purchase common stock issued to employees; and the values of options to purchase common stock issued to non-employees. With respect to stock options granted to employees, we record deferred stock-based compensation for financial reporting purposes as the difference between the exercise price of options granted to employees and the estimated fair value of our common stock at the time of grant. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and a compensation charge recorded over the period that the options are expected to be earned by the non-employee. Deferred stock-based compensation is amortized on a straight-line basis to the respective departments that benefit from the services of the individuals who were granted the equity based compensation. During the quarter ended September 30, 2005, we recorded $1.4 million of deferred stock based compensation for restricted stock units granted to employees, which will vest over four years.

Amortization of deferred stock-based compensation was $473,000 for the three months ended September 30, 2005, compared to $356,000 in the same period in 2004. For the nine months ended September 30, 2005 and

2004, amortization of stock-based compensation was $1,202,000 and $1,083,000 respectively. As of September 30, 2005, the unamortized balance of our deferred stock-based compensation was $2.4 million. The amount of stock-based compensation expenses to be recorded in future periods may decrease if unvested employee options or unvested restricted stock units are subsequently cancelled.

Liquidity and Capital Resources

Cash Provided by Operations.

For the nine months ended September 30, 2005, net cash provided by operations was $12.8 million. This was primarily attributable to net income of $8.0 million; cash provided from tax benefits related to employee stock option exercises of $3.1 million; amortization of deferred stock-based compensation of $1.2 million; and a reduction of accounts receivable by $1.6 million due to collections of the cyclically high revenue generated in December 2004. This was offset by cash used to increase inventories by $2.4 million for anticipated shipments and a broader product offering; and an increase in other assets of $1.6 million due primarily to pre-paid income taxes.

For the nine months ended September 30, 2004, net cash provided by operating activities was $5.3 million. This primarily resulted from $1.7 million in net income; adjusted for $1.1 million of stock-based compensation expense; a decrease in accounts receivable of $1.2 million due to an improvement in cash collections efforts; and an increase in accrued liabilities of $1.0 million due to accounting and legal fee accruals and outstanding quarterly employee bonus and commission payments. This was offset by a $1.0 million increase in inventory for anticipated revenue shipments.

Cash Used in Investing Activities.

For the nine months ended September 30, 2005, net cash used in investing activities was $18.9 million. Of this amount, $18.3 million, net, was used to purchase additional marketable investments and $579,000 was used to purchase property, equipment and intangibles partly associated with the set up of a new office in Zurich, Switzerland through the acquisition of a distributor.

For the nine months ended September 30, 2004, net cash used in investing activities was $6.5 million. Of this amount, $6.1 million was used to purchase marketable investments and $652,000 was used for the purchase of machinery and equipment for manufacturing, research and development, and office equipment relating to our move to the Brisbane, California, facility. This was partly offset by $250,000 of cash generated from the removal of restrictions on cash deposits with our bank.

Net Cash Provided by Financing Activities.

Net cash provided by financing activities for the nine months ended September 30, 2005, was $3.7 million, which was attributable to proceeds from the exercise of stock options. For the nine months ended September 30, 2004, net cash provided by financing activities was $46.8 million. Of this amount, $46.3 was from the sale of common stock associated with our initial public offering; and $441,000 was attributable to the proceeds from the purchase of stock through our stock options and employee stock purchase plans.

Summary

In April 2004, we received net proceeds of $46.3 million from our initial public offering of common stock, all of which has been utilized as of September 30, 2005. As of September 30, 2005, we had cash, cash equivalents and marketable investments of $82.2 million. We consider all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Investments held for use in current operations are classified in current assets as “Marketable Investments.”

As disclosed in Note 8 to the Notes to Condensed Consolidated Financial Statements—"Contingencies," we are involved in patent litigation with Palomar Medical Technologies, Inc. Since the outcome of this litigation is unpredictable, and since management believes that a significant adverse result for the Company is not probable, no expense has been recorded with respect to the contingent liability associated with this matter. If we do not prevail in this litigation, we could be ordered to pay substantial damages, which could adversely impact the working capital available for use in future operations. See the section entitled "Factors That May Affect Future Results" relating to this litigation. We believe that unless there is a settlement, the cost of this litigation will increase in 2006.

We believe that our current cash and investment balances, and future cash generated from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

Contractual Cash Obligations

The following table discloses aggregate information about the Company's contractual obligations for minimum lease payments related to facility leases and the periods in which these payments are due as of September 30, 2005.

	Payments Due by Period ($'000's)				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
Operating leases	$9,434	$ 902	$ 1,919	$ 2,049	$ 4,564

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (Revised 2004), "Share-Based Payment." Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's entity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, "Accounting for Stock Issued to Employees," which was permitted under SFAS No. 123, as originally issued. The revised Statement also requires entities to disclose information about the nature of the share based payment transactions and the effects of those transactions on the financial statements. We are currently evaluating the impact of the adoption of this Statement, which must be adopted commencing January 1, 2006.

Factors That May Affect Future Results

We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or increased operating results.

Our products compete against similar products offered by public companies, such as Candela, Laserscope, Lumenis, Palomar, and Syneron as well as private companies such as Reliant Technologies and Thermage. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. We also face competition from medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include sclerotherapy, a procedure involving the injection of a solution into the vein to collapse it, electrolysis, a procedure involving the application of electric current to eliminate hair follicles, and chemical peels. We may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products, and includes such factors as:

- product performance;

- product pricing;
- intellectual property protection;
- quality of customer support;
- success and timing of new product development and introductions; and
- development of successful distribution channels, both domestically and internationally.

Some of our competitors have more established products and customer relationships than we do, which could inhibit our market penetration efforts. For example, we have encountered, and expect to continue to encounter, situations where, due to pre-existing relationships, potential customers decided to purchase additional products from our competitors. Potential customers also may need to recoup the cost of expensive products that they have already purchased from our competitors and may decide not to purchase our products, or to delay such purchases. If we are unable to achieve continued market penetration, we will be unable to compete effectively and our business will be harmed.

In addition, some of our current and potential competitors have significantly greater financial, research and development, manufacturing, and sales and marketing resources than we have. Our competitors could utilize their greater financial resources to acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing product lines. For example, ESC Medical purchased Coherent's medical business in 2001 and the surviving company, Lumenis, incorporated competitive product lines and technologies of the predecessor companies into its current products. Given the relatively few competitors currently in the market, any business combination could exacerbate any existing competitive pressures, which could harm our business.

Competition among providers of laser and other light-based devices for the aesthetic market is characterized by rapid innovation, and we must continuously develop new products or our revenues may decline.

While we attempt to protect our products through patents and other intellectual property, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with ours. For example, while our CoolGlide product was the first long-pulse Nd:YAG, or long wavelength, laser system cleared by the FDA for permanent hair reduction on all skin types, competitors have subsequently introduced systems that utilize Nd:YAG lasers, and received FDA clearances to market these products as treating all skin types. We expect that any competitive advantage we may enjoy from other current and future innovations, such as combining multiple handpieces in a single system to treat a variety of applications, may diminish over time, as companies successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue will decline as our customers purchase our competitors' products.

Our ability to compete depends upon our ability to innovate, to develop and commercialize new products and product enhancements, and to identify new markets for our technology.

We have created products to apply our technology to hair removal, treatment of veins, skin rejuvenation, treatment of pigmented lesions and treatment of wrinkles. Currently, these applications represent the majority of laser and other light-based aesthetic procedures. To be successful in the future, we must develop new and innovative applications of laser and other light-based technology, identify new markets for our existing technology, and develop new technology that is not light-based. To successfully expand our product offerings, we must:

- develop or acquire new products that either add to or significantly improve our current products;
- convince our target customers that our new products or product upgrades would be an attractive revenue-generating addition to their practices;

- sell our products to non-traditional customers;
- identify new markets and alternative applications per our technology;
- protect our products with defensible intellectual property; and
- satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, we have introduced at least one new product and a corresponding upgrade to our existing products. Historically, these introductions have been a significant component of our financial performance. Our business strategy is based, in part, on our expectation that we will continue to make annual product introductions that we can sell to new customers and to existing customers as upgrades. In the future we plan to invest between 7-10% of net revenue in our research and development department. Even with a significant investment in research and development, we may be unable, however, to continue to develop new products and technologies annually, or at all, which could adversely affect our expected growth rate.

We are involved in costly intellectual property litigation with Palomar Medical Technologies that may hurt our competitive position and may prevent us from selling many of our products and generating revenue.

Since February 2002, we have been involved in litigation with one of our public company competitors, Palomar Medical Technologies, who alleges that the manufacture, use and sale of our products for hair removal infringes certain United States patents. In this litigation, Palomar is attempting to stop us from selling our products for hair removal and to obtain compensatory and treble damages. We are defending ourselves by claiming that we do not infringe the patents, and that the patents are invalid and unenforceable. The litigation is active and the parties are moving toward trial, although a trial date has not yet been set by the court. Palomar has filed additional claims against us, and we have filed additional claims against Palomar.

Although we believe that our defenses are meritorious, litigation is unpredictable, and we may not prevail. If we do not prevail, we may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. We could also be ordered to stop selling any products that perform hair removal. Most of our products include an application for hair removal. If found liable, we do not know whether we could redesign our products to avoid future infringement. Any public announcement concerning the litigation that is unfavorable to us may result in a decline in our stock price.

This litigation has been and will continue to be expensive and protracted, and our intellectual property position may be weakened as a result of an adverse ruling. Whether or not we are successful in this lawsuit, this litigation consumes substantial amounts of our financial resources and diverts management’s attention away from our core business. See Part II, Item 1, “Legal Proceedings.” We believe the cost of this litigation will increase in 2006, and that such increase will be substantial as the matter nears a trial date.

If we fail to obtain and maintain necessary U.S. Food and Drug Administration clearances for our products and indications, if clearances for future products and indications are delayed or not issued, or if there are federal or state level regulatory changes, our commercial operations would be harmed.

Our products are medical devices that are subject to extensive regulation in the United States by the Food and Drug Administration, or FDA, for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. For example, with regard to our recently introduced Titan product, we currently have FDA clearance to market the product in the United States for only dermal heating and not for other indications, such as for treating wrinkles. The FDA has determined that our 510(k) application for wrinkle reduction was not substantially equivalent to predicate devices for the treatment of wrinkles. We are continuing to seek a clearance from the FDA to market Titan for additional indications, but there are no assurances as to when, or whether, we will ever obtain such a clearance. We cannot promote or advertise in the United States for

any indications other than dermal heating until we receive additional FDA clearances. Clinical trials in support of a clearance for treating wrinkles may be costly, time-consuming, and a distraction to management. In the event that we do not obtain additional FDA clearances, our ability to market the Titan in the United States and revenue derived there from may be adversely affected.

Medical devices may be marketed only for the indications for which they are approved or cleared and if we are found to be marketing our products for off-label, or non-approved, uses we might be subject to FDA enforcement action or have other resulting liability. We have obtained 510(k) clearance for treatments for which we offer our products. However, our clearances can be revoked if safety or effectiveness problems develop. We also are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. Our products are also subject to state regulations, which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations allow our products to be sold to, or on the order of, "licensed practitioners," as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase our products. However, a state could change its regulations at any time disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business

We may be involved in future costly intellectual property litigation, which could impact our future business and financial performance.

As with Palomar, our competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. In addition, we do not know whether our competitors will apply for and obtain patents that will prevent, limit or interfere with our ability to make, use, sell or import our products. Although we may seek to resolve any potential future claims or actions, we may not be able to do so on reasonable terms, or at all. If, following a successful third-party action for infringement, we cannot obtain a license or redesign our products, we may have to stop manufacturing and marketing our products and our business would suffer as a result.

We may become involved in litigation not only as a result of alleged infringement of a third party's intellectual property rights but also to protect our own intellectual property. For example, we have been, and may hereafter become, involved in litigation to protect the trademark rights associated with our company name or the names of our products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management's attention from our core business. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our products or processes to avoid infringement. If we lose this kind of litigation, a court could require us to pay

substantial damages, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition.

Intellectual property rights may not provide adequate protection for some or all of our products, which may permit third parties to compete against us more effectively.

We rely on patent, copyright, trade secret and trademark laws, and confidentiality agreements to protect our technology and products. We have four issued U.S. patents, mostly covering our ClearView handpiece design and cooling method. Some of our other components, such as our laser module, electronic control system and high-voltage electronics, are not, and in the future may not, be protected by patents. Additionally, our patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we obtain may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products, and use manufacturing processes that are substantially similar to, or superior to, ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

The absence of complete intellectual property protection exposes us to a greater risk of direct competition. Competitors could purchase one of our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected against competitors' products and methods, our competitive position could be adversely affected, as could our business.

To successfully market and sell our products internationally, we must address many issues with which we have little or no experience.

We currently derive approximately one quarter of our revenue from international sales. We depend on third-party distributors and a relatively new direct sales operation to sell our products internationally, and if these distributors or direct sales personnel underperform we may be unable to increase or maintain our level of international revenue. We will need to attract additional distributors to grow our business and expand the territories in which we sell our products. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize expected international revenue growth. Additionally, we expect to expand our direct sales force in Europe and Asia. If we are unable to do so successfully, our revenue from international operations may be adversely affected.

We believe that an increasing amount of our future revenue will come from international sales as we expand our overseas operations and develop opportunities in additional international territories. International sales are subject to a number of risks, including:

- difficulties in staffing and managing our foreign operations;
- difficulties in penetrating markets in which our competitors' products are more established;
- reduced protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification and regulatory requirements;

- lengthy payment cycles and difficulty in collecting accounts receivable;
- customs clearance and shipping delays;
- political and economic instability; and
- preference for locally-produced products.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and if we are unsuccessful at finding a solution, our revenue may decline.

The expense and potential unavailability of insurance coverage for our customers and our company could adversely affect our ability to sell our products and our financial condition.

Some of our customers and prospective customers have had difficulty in procuring or maintaining liability insurance to cover their operation and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and, industry-wide, potential customers may opt against purchasing laser and other light-based products due to the cost and inability to procure insurance coverage.

We have been experiencing steep increases in our product liability insurance premiums. If our premiums continue to rise, we may no longer be able to afford adequate insurance coverage. If we are unable to maintain adequate coverage, potential product liability claims would be paid out of cash reserves, harming our financial condition, operating results and profitability.

If we modify one of our FDA-approved devices, we may need to seek re-approval, which, if not granted, would prevent us from selling our modified products or cause us to redesign our products.

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. We may not be able to obtain additional 510(k) clearance or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearance would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearance or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

If we fail to comply with the FDA's Quality System Regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.

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

We may be unable to obtain or maintain international regulatory qualifications or approvals for our current or future products and indications, which could harm our business.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the United States are regulated by the FDA. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may be unable to obtain or maintain regulatory qualifications, clearances or approvals in other countries. We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications. If we experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if we fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in international markets effectively, or at all.

Because we do not require training for users of our products, and sell our products to non-physicians, there exists an increased potential for misuse of our products, which could harm our reputation and our business.

Federal regulations allow us to sell our products to or on the order of "licensed practitioners." The definition of "licensed practitioners" varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We, and our distributors, offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

Product liability suits could be brought against us due to a defective design, material or workmanship, or misuse of our products and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our products or failing to adhere to operating guidelines could cause significant eye and skin damage, and underlying tissue damage. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. We have been involved, and may in the future be involved, in litigation related to the use of our products. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all future claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and reducing our operating results.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

Many of the components and materials that comprise our products are currently manufactured by a limited number of suppliers. A supply interruption or an increase in demand beyond our current suppliers' capabilities

could harm our ability to manufacture our products until a new source of supply is identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or on commercially reasonable terms;
- difficulty locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

Any interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers, which would have an adverse effect on our business.

Components used in our products are complex in design, and any defects may not be discovered prior to shipment to customers, which could result in warranty obligations, reducing our revenue and increasing our cost.

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to produce. If our suppliers fail to produce components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects that cannot be repaired easily and inexpensively, we may experience:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal action.

The occurrence of any one or more of the foregoing could materially harm our business.

We forecast sales to determine requirements for components and materials used in our products and if our forecasts are incorrect, we may experience either delays in shipments or increased inventory costs.

We keep limited materials and components on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to nine months in advance and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand.

If we overestimate our component and material requirements, we will have excess inventory, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of our products to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

If there is not sufficient demand for the procedures performed with our products, practitioner demand for our products could be inhibited, resulting in unfavorable operating results.

Most procedures performed using our products are not reimbursable through government or private health insurance and are therefore elective procedures, the cost of which must be borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including:

- the cost of procedures performed using our products;
- the cost, safety and effectiveness of alternative treatments;
- the success of our sales and marketing efforts; and
- consumer confidence, which may be impacted by economic and political conditions.

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

If a key distributor fails to perform to our expectations, we may fail to achieve anticipated operating results.

We have a distribution arrangement with PSS World Medical, an organization of over 750 U.S. medical product sales consultants covering a wide range of medical specialties. PSS World Medical sales representatives work in coordination with our sales force to locate new potential customers for our products. If PSS World Medical does not perform adequately under the arrangement or terminates our relationship, it may have a material adverse effect on our business, financial condition, results of operations and future cash flows.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers and other key employees. We do not have employment contracts with any of our officers or other key employees. Any of our officers and other key employees may terminate their employment at any time. In addition, we do not maintain “key person” life insurance policies covering any of our employees. The loss of any of our senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

Our financial results will be affected by the changed accounting rules governing the recognition of stock-based compensation expense.

We measure compensation expense relating to stock-based employee compensation arrangements, using the intrinsic value method of accounting prescribed by APB Opinion No. 25, “Accounting for Stock Issued to Employees.” Under this method, we recognized compensation charges related to employee stock-based

compensation, net of related tax effect, of $716,000 and $865,000 in the nine months ended September 30, 2005 and 2004, respectively. In accordance with SFAS No. 123, “Accounting for Stock-Based Compensation,” we provide disclosures of our operating results as if we had applied the fair value method of accounting (pro-forma basis). Included in our Quarterly Reports on Form 10-Q we have provided such disclosures in accordance with SFAS No. 148, “Accounting for Stock-Based Compensation—Transition and Disclosure.” Had we accounted for our compensation expense under the fair value method of accounting prescribed by SFAS No. 123, the charges, net of tax, would have been significantly higher than the intrinsic value method used by us. The Financial Accounting Standards Board has announced changes to accounting rules concerning the recognition of stock option compensation expense. Beginning in the first quarter of fiscal 2006 when these changes are expected to be implemented, we and other companies will be required to measure compensation expense using the fair value method, which will adversely affect our results of operations by increasing our cost by the additional amount of such stock option charges.

Failure to maintain effective internal controls over financial reporting could have a material adverse effect on our business, operating results and stock price.

Beginning with our annual report for our fiscal year ending on December 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 will require us to include a report by our management on our internal controls over financial reporting. Such report must contain an assessment by management of the effectiveness of our internal controls over financial reporting as of the end of our fiscal year and a statement as to whether or not such internal controls are effective. Such report must also contain a statement that our independent registered public accounting firm has issued an attestation report on management’s assessment of such internal controls.

To achieve timely compliance with Section 404, in 2004 we began a process to document and evaluate our internal controls over financial reporting. Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, the commitment of time and operational resources and the diversion of management’s attention. If our management identifies one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that such internal controls are effective. If we are unable to assert that our internal controls over financial reporting are effective as of December 31, 2005, our business may be harmed.

Any acquisitions that we make could disrupt our business and harm our financial condition.

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate any businesses, products or technologies that we acquire. Furthermore, the integration of any acquisition and management of any collaborative project may divert management’s time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies or products. If we decide to expand our product offerings beyond laser and other light-based products, we may spend time and money on projects that do not increase our revenue.

Any cash acquisition we pursue would diminish our available cash balances to us for other uses, and any stock acquisition would be dilutive to our stockholders. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any acquisitions or collaborative projects.

Anti-takeover provisions in our Amended and Restated Certificate of Incorporation and Bylaws, and Delaware law, contain provisions that could discourage a takeover.

Our Amended and Restated Certificate of Incorporation and Bylaws, and Delaware law, contain provisions that might enable our management to resist a takeover, and might make it more difficult for an investor to acquire a substantial block of our common stock. These provisions include:

- a classified board of directors;
- advance notice requirements to stockholders for matters to be brought at stockholder meetings;
- a supermajority stockholder vote requirement for amending certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws;
- limitations on stockholder actions by written consent; and
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies, municipal bonds and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity (interest reset date for auction-rate securities and variable rate demand notes) of generally less than eighteen months. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. To date, our exposure to exchange rate volatility has not been significant. We cannot assure you that there will not be a material impact in the future. Although the majority of our sales and purchases are denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Our management, including our President and Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of September 30, 2005 of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e)). Based on that evaluation, the President and Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective in ensuring that all material information required to be disclosed in the reports we file and submit under the Securities and Exchange Act of 1934 has been made known to them on a timely basis and that such information has been properly recorded, processed, summarized and reported, as required.

Changes in Internal Control over Financial Reporting. There have been no significant changes in our internal control over financial reporting during the most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Sarbanes-Oxley Section 404 Compliance. Section 404 of the Sarbanes-Oxley Act of 2002 (the "Act") will require us to include an internal control report from management in our annual report on Form 10-K for the year ending December 31, 2005 and in subsequent annual reports thereafter. The internal control report must include the following: (1) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our Independent Registered Public Accounting Firm has issued an attestation report on management's assessment of internal control over financial reporting.

Management acknowledges its responsibility for establishing and maintaining internal controls over financial reporting and seeks to continually improve those controls. In addition, in order to achieve compliance with Section 404 of the Act within the required timeframe, we have been conducting a process to document and evaluate our internal controls over financial reporting since 2004. In this regard, we have dedicated internal resources, engaged outside consultants and adopted a detailed work plan to: (i) assess and document the adequacy of internal control over financial reporting; (ii) take steps to improve control processes where required; (iii) validate through testing that controls are functioning as documented; and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. We believe our process for documenting, evaluating and monitoring our internal control over financial reporting is consistent with the objectives of Section 404 of the Act.

We are continuing our evaluation of our internal controls versus the standards adopted by the Public Company Accounting Oversight Board (PCAOB). Given the risks inherent in the design and operation of internal controls over financial reporting, we can provide no assurance as to our, or our Independent Registered Public Accounting Firm's, conclusions at December 31, 2005 with respect to the effectiveness of our internal controls over financial reporting.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the SEC of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial

officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), our management, including our chief executive officer and chief financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2005. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures appear to be effective.

There has been no change in our internal controls over financial reporting during our most recent fiscal three and nine months that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In February 2002, we were sued by Palomar Medical Technologies in the United States District Court, District of Massachusetts. The plaintiff alleges that by making, using, selling or offering for sale our CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, we are willfully and deliberately infringing U.S. Patent No. 5,735,844. This patent concerns a method and apparatus for removing hair with light energy. Massachusetts General Hospital later joined the lawsuit as an additional plaintiff, since Palomar is the exclusive licensee, and MGH is the owner, of the patent at issue in the lawsuit. Palomar and MGH are seeking to enjoin us from selling products found to infringe the patent, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. We are defending the action vigorously, claiming that our products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, we have filed a counterclaim alleging that the patent should be declared unenforceable because of inadequate disclosures made to the U.S. Patent and Trademark Office by the plaintiffs during that patent's prosecution with the U.S. Patent and Trademark Office. The litigation is active, although a trial date has not yet been set by the court. The court has heard our summary judgment motion but has not yet issued a ruling. The outcome of this motion could accelerate the litigation's determination

In April 2005, the plaintiffs filed a second lawsuit in this same court, alleging that by making, using, selling or offering for sale products using pulsed-light technology for hair removal, the Company is willfully and deliberately infringing U.S. Patent Nos. 5,735,844 and 5,595,568. The plaintiffs are seeking to enjoin us from selling products found to infringe those patents, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. We responded by filing a motion to dismiss this second lawsuit on the grounds of lack of jurisdiction, and by filing complaints for declaratory relief against these plaintiffs in California and Delaware. This motion is pending with the court.

Item 2. Changes in Securities and Use of Proceeds

We registered the initial public offering of our common stock on a Registration Statement on Form S-1 (File No. 333-111928), which was declared effective on March 30, 2004, and pursuant to which we raised $46.3 million in net proceeds. As of September 30, 2005, all proceeds from the offering have been utilized.

We did not sell any unregistered securities during the period covered by this quarterly report on Form 10-Q.

Item 5. Other Information

Our Board of Directors, upon the review and recommendation by the Compensation Committee, has approved increases to the annual base salaries and established the annual target bonus levels as a percentage of base salary for our named executive officers set forth below.

Name	Title	Annual Base Salary	2005 Target Bonus
Kevin P. Connors	President and Chief Executive Officer	$ 300,000	45%
Ronald J. Santilli	Chief Financial Officer and Vice President of Finance and Administration	$ 200,000	30%
David A. Gollnick	Vice President of Research and Development	$ 200,000	30%
Tom J. Liolios	Vice President of International Sales	$ 150,000	10%(2)
John J. Connors	Vice President of North American Sales	$ 103,000	7.5%(1)

(1) John Connors participates in a sales commission plan that compensates him on actual North American revenue and quota achievements, compared to targets set at the beginning of the year.

(2) Tom Liolios participates in a sales commission plan that compensates him on actual International revenue and quota achievements, compared to targets set at the beginning of each year.

All base salary increases are retroactive to June 1, 2005. The above mentioned target bonus levels are effective June 1, 2005. Target bonuses are calculated based upon a matrix of revenue growth and operating profit percent before amortization of stock-based compensation. For example, at 10% revenue growth and 10% operating profit, an individual will receive 100% of their target bonus. At 50% revenue growth and 25% operating profit, an individual would receive 375% of their target bonus. Payments under the bonus program are made quarterly and only in the event that we have a quarterly operating profit before amortization of deferred stock-based compensation.

During the quarter ended September 30, 2005, we began issuing performance unit awards as provided for in our 2004 Equity Incentive Plan (“Incentive Plan”). Each recipient of an award, enters into a performance unit award agreement (the “Award Agreement”), which is filed as Exhibit 10.11 to this Quarterly Report on Form 10-Q. Under the terms of the Incentive Plan and the Award Agreement, each unit has an initial value equal to the fair market value of our common stock on the date of grant. On its vesting date, the unit has a value equivalent to the fair market value on the date of vesting. Upon vesting, the Company will issue to the recipient the net number of shares, after withholding the number of shares required to pay the statutory minimum income tax associated with the gain earned. The awards vest 25% of the units per year for four years, provided the recipient continues to provide us with services.

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Item 6. Exhibits

Exhibit No.	Description
3.2[1]	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4[1]	Bylaws of the Registrant.
4.1[2]	Specimen Common Stock certificate of the Registrant.
10.1[1]	Form of Indemnification Agreement for directors and executive officers.
10.2[1]	1998 Stock Plan.
10.3[1]	2004 Equity Incentive Plan.
10.4[1]	2004 Employee Stock Purchase Plan.
10.5[1]	Amended and Restated Investor Rights Agreement dated November 12, 1999 by and among the Registrant and certain stockholders.
10.6[1]	Brisbane Technology Park Lease dated August 5, 2003 by and between the Registrant and Gal-Brisbane, L.P. for office space located at 3240 Bayshore Boulevard, Brisbane, California.
10.7[1]†	Sales Agent Agreement dated February 14, 2003 by and between the Registrant and PSS World Medical, Inc. and the Amendments thereto.
10.10†	Seventh Amendment to the Sales Agent Agreement dated September 22, 2005 by and between Registrant and PSS World Medical, Inc.
10.11	Form of Performance Unit Award Agreement.
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 and Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.
(2) Incorporated by reference from our Annual Report on Form 10-K filed on March 25, 2005.
† Portions of the Exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the Securities and Exchange Commission.

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.

CUTERA, INC.

Date: November 14, 2005

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial Officer and
Vice President of Finance and Administration
(Principal Financial and Accounting Officer;
and Authorized Signatory)

Exhibit 10.10

AMENDMENT NO. 7 TO SALES AGENT AGREEMENT

This Amendment No. 7 To Sales Agent Agreement ("Amendment No. 7") is made this 22nd day of September, 2005, between Cutera Inc. ("Cutera") and PSS World Medical, Inc. ("PSS").

WHEREAS, Cutera and PSS entered into that February 14, 2003 Sales Agent Agreement, and six related amendments, the last one being that November 10, 2004 Amendment No. 6 to Sales Agent Agreement (collectively, "Agreement"), and are hereby amending the Agreement as follows:

1. The first sentence of Section 1.4 is hereby deleted and replaced with the following:

> "1.4 Products means Cutera's CoolGlide CV-, CoolGlide Excel-, CoolGlide Vantage-, Solera Opus-, Solera Titan-, Xeo SA-, Xeo Rejuvenation-, Xeo Vantage-, Xeo Limited- and Full Xeo systems, and related Product Upgrades."

2. Exhibit A is hereby deleted and replaced with the following:

"Product Pricing

For Products sold to PSS from November 1, 2005, the unit pricing will be as set forth below. All Product pricing information will be deemed Cutera's Confidential Information.

Products	Unit Price
CoolGlide Platform	
CoolGlide CV	$ [****]
CoolGlide Excel	$ [****]
CoolGlide Vantage	$ [****]
Solera Platform	
Solera Opus	$ [****]
Solera Titan	$ [****]
Xeo Platform*	
A. Xeo SA – w/ IPL	$ [****]
A1. Xeo SA – w/ Titan	$ [****]
B. Xeo Rejuvenation – Xeo + FV, Genesis and IPL	$ [****]
C. Xeo Vantage – Xeo + HR, FV, LV and Genesis	$ [****]
D. Xeo Limited – Xeo + HR, Genesis and IPL	$ [****]
E. Full Xeo – Xeo + HR, FV, LV, Genesis and IPL	$ [****]

* All Xeo products can include Titan for an additional $[****]

Upgrades	Unit Price
CV -> Excel	$ [****]
CV -> Vantage	$ [****]
CV -> Full Xeo	$ [****]
Excel -> Vantage	$ [****]
Excel -> Full Xeo	$ [****]
Vantage -> Full Xeo	$ [****]
Solera Opus -> Full Xeo	$ [****]
Solera Titan -> Full Xeo	$ [****]
Xeo SA w/ IPL -> Full Xeo	$ [****]
Xeo SA w/ Titan -> Full Xeo	$ [****]
Xeo Rejuvenation -> Full Xeo	$ [****]
Xeo Vantage -> Full Xeo	$ [****]
Xeo Limited -> Full Xeo	$ [****]
Titan added to Full Xeo	$ [****]
IPL added to system	$ [****]
New IPL handpiece	$ [****]
New Titan handpiece	$ [****]

2. The capitalized terms that are used, but not defined, in this Amendment No. 7 shall have the same definitions provided in the Agreement. Except as expressly stated in this Amendment No. 7, the Agreement shall remain unmodified and in full force and effect.

Cutera, Inc.	PSS World Medical, Inc.
By: /s/ Ronald J. Santilli	By: /s/ Mark Steele
Printed: Ronald J. Santilli	Printed: Mark Steele
Its: V.P. and CFO	Its: V.P. Marketing

**** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 10.11

CUTERA, INC.

Performance Unit Award Agreement

Grant #_____

Cutera, Inc. (the "Company") hereby grants you, _____ (the "Participant"), an award of performance units ("Performance Units") under the Cutera, Inc. 2004 Equity Incentive Plan (the "Plan"). The date of this Performance Unit Award Agreement is _____, 200__. Subject to the provisions of Appendix A (attached) and of the Plan, the principal features of this Award are as follows:

Number of Performance Units: _____

Vesting Commencement Date: _____

Vesting of Performance Units: The Performance Units will vest according to the following schedule:

Twenty-five percent (25%) of the Performance Units will vest on each of the first four anniversaries of the Vesting Commencement Date, subject to Participant continuing to be a Service Provider through each such date.

Unless otherwise defined herein or in Appendix A, capitalized terms herein or in Appendix A will have the defined meanings ascribed to them in the Plan.

Your signature below indicates your agreement and understanding that this Award is subject to all of the terms and conditions contained in Appendix A and the Plan. For example, important additional information on vesting and forfeiture of the Performance Units is contained in Paragraphs 3 through 5 of Appendix A. PLEASE BE SURE TO READ ALL OF APPENDIX A, WHICH CONTAINS THE SPECIFIC TERMS AND CONDITIONS OF THIS AGREEMENT.

CUTERA, INC.	PARTICIPANT
By: _____	_____
[NAME]	[NAME] «First» «Middle» «Last»
[TITLE]	Date: _____

APPENDIX A

TERMS AND CONDITIONS OF PERFORMANCE UNITS

Grant # _____

1. Grant. The Company hereby grants to the Participant under the Plan an Award of Performance Units, subject to all of the terms and conditions in this Performance Unit Award Agreement (the "Award Agreement") and the Plan.

2. Company's Obligation to Pay. Each Performance Unit has a value equal to the Fair Market Value of a Share on the date it becomes vested. Unless and until the Performance Units will have vested in the manner set forth in Sections 3 and 4, the Participant will have no right to payment of any such Performance Units. Prior to actual payment of any vested Performance Units, such Performance Units will represent an unsecured obligation of the Company, payable (if at all) only from the general assets of the Company.

3. Vesting Schedule. Subject to paragraph 4, the Performance Units awarded by this Award Agreement will vest in the Participant according to the vesting schedule set forth on the attached Performance Unit Agreement, subject to the Participant's continuing to be a Service Provider through each such date.

4. Forfeiture upon Termination of Continuous Service. Notwithstanding any contrary provision of this Agreement, if Participant ceases to be a Service Provider for any or no reason, the then-unvested Performance Units awarded by this Agreement will thereupon be forfeited at no cost to the Company and the Participant will have no further rights thereunder.

5. Payment after Vesting. Any Performance Units that vest in accordance with paragraph 3 will be paid to the Participant (or in the event of the Participant's death, to his or her estate) in whole Shares, provided that to the extent determined appropriate by the Company in its discretion, any federal, state and local withholding taxes with respect to such Performance Units will be paid by reducing the number of Shares actually paid to the Participant.

6. Payments after Death. Any distribution or delivery to be made to the Participant under this Award Agreement will, if the Participant is then deceased, be made to the Participant's designated beneficiary, or if no beneficiary survives the Participant, the administrator or executor of the Participant's estate. Any such transferee must furnish the Company with (a) written notice of his or her status as transferee, and (b) evidence satisfactory to the Company to establish the validity of the transfer and compliance with any laws or regulations pertaining to said transfer.

7. Withholding of Taxes. The Company will withhold otherwise deliverable Shares upon vesting of Performance Units having a Fair Market Value equal to the minimum amount required to be withheld for the payment of income, employment and other taxes which the Company determines must be withheld (the "Withholding Taxes") pursuant to such procedures as the Administrator may specify from time to time. The Company will not retain fractional

Shares to satisfy any portion of the Withholding Taxes. Accordingly, Purchaser will pay to the Company an amount in cash sufficient to satisfy the remaining Withholding Taxes due and payable as a result of the Company not retaining fractional Shares. Should the Company be unable to procure such cash amounts from Purchaser, Purchaser agrees and acknowledges that Purchaser is giving the Company permission to withhold from Purchaser's paycheck(s) an amount equal to the remaining Withholding Taxes due and payable as a result of the Company not retaining fractional Shares.

9. Rights as Stockholder. Neither the Participant nor any person claiming under or through the Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares will have been issued, recorded on the records of the Company or its transfer agents or registrars, and delivered to the Participant.

10. No Effect on Employment or Service. The Participant's employment or other service with the Company and its Subsidiaries is on an at-will basis only. Accordingly, the terms of the Participant's employment or service with the Company and its Subsidiaries will be determined from time to time by the Company or the Subsidiary employing the Participant (as the case may be), and the Company or the Subsidiary will have the right, which is hereby expressly reserved, to terminate or change the terms of the employment or service of the Participant at any time for any reason whatsoever, with or without good cause.

11. Address for Notices. Any notice to be given to the Company under the terms of this Agreement will be addressed to the Company at 3240 Bayshore Blvd., Brisbane, CA 94005, Attn: Stock Administrator, or at such other address as the Company may hereafter designate in writing.

12. Grant is Not Transferable. Except to the limited extent provided in paragraph 6, this grant and the rights and privileges conferred hereby will not be transferred, assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and will not be subject to sale under execution, attachment or similar process. Upon any attempt to transfer, assign, pledge, hypothecate or otherwise dispose of this grant, or any right or privilege conferred hereby, or upon any attempted sale under any execution, attachment or similar process, this grant and the rights and privileges conferred hereby immediately will become null and void.

13. Binding Agreement. Subject to the limitation on the transferability of this grant contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

14. Additional Conditions to Issuance of Stock. If at any time the Company will determine, in its discretion, that the listing, registration or qualification of the Shares upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory authority is necessary or desirable as a condition to the issuance of shares to the Participant (or his or her estate), such issuance will not occur unless and until such listing, registration, qualification, consent or approval will have been effected or obtained free of any conditions not acceptable to the Company. The Company will make all reasonable efforts to meet the requirements of any such state or federal law or securities exchange and to obtain any such consent or approval of any such governmental authority.

15. Plan Governs. This Award Agreement is subject to all terms and provisions of the Plan. In the event of a conflict between one or more provisions of this Award Agreement and one or more provisions of the Plan, the provisions of the Plan will govern.

16. Administrator Authority. The Administrator will have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret or revoke any such rules (including, but not limited to, the determination of whether or not any Performance Units have vested). All actions taken and all interpretations and determinations made by the Administrator in good faith will be final and binding upon Participant, the Company and all other interested persons. No member of the Board or its Committee administering the Plan will be personally liable for any action, determination or interpretation made in good faith with respect to the Plan or this Award Agreement.

17. Captions. Captions provided herein are for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

18. Agreement Severable. In the event that any provision in this Award Agreement will be held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of this Award Agreement.

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End of text

EXHIBIT 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Kevin P. Connors, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cutera, Inc.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal three and nine months (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ Kevin P. Connors

Kevin P. Connors
President, Chief Executive Officer
and Director (Principal Executive Officer)

EXHIBIT 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Ronald J. Santilli, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cutera, Inc.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal three and nine months (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial Officer and
Vice President of Finance and Administration
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin P. Connors, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2005 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2005

/s/ Kevin P. Connors

Kevin P. Connors
President, Chief Executive Officer and Director
(Principal Executive Officer)

I, Ronald J. Santilli, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2005 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2005

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial Officer and Vice President of Finance and Administration
(Principal Financial and Accounting Officer)

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended.