
**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 June 30, 2004

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
(State or other jurisdiction of
incorporation or organization)

77-0492262
(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

The number of shares of Registrant's common stock issued and outstanding as of August 3, 2004 was 10,709,025.

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FORM 10-Q
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Forward-Looking Statements

This report contains forward-looking statements within the meaning of the U.S. federal securities laws that involve risks and uncertainties. Certain statements contained in this report are not purely historical including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future that are forward-looking. These statements include those discussed in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, including "Liquidity and Capital Resources," and "Factors That May Affect Future Results," and elsewhere in this report. These statements include statements concerning projected revenues, international revenues, expenses, gross profit, income, product development and market acceptance of our products.

In this report, the words "anticipate," "believe," "expect," "intend," "future," and similar expressions also identify forward-looking statements. Our actual results could differ materially from those 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" 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.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,652	\$ 10,290
Restricted cash	250	250
Short-term investments	6,090	—
Accounts receivable, net	6,543	7,597
Inventory	2,935	2,239
Current portion of deferred tax asset	2,107	1,699
Other current assets	993	879
	<hr/>	<hr/>
Total current assets	71,570	22,954
Property and equipment, net	976	734
Intangibles, net	426	453
Deferred tax asset, net of current portion	46	57
	<hr/>	<hr/>
Total assets	\$ 73,018	\$ 24,198
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Liabilities:		
Accounts payable	\$ 2,387	\$ 1,915
Accrued liabilities	5,317	5,709
Deferred revenue	1,046	1,125
	<hr/>	<hr/>
Total current liabilities	8,750	8,749
Deferred rent	424	—
Deferred revenue, net of current portion	592	202
	<hr/>	<hr/>
Total liabilities	9,766	8,951
Contingencies (Note 6):		
Redeemable convertible preferred stock	—	7,372
	<hr/>	<hr/>
Stockholders' equity:		
Common stock	11	2
Additional paid-in capital	61,253	7,579
Deferred stock-based compensation	(3,002)	(3,888)
Retained earnings	4,994	4,182
Other comprehensive loss	(4)	—
	<hr/>	<hr/>
Total stockholders' equity	63,252	7,875
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 73,018	\$ 24,198
	<hr/>	<hr/>

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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net revenue	\$ 12,265	\$ 9,018	\$ 23,845	\$ 15,614
Cost of revenue ⁽¹⁾	3,400	2,760	7,049	4,993
Gross profit	8,865	6,258	16,796	10,621
Operating expenses:				
Sales and marketing	4,623	3,049	8,901	5,537
Research and development	1,047	683	2,006	1,435
General and administrative	1,909	1,179	3,978	2,261
Amortization of deferred stock compensation ⁽¹⁾	316	196	637	373
Total operating expenses	7,895	5,107	15,522	9,606
Income from operations	970	1,151	1,274	1,015
Interest and other income (expense), net	(2)	12	57	30
Income before income taxes	968	1,163	1,331	1,045
Provision for income taxes	(377)	(468)	(519)	(421)
Net income	\$ 591	\$ 695	\$ 812	\$ 624
Net income available to common stockholders used in basic earnings per share (see Note 3 Recent Accounting Pronouncements)	\$ 576	\$ 213	\$ 648	\$ 192
Net income per share: (see Note 7 Net Income Per Share)				
Basic	\$ 0.06	\$ 0.10	\$ 0.11	\$ 0.09
Diluted	\$ 0.05	\$ 0.08	\$ 0.07	\$ 0.07
Weighted-average number of shares used in per share calculations:				
Basic	10,289	2,071	5,997	2,036
Diluted	12,960	8,799	10,921	8,711
⁽¹⁾ Amortization of deferred stock compensation related to:				
Cost of revenue	\$ 39	\$ 46	\$ 90	\$ 89
Operating expenses:				
Sales and marketing	64	45	147	73
Research and development	105	73	204	145
General and administrative	147	78	286	155
	316	196	637	373
Total deferred stock compensation expense	\$ 355	\$ 242	\$ 727	\$ 462

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

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

	Six Months Ended June 30,	
	2004	2003
Cash flows from operating activities:		
Net income	\$ 812	\$ 624
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	246	194
Allowance for doubtful accounts	102	—
Stock based compensation	727	462
Reserve for excess and obsolete inventory	95	—
Change in deferred tax asset	(397)	—
Tax benefit related to employee stock options	88	—
Change in other comprehensive loss	(4)	—
Loss on disposal of assets	104	29
Changes in assets and liabilities:		
Accounts receivable	952	(1,773)
Inventory	(791)	(220)
Other current assets	(114)	(51)
Accounts payable	472	433
Accrued liabilities	(545)	280
Deferred rent	424	—
Deferred revenue	311	402
Net cash provided by operating activities	<u>2,482</u>	<u>380</u>
Cash flows used in investing activities:		
Acquisition of property and equipment	(565)	(246)
Purchase of short-term investments	(6,090)	—
Change in restricted cash	—	(60)
Net cash used in investing activities	<u>(6,655)</u>	<u>(306)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	199	76
Proceeds from issuance of common stock, net	46,336	—
Net cash provided by financing activities	<u>46,535</u>	<u>76</u>
Net increase in cash and cash equivalents	42,362	150
Cash and cash equivalents at beginning of period	10,290	8,276
Cash and cash equivalents at end of period	<u>\$52,652</u>	<u>\$ 8,426</u>
Supplemental disclosure of cash flow information:		
Conversion of preferred to common stock	\$ 7,372	\$ —
Deferred stock-based compensation	\$ 159	\$ —
Cash paid for taxes	\$ 1,123	\$ 213

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

CUTERA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

While 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, 2003 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 final prospectus filed with the SEC on March 31, 2004. Upon completion of the Company's initial public offering, the Company sold 3,629,800 shares of its common stock at a price of \$14.00 per share receiving cash proceeds of \$46.3 million, net of fees.

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 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 operating results as if it had elected to use the fair value approach to account for all its stock-based employee compensation plans. 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 and are subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period, on a straight-line basis.

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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income, as reported	\$ 591	\$ 695	\$ 812	\$ 624
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	283	236	581	453
Less: Total stock-based employee compensation determined under fair-valued based method for all awards, net of related tax effects	(352)	(274)	(661)	(517)
Pro forma net income	\$ 522	\$ 657	\$ 732	\$ 560
Pro forma net income available to common stockholders, used in basic earnings per share: (see Note 3 Recent Accounting Pronouncements)	\$ 509	\$ 202	\$ 517	\$ 124
Basic net income per share:				
As reported	\$ 0.06	\$ 0.10	\$ 0.11	\$ 0.09
Pro forma	\$ 0.05	\$ 0.10	\$ 0.09	\$ 0.06
Diluted net income per share:				
As reported	\$ 0.05	\$ 0.08	\$ 0.07	\$ 0.07
Pro forma	\$ 0.04	\$ 0.07	\$ 0.07	\$ 0.06

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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 following assumptions were used for the Black-Scholes option pricing model for options granted in the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk-free interest rate	3.42%	1.73%	3.06%	2.04%
Expected life (in years)	4	4	4	4
Dividend yield	— %	— %	— %	— %
Volatility	60.6%	— %	59.8%	— %

3. Recent Accounting Pronouncements

In April 2004, the Emerging Issues Task Force issued Statement No. 03-06 "Participating Securities and the Two Class Method Under FASB Statement No. 128, Earnings Per Share" ("EITF 03-06"). EITF 03-06 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-06 is effective for fiscal periods beginning after March 31, 2004 and requires retroactive adjustment of prior period earnings per share to ensure comparability. The Company adopted EITF 03-06 during the period ended June 30, 2004 and has retroactively adjusted reported basic earnings per share for the three and six month periods ended June 30, 2003. There was no effect on diluted earnings per share.

4. Inventories, net (in thousands):

	June 30, 2004	December 31, 2003
Raw materials	\$ 2,096	\$ 1,110
Finished goods	839	1,129
	<u>\$ 2,935</u>	<u>\$ 2,239</u>

5. Warranty and Service Contracts

The Company has a direct field service organization in the United States that provides service for its products. The Company generally provides a warranty with its products, depending on the type of product. After the warranty period, maintenance and support are provided on a service contract basis or on a time and materials basis.

Warranty reserve (in thousands):

Balance, December 31, 2003	\$1,700
Add: Accruals for warranties issued in 2004	578
Less: Settlements made during the period	428
Balance, June 30, 2004	<u>\$1,850</u>

Service contracts

Service contract revenue is recognized on a straight-line basis over the period of the applicable service contract.

Deferred service contract revenue (in thousands):

Balance, December 31, 2003	\$1,322
Add: Payments received	1,043
Less: Revenue recognized	727
Balance, June 30, 2004	<u>\$1,638</u>

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Costs incurred under service contracts during the three months ended June 30, 2004 and 2003 amounted to \$223,000 and \$224,000, respectively. For the six months ended June 30, 2004 and 2003, costs incurred under service contracts were \$352,000 and \$355,000, respectively. All service contract costs are recognized as incurred.

6. 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 and the parties are continuing with the discovery phase of this lawsuit, although either party may file a motion for summary judgment at any time, which could accelerate the litigation’s determination. The Company believes that it has meritorious defenses of non-infringement and invalidity in this action. However, litigation is unpredictable and the Company may not prevail in successfully defending or asserting its position. 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 hair removal, currently representing substantially all of its revenues. The financial statements do not include any amounts related to this contingency.

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.

7. Net Income Per Share

The Company adopted Emerging Issues Task Force Statement No. 03-06 “Participating Securities and the Two Class Method Under FASB Statement No. 128, Earnings Per Share” during the period ended June 30, 2004 and has retroactively adjusted reported earnings per share for the three and six month periods ended June 30, 2003 (see Note “3” Recent Accounting Pronouncements).

Basic net income per share is computed by dividing net income available to the common stockholders, by the weighted-average number of common shares outstanding during the period.

Diluted net income per share is computed by giving effect to all dilutive potential common shares, including options, common stock subject to repurchase, warrants and redeemable convertible preferred stock. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net income per share follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Numerator:				
Net income	\$ 591	\$ 695	\$ 812	\$ 624
Less Amount allocated to participating preferred stockholders:	(15)	(482)	(164)	(432)
Net income available to common stockholders –Basic	\$ 576	\$ 213	\$ 648	\$ 192
Net income available to common stockholders – Diluted	\$ 591	\$ 695	\$ 812	\$ 624
Denominator:				
Weighted-average number of common shares outstanding used in computing basic net income per share	10,289	2,071	5,997	2,036
Add: Dilutive potential common shares used in computing diluted net income per share:	2,671	6,728	4,924	6,675
Total weighted-average number of shares used in computing diluted net income per share	12,960	8,799	10,921	8,711

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Anti-dilutive securities

The following outstanding options and warrants (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 anti-dilutive effect (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Options to purchase common stock	\$ 500	\$ 222	\$ 383	\$ 410

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

**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, 2003. This quarterly report, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include statements relating to our expectations as to future capital expenditures and requirements, growth in our operations, the impact of exchange rate volatility, and the current litigation against Palomar Medical Technologies. These forward-looking statements involve risks and uncertainties. The cautionary statements set forth below and those contained in “Factors That May Affect Future Results,” commencing on page 14, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements.

Overview

We design, develop, manufacture and market the CoolGlide family of laser and other light-based products for aesthetic treatments. Our products enable our customers to remove hair, treat leg and facial veins, rejuvenate skin and treat pigmented lesions. Our customers consist generally of dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners.

Based in Brisbane, California, we sell our products directly in the United States, Canada, Australia, Japan and major European markets, and use distributors to sell our products in countries where we do not have a direct presence, or to complement our direct sales force in selected countries. We expect to generate a greater percentage of our revenue from international sales in the future. As of June 30, 2004, we had approximately 44 sales employees worldwide, and distributors located in more than 25 countries. As our international sales increase, currency fluctuations may affect our international revenue.

We derive revenue primarily from the sale of our aesthetic laser and other light-based products and upgrades. We also derive revenue from product service, which we expect to increase over time as our installed base grows and related warranties expire. As we introduce new products with greater functionality, our revenue tends to shift towards these newer products. Due to the high dollar revenue per system sold, variations in unit sales may significantly impact revenue in a given quarter.

We have a limited history of operations. We anticipate that our quarterly results of operations may fluctuate for the foreseeable future due to several factors, including delays in introduction and acceptance of future products, delays in our manufacturing operations, introduction of new and improved products by competitors, and the performance of our direct sales force and distributors. We expect our operating expenses to increase in the future as a result of increased sales and marketing expenses to promote revenue growth and geographic expansion, continued research and development of new products and technologies, and increased general and administrative expenses to keep pace with our overall growth and the costs of being a public company. Our limited history makes accurate predictions of future operating results difficult.

Results of Operations

Three months ended June 30, 2004 and June 30, 2003 and six months ended June 30, 2004 and June 30, 2003.

Net Revenue.

Revenue is derived from the sale of products and upgrades, and product service. For the three months ended June 30, 2004, net revenue increased \$3.3 million, or 36.0%, from \$9.0 million in the quarter ended June 30, 2003 to \$12.3 million in the quarter ended June 30, 2004. U.S. and international revenues accounted for \$1.2 million and \$2.1 million of the increase, respectively. \$2.6 million was attributable to higher sales of our CoolGlide Xeo products and upgrades, approximately \$500,000 was attributed to other products and the remaining \$235,000 increase was due to service revenues primarily from more service contracts sold.

For the six months ended June 30, 2004, net revenue increased \$8.2 million, or 52.7%, from \$15.6 million in the six months ended June 30, 2003 to \$23.8 million in the six months ended June 30, 2004. U.S. and international revenues increased by \$3.4 million and \$4.8 million respectively. \$7.8 million of the increase was attributable to sales of our CoolGlide Xeo products and upgrades. Service revenues also increased \$394,000 from additional service contracts sold during this same period.

Cost of Revenue.

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the three months ended June 30, 2004, cost of revenue increased \$640,000, or 23.2%, from \$2.8 million in the quarter ended June 30, 2003 to \$3.4 million in the quarter ended June 30, 2004. The increase was primarily attributable to \$343,000 of higher labor and overhead costs associated with the higher revenue volume and \$297,000 in higher material costs. As a percentage of net revenue, cost of revenue decreased from 30.6% in the quarter ended June 30, 2003 to 27.7% in the quarter ended June 30, 2004, primarily due to reduced material costs.

For the six months ended June 30, 2004, cost of revenue increased \$2.1 million, or 41.2%, from \$5.0 million in the six months ended June 30, 2003 to \$7.1 million in the six months ended June 30, 2004. The increase is primarily attributable to \$1.1 million of higher labor and overhead costs associated with the higher revenue volume, \$811,000 in higher material costs and other costs of approximately \$300,000. As a percentage of net revenue, cost of revenue decreased from 32.0% in the quarter ended June 30, 2003 to 29.6% in the quarter ended June 30, 2004, primarily due to higher average selling prices.

Sales and Marketing.

Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops, trade shows and advertising. For the three months ended June 30, 2004, sales and marketing expenses increased \$1.6 million, or 51.6%, from \$3.0 million in the quarter ended June 30, 2003 to \$4.6 million in the quarter ended June 30, 2004. The increase was primarily attributable to an increase of \$789,000 in promotional efforts, \$580,000 of personnel costs and \$205,000 in travel due to the expansion of our direct sales force. Promotional efforts primarily include customer workshops and industry trade shows. As a percentage of net revenue, sales and marketing increased from 33.8% in the quarter ended June 30, 2003 to 37.7% in the quarter ended June 30, 2004.

For the six months ended June 30, 2004, sales and marketing expenses increased \$3.4 million, or 60.8%, from \$5.5 million in the six months ended June 30, 2003 to \$8.9 million in the six months ended June 30, 2004. The increase was primarily attributable to an increase of \$1.8 million in promotional efforts, \$1.2 million of personnel costs and \$379,000 in travel. Promotional efforts primarily include customer workshops and industry trade shows. As a percentage of net revenue, sales and marketing increased from 35.5% in the quarter ended June 30, 2003 to 37.3% in the quarter ended June 30, 2004.

Research and Development.

Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, and material costs. For the three months ended June 30, 2004, research and development expenses increased \$364,000, or 53.3%, from \$683,000 in the quarter ended June 30, 2003 to \$1.0 million in the quarter ended June 30, 2004. The increase was primarily attributable to \$186,000 of materials and outside services associated with new product development, facility expenses of \$80,000 due to the move to our new Brisbane facility and \$80,000 of other expenses. As a percentage of net revenue, research and development expenses increased from 7.6% in the quarter ended June 30, 2003 to 8.5% in the quarter ended June 30, 2004.

For the six months ended June 30, 2004 research and development expenses increased \$571,000, or 39.8%, from \$1.4 million in the six months ended June 30, 2003 to \$2.0 million in the six months ended June 30, 2004. The increase was primarily attributable to approximately \$169,000 of materials and outside services associated with new product development, facility expenses of \$178,000 due to our new Brisbane facility and expenses associated with clinical studies of \$131,000 and approximately \$100,000 of other expenses. As a percentage of net revenue, research and development expenses decreased from 8.4% in the quarter ended June 30, 2003 to 9.2% in the quarter ended June 30, 2004.

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General and Administrative.

General and administrative expenses consist primarily of personnel costs, legal and accounting fees, and other general operating expenses. For the three months ended June 30, 2004, general and administrative expenses increased \$730,000, or 61.9%, from \$1.2 million in the quarter ended June 30, 2003 to \$1.9 million in the quarter ended June 30, 2004. The increase was primarily attributable to \$342,000 in increased audit and tax fees, insurance and other items associated with being a public company, \$222,000 in increased personnel costs, and higher legal expenses associated with the Palomar litigation.

As a percentage of net revenue, general and administrative expenses increased from 13.1% in the quarter ended June 30, 2003 to 15.6% in the quarter ended June 30, 2004.

For the six months ended June 30, 2004, general and administrative expenses increased \$1.7 million, or 76.0%, from \$2.3 million in the six months ended June 30, 2003 to \$4.0 million in the six months ended June 30, 2004. The increase was primarily attributable to approximately \$733,000 of higher audit and tax fees, insurance and other items associated with being a public company, \$291,000 lease settlement on our facility move, \$323,000 of higher personnel expenses and \$175,000 Allied Health legal settlement. As a percentage of net revenue, general and administrative increased from 14.5% in the quarter ended June 30, 2003 to 16.7% in the quarter ended June 30, 2004.

Interest and Other Income (Expense), Net.

For the three months ended June 30, 2004, interest and other income (expense), net decreased by \$14,000 from income of \$12,000 to an expense of \$2,000 due to unfavorable foreign exchange losses offsetting our interest income. Interest and other income, net increased \$27,000 in the six months ended June 30, 2004 from \$30,000 in June 30, 2003 to \$57,000 in June 30, 2004. The increase was primarily attributable to higher tax-exempt interest income from short-term investments offset by foreign exchange losses for the six months ended June 30, 2004.

Provision for Income Taxes.

Provision for income taxes decreased by \$91,000 from \$468,000 to \$377,000 for the three months ended June 30, 2004 compared to the same period in 2003 due to lower net income. Provision for income taxes for the six months ended June 30, 2004 increased by \$98,000 to \$519,000 from a tax provision of \$421,000 in June 30, 2003. The increase was attributable to higher net income. The effective tax rate for 2004 is expected to be approximately 39%. For 2003, the effective tax rate was approximately 40%.

Deferred Stock-Based Compensation.

For the three months ended June 30, 2004, stock compensation expense increased by \$113,000 from \$242,000 to \$355,000 compared to the same period in 2003. Deferred stock-based compensation increased \$266,000 from \$461,000 in the six months ended June 30, 2003 to \$727,000 in the six months ended June 30, 2004. 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. Deferred stock-based compensation is amortized on a straight-line basis to cost of revenue, sales and marketing expenses, research and development expenses, and general and administrative expenses. Stock-based compensation expenses related to stock options granted to non-employees are recognized as the stock options are earned. The amount of stock-based compensation expenses to be recorded in future periods may decrease if unvested options are subsequently cancelled. Our stock-based compensation expenses will fluctuate as the fair market value of our common stock fluctuates. As of June 30, 2004, our deferred stock-based compensation was \$3.0 million. We currently expect to record remaining amortization expense for employee deferred stock-based compensation as follows:

<u>For the Year</u>	<u>Amount</u>
Six months ended December 31, 2004	\$ 0.7 million
2005	\$ 1.2 million
2006	\$ 0.7 million
2007	\$ 0.4 million

Stockholder's Equity

Stock option grants are designed to reward employees, officers, and directors for their long-term contribution to the Company and to provide retention incentives for them. The number and frequency of stock option grants is based on competitive practices, the Company's operating results, and government regulations. The following table shows the grant dilution and exercise dilution as of August 3, 2004:

	<u>Since inception</u>
Shares of common stock outstanding	10,709,025
Options granted	6,146,257
Options cancelled	(1,222,160)
Net options granted	4,924,097
Grant dilution *	46.0%
Options exercised	741,238
Exercise dilution **	6.9%

* The percentage for grant dilution is computed based on options granted less options cancelled as a percentage of total outstanding shares of common stock.

** The percentage for exercise dilution is computed based on options exercised as a percentage of total outstanding shares of common stock.

Liquidity and Capital Resources

Net Cash Provided by Operating Activities. For the six months ended June 30, 2004 and June 30, 2003, net cash provided in operating activities was \$2.5 million and \$380,000, respectively. The increase in cash provided by operating activities for the six-month period ended June 30, 2004 compared to the same period a year earlier primarily resulted from \$812,000 in net income adjusted for \$727,000 of stock-based compensation expense, a decrease in accounts receivable of \$952,000 due to an improvement in cash collections efforts, offset by \$791,000 increase in inventory for anticipated revenue shipments and a decrease of \$545,000 in accrued liabilities due to our payment of accounting and legal fee accruals associated with our initial public offering.

Net Cash Used in Investing Activities. Net cash used in investing activities was \$6.7 million and \$306,000 for the six months ended June 30, 2004 and June 30, 2003, respectively. For the six months ended June 30, 2004, we used \$565,000 for capital purchases compared with \$246,000 for the same period a year earlier. These capital purchases consisted of payments made for equipment and machinery relating to manufacturing, research and development, and office equipment relating to our new Brisbane facility. For the six months ended June 30, 2004, we also purchased \$6.1 million of short-term investments.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was \$46.5 million and \$76,000 for the six months ended June 30, 2004 and June 30, 2003, respectively. The increase in cash provided by financing activities for the six months ended June 30, 2004, compared to the same period a year earlier primarily resulted from net proceeds of \$46.3 million from the sale of common stock, net of issuance, legal and accounting costs associated with our initial public offering. Increase in cash provided by financing activities was also attributable to \$199,000 of proceeds from the exercise of stock options and our employee stock purchase plan.

Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, and continued progress of our research and development of new products.

We expect to increase capital expenditures consistent with our anticipated growth in manufacturing, infrastructure and personnel. We also may increase our capital expenditures as we expand our product lines or invest to address new markets.

As of June 30, 2004, we had \$52.7 million in cash and cash equivalents and \$6.1 million in short-term investments.

We believe that our current cash and investment balances and 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. If existing cash and cash generated from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or convertible debt securities would result in dilution to our stockholders. If additional funds are raised through the issuance of debt or preferred equity securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

Recent Accounting Pronouncements

For information relating to recent accounting pronouncements, we refer you to the footnote section of this Form 10-Q.

FACTORS THAT MAY AFFECT FUTURE RESULTS

We have a limited history of operations, which could impair our ability to grow significantly.

We were incorporated in 1998 and commercially launched our first product in 2000. Consequently, we have a limited history of operations. The future success of our business will depend on our ability to increase product sales, successfully introduce new products, expand our sales force and distribution network, and control costs, which we may be unable to do. As a result, we may not be able to continue our revenue growth and maintain profitability.

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. It may be difficult for us to control costs if we significantly expand our manufacturing capacity. Our success in growing our business also will depend upon the ability of our management team to implement improvements in our operational systems, realize economies of scale, manage multiple development projects, and continue to expand, train and manage our personnel worldwide. If we cannot scale and manage our business appropriately, or manage the introduction of new products, we will not experience our projected growth and our financial results will suffer.

It is difficult to predict future performance, and our success is dependent on a number of factors over which we have limited control. As a result, our financial results may fluctuate unpredictably.

Our limited operating history makes it difficult for us to predict future performance. Historically, the demand for our products has varied from quarter to quarter. Due to the high dollar revenue per system sold, variations in unit sales may cause revenue to vary significantly from quarter to quarter. As a result, it is difficult for us to accurately predict sales for subsequent periods. In addition, we base our production, inventory and operating expenditure levels on anticipated orders. If orders are not received when expected in any given quarter, expenditure levels could be disproportionately high in relation to revenue for that quarter. A number of additional factors, over which we have limited control, may contribute to fluctuations in our financial results, such as:

- delays in introductions and acceptance of our future products;
- delays in, or failure of, delivery of components by our suppliers;
- introductions of new and improved products by competitors;
- performance of our independent distributors;
- increases in the length of our sales cycle;
- fluctuations in foreign currency;
- changes in our ability to obtain and maintain regulatory approvals; and
- reductions in the efficiency of our manufacturing processes.

In the event our actual revenue and operating results do not meet our forecasts for a particular period, the market price of our common stock may decline substantially.

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 and the treatment of pigmented lesions. 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;
- 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. 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.

Our success depends on market acceptance of our products, many of which have been recently introduced.

All of our products have been introduced within the last four years. It is difficult for us to predict how successful recently introduced products will be over the long term. Our failure to significantly penetrate current or new markets with our products could negatively impact our business, financial condition and results of operations. The market for aesthetic devices is highly competitive and dynamic, and marked by rapid and substantial technological development and product innovations. Demand for our products could be diminished by equivalent or superior products and technologies offered by competitors. Decreases in forecasted demand could leave us with excess inventory, which could become obsolete and have to be written off.

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.

We are currently involved in a lawsuit brought by one of our public company competitors, Palomar Medical Technologies, which alleges that the manufacture, use and sale of our products for hair removal infringes a patent it has licensed. In the lawsuit, 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 patent and that the patent is invalid and unenforceable. Although we believe that these 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. If found liable, we may also be ordered to stop selling any products that perform hair removal, which represented substantially all of our revenue in 2003. 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 is active and the parties are continuing with the discovery phase of this lawsuit. Either party may file a motion for summary judgment at any time, which could accelerate the litigation's determination. 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.

Palomar may file additional claims against us, or we may file additional claims against Palomar, which could increase the risk, expense and duration of the litigation. For more information regarding this litigation, see "PART II, Item 1. Legal Proceedings."

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. We have and may hereafter become involved in litigation to protect the trademark rights associated with our company name or the names of our products. We have only recently adopted the name "Cutera," and do not know whether others will assert that our company name infringes their trademark rights. In addition, names we choose for our products, such as CoolGlide, may be claimed to infringe names held by others. If we have to change the name of our company or products, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

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.

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 and Palomar Medical Technologies, as well as other smaller, specialized private companies. 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;

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- 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.

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

In the future, we expect our revenue from international operations to comprise a growing percentage of overall revenue. We currently 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 will be adversely affected.

We believe that an increasing percentage 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;

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- 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 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 premarketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. The FDA's 510(k) clearance process usually takes from three to twelve months, but it can last longer. The process of obtaining premarketing approval is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current 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 and operate 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 premarket approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

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

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

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket 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 clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and 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;

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- 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 six 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.

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, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use and benefits of our products. 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.

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.

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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.

Our recent name change may lead to customer confusion and increased marketing expense, which would affect our operating results.

Our recent name change from Altus Medical, Inc. to Cutera, Inc. may confuse customers and potential customers who associate our products with our former name. If our customers are confused by the name change, they may not order our products and our operating results would suffer. In addition, we will incur marketing costs in order to promote our new name, which will reduce our overall operating results in the near term.

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 short-term investment portfolio. Our future investment income may fluctuate 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 our excess cash primarily in money market instruments, municipal securities, U.S. government securities and investment-grade marketable debt securities of financial institutions and corporations. These instruments have maturities of two years or less when acquired. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our short-term investment portfolio as of June 30, 2004 would have declined by \$40,000.

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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.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act 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 Securities and Exchange Commission 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 June 30, 2004. 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 six 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, 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 and the parties are continuing with the discovery phase of this lawsuit, although either party may file a motion for summary judgment at any time, which could accelerate the litigation’s determination. The Company believes that it has meritorious defenses of non-infringement and invalidity in this action. However, litigation is unpredictable and the Company may not prevail in successfully defending or asserting its position. 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 hair removal, currently representing substantially all of its revenues.

Item 2. Changes in Securities and Use of Proceeds

In April 2004, upon the closing of our initial public offering, we converted 7,372,000 shares of preferred stock to common stock. A total of 3,629,800 shares of common stock were sold in the offering including the underwriters over-allotment exercise at a price of \$14.00 per share, resulting in gross proceeds of \$50.8 million.

The underwriting discount was \$3.5 million and other expenses related to the initial public offering totaled approximately \$1 million. The Company’s net proceeds from the initial public offering were \$46.3 million.

Of the approximately \$46.3 million in net offering proceeds, through June 30, 2004, we have spent \$4.6 million for sales and marketing initiatives, and \$1.0 million for product research and development.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Company's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Company's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K.

- On April 29, 2004, we filed a Form 8-K under Item 9, announcing Mr. Timothy J. O'Shea's election to our board of directors. We also announced the sale of an additional 529,800 shares of Common Stock to certain of our underwriters in connection with the exercise of their over-allotment option.
- On May 3, 2004, we filed a Form 8-K under Item 7, announcing our first quarter 2004 results.
- On June 9, 2004, we filed a Form 8-K under Item 9, announcing the increase in the number of directors on our board and the election of W. Mark Lortz as a member to the board of directors.

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.

Date: August 12, 2004

CUTERA, INC.

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial Officer
(Principal Financial Officer and Authorized Signatory)

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

I, Kevin 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 six months (the registrant's fourth fiscal three and six months 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: August 12, 2004

/s/ Kevin P. Connors

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

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 six months (the registrant's fourth fiscal three and six months 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: August 12, 2004

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial Officer
(Principal Financial and Accounting Officer)

Certification of Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cutera, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2004 (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: August 12, 2004

/s/ Kevin P. Connors

Kevin P. Connors
Chief Executive 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.

Certification of Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cutera, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2004 (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: August 12, 2004

/s/ Ronald J. Santilli

Ronald J. Santilli
Chief Financial 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.