

CUTERA INC
Form 10-Q
May 10, 2006
Table of Contents

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 March 31, 2006

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)

3240 Bayshore Blvd., Brisbane, California 94005

(Address of principal executive offices)

(415) 657-5500

(Registrant's telephone number, including area code)

77-0492262
(I.R.S. employer

identification no.)

Edgar Filing: CUTERA INC - Form 10-Q

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

The number of shares of Registrant's common stock issued and outstanding as of April 30, 2006 was 12,379,339.

Table of Contents

CUTERA, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
Part I. <u>Financial Information</u>	3
Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	20
Part II <u>Other Information</u>	20
Item 1. <u>Legal Proceedings</u>	20
Item 1A. <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	32
<u>Signature</u>	33

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****CUTERA, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands)****(unaudited)**

	March 31,	December 31,
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,951	\$ 5,260
Marketable investments	92,560	86,736
Accounts receivable, net	6,647	6,478
Inventory	6,684	5,245
Deferred tax asset	3,005	3,027
Other current assets	3,940	3,728
Total current assets	115,787	110,474
Property and equipment, net	965	1,015
Intangibles, net	434	469
Total assets	\$ 117,186	\$ 111,958
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	\$ 2,387	\$ 1,352
Accrued liabilities	8,873	9,131
Deferred revenue	2,126	1,673
Total current liabilities	13,386	12,156
Deferred rent	1,178	1,096
Deferred revenue, net of current portion	1,668	1,469
Deferred tax liability	60	60
Total liabilities	16,292	14,781
Contingencies (Note 8)		
Stockholders equity:		
Common stock	12	12
Additional paid-in capital	78,956	77,705
Deferred stock-based compensation	(774)	(2,171)
Retained earnings	22,850	21,743
Accumulated other comprehensive loss	(150)	(112)
Total stockholders equity	100,894	97,177

Edgar Filing: CUTERA INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 117,186	\$ 111,958
--	------------	------------

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

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

	Three Months Ended	
	March 31, 2006	2005
Net revenue	\$ 20,757	\$ 15,147
Cost of revenue ⁽¹⁾	5,811	4,014
Gross profit	14,946	11,133
Operating expenses:		
Sales and marketing ⁽¹⁾	8,546	5,800
Research and development ⁽¹⁾	1,307	1,185
General and administrative ⁽¹⁾	4,375	2,312
Total operating expenses	14,228	9,297
Income from operations	718	1,836
Interest and other income, net	956	286
Income before income taxes	1,674	2,122
Provision for income taxes	(567)	(636)
Net income	\$ 1,107	\$ 1,486
Net income per share:		
Basic	\$ 0.09	\$ 0.13
Diluted	\$ 0.08	\$ 0.11
Weighted-average number of shares used in per share calculations:		
Basic	12,257	11,093
Diluted	14,174	13,532

⁽¹⁾ Stock-based compensation expense was attributable to the following categories:

Cost of revenue	\$ 171	\$ 29
Sales and marketing	402	52
Research and development	159	104
General and administrative	354	241
Total stock-based compensation	\$ 1,086	\$ 426

Edgar Filing: CUTERA INC - Form 10-Q

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

Table of Contents**CUTERA, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

	Three Months Ended	
	March 31,	
	2006	2005
Cash flows from operating activities:		
Net income	\$ 1,107	\$ 1,486
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	199	161
Change in allowance for doubtful accounts	83	(39)
Provision for excess and obsolete inventory		250
Change in deferred taxes	22	2
Stock-based compensation	1,086	426
Tax benefit from stock option exercises	1,006	553
Excess tax benefit related to stock-based compensation expense	(999)	
Changes in assets and liabilities:		
Accounts receivable	(252)	757
Inventory	(1,439)	(989)
Other current assets	(212)	(232)
Accounts payable	1,035	(228)
Accrued liabilities	(258)	(659)
Deferred rent	82	112
Deferred revenue	652	15
Net cash provided by operating activities	2,112	1,615
Cash flows from investing activities:		
Acquisition of property and equipment	(114)	(130)
Proceeds from sales of marketable investments	439	3,950
Proceeds from maturities of marketable investments	18,688	1,010
Purchase of marketable investments	(24,989)	(4,620)
Net cash provided by (used in) investing activities	(5,976)	210
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	556	1,367
Excess tax benefit related to stock-based compensation expense	999	
Net cash provided by financing activities	1,555	1,367
Net (decrease) increase in cash and cash equivalents	(2,309)	3,192
Cash and cash equivalents at beginning of period	5,260	7,070
Cash and cash equivalents at end of period	\$ 2,951	\$ 10,262

Supplemental disclosure of non-cash information:

Edgar Filing: CUTERA INC - Form 10-Q

Change in deferred stock-based compensation, net of terminations \$ (1,255) \$ 63
The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Table of Contents

CUTERA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Basis of Presentation

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

The financial information furnished is unaudited. The condensed consolidated financial statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that the Company considers necessary for the fair statement 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 December 31, 2005 condensed balance sheet was derived from audited financial statements, but does not include all disclosure required by accounting principles generally accepted in the United States of America. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The condensed consolidated financial statements should be read in conjunction with the Company's financial statements and the notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2005 filed with the Securities and Exchange Commission (SEC) on March 16, 2006.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's annual report on Form 10-K for the year ended December 31, 2005 and have not changed significantly as of March 31, 2006, with the exception of the following policies:

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)), using the modified prospective transition method and therefore has not restated results for prior periods. Under this transition method, stock-based compensation expense for the first quarter of fiscal 2006 includes compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the vesting term of four years. Prior to the adoption of SFAS 123(R) the Company recognized stock-based compensation expense in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). In March 2005, the SEC issued Staff Accounting Bulletin No. 107 *Share-Based Payment* (SAB 107) regarding the SEC's interpretation of SFAS 123(R) and the valuation of stock-based payments for public companies. The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R). See Note 2 to the Condensed Consolidated Financial Statements for a further discussion on stock-based compensation.

Net income per share

Basic earnings per share are calculated based on net earnings and the weighted-average number of shares of common stock outstanding during the reported period. Diluted earnings per share is calculated by increasing the weighted-average number of common shares outstanding during the period, by the number of additional shares of common stock that would have been outstanding if the dilutive potential shares of common stock had been issued. The dilutive effect of potential common stock (including outstanding stock options, ESPP shares, non-employee director stock units and restricted stock units) is reflected in diluted earnings per share by application of the treasury stock method, which includes consideration of stock-based compensation to be recognized for the options, net of the tax, as required by SFAS 123(R) in the first quarter of fiscal year 2006.

Table of Contents**Note 2. Accounting for Stock-Based Compensation**

As of March 31, 2006, as described below, the Company had the following stock-based employee compensation plans. The total compensation expense related to these plans was \$1.1 million for the three months ended March 31, 2006. Prior to January 1, 2006, the Company accounted for these plans under the recognition and measurement provisions of APB 25. Accordingly, the Company generally recognized compensation expense only when it granted options with a discounted exercise price. Any resulting compensation expense was recognized ratably over the associated service period, which was generally the option vesting term of four years.

The modified prospective transition method of SFAS 123(R), requires the presentation of pro-forma information for periods prior to the adoption of SFAS 123(R) regarding the net income and net income per share as if the Company had accounted for its stock options under the fair value method of SFAS 123(R). If compensation had been determined based upon the fair value at the grant date for employee compensation arrangements, consistent with the methodology prescribed in SFAS 123, the Company's pro-forma net income and pro-forma net income per share under SFAS 123 would have been as shown in the following table. For the purpose of this pro-forma disclosure, the estimated value of the stock awards is recognized on a straight line basis over the vesting periods of the awards (in thousands, except per share data):

	Three Months Ended
	March 31, 2005
Net income, as reported	\$ 1,486
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	270
Less: Total stock-based employee compensation determined under fair-valued based method for all awards, net of related tax effects	(497)
Pro forma net income available to common stockholders, used in basic and diluted earnings per share	\$ 1,259
Basic net income per share:	
As reported	\$ 0.13
Pro forma	\$ 0.11
Diluted net income per share:	
As reported	\$ 0.11
Pro forma	\$ 0.09

2004 Employee Stock Purchase Plan

The Company sponsors the 2004 Employee Stock Purchase Plan (2004 ESPP), pursuant to which eligible employees are permitted to purchase common stock at a fifteen percent discount through payroll deductions. The price of the common stock purchased, is the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. Shares of common stock eligible for purchase are increased on the first day of each fiscal year by an amount equal to the lesser of (i) 600,000 shares, (ii) 2.0% of the outstanding shares of common stock on such date or (iii) an amount as determined by the Board of Directors. Each offering period includes two six-month purchase periods. The Company added 244,269 reserved shares to the 2004 ESPP on January 1, 2006. The price of the common stock purchased shall be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. As of March 31, 2006, 569,855 shares remained available for future issuance.

2004 Equity Incentive Plan and 1998 Stock Plan

The Company has two stock option plans- the 1998 Stock Plan (the 1998 Plan) and the 2004 Equity Incentive Plan (the 2004 Equity Incentive Plan). Shares of common stock approved under the 2004 Equity Incentive Plan will be increased on the first day of each fiscal year, by an amount equal to the lesser of: (i) 5% of the outstanding shares of the first day of such year; (b) 2 million shares; or, (c) an amount

Table of Contents

determined by our board. On January 1, 2006, the Company added 610,674 shares to the 2004 Equity Incentive Plan. As of March 31, 2006, a total of 2,068,896 shares of common stock were reserved for issuance pursuant to the 2004 Equity Incentive Plan and the 1998 Plan.

Options granted under the 1998 Plan and 2004 Equity Incentive Plan may be incentive stock options or non-statutory stock options. Stock purchase rights, or restricted stock units, may also be granted under the 2004 Equity Incentive Plan. Incentive stock options may only be granted to employees. The Board of Directors determines the period over which options become exercisable, however, except in the case of options granted to officers, directors and consultants, options shall become exercisable at a rate of no less than 20% per year over five years from the date the options are granted. Options are to be granted at an exercise price not less than the fair market value per share on the grant date for incentive options or 85% of fair market value for nonqualified stock options. The Company has not granted any discounted options since fiscal 2003. Options granted under the Plan generally become exercisable 25% on the first anniversary of the vesting commencement date and an additional 1/48th of the total number of shares subject to the option shares shall become exercisable on the last day of each calendar month thereafter until all of the shares have become exercisable. The term of the Company's options is ten years.

During the year ended December 31, 2005, under the 2004 Equity Incentive Plan, the Company's Board of Directors approved the grant of performance unit awards (more commonly referred to as restricted stock units) for a total aggregate of 71,500 shares of restricted stock units to selected members of the Company's management. These restricted stock unit awards are independent of option grants and will not vest if employment terminates prior to the release of the restrictions. These restricted stock unit awards vest in four equal, annual installments on the anniversaries of the date of grant. Restricted stock units do not have the voting rights of common stock, and the shares underlying the restricted stock units are not considered issued and outstanding until they vest and are issued. The Company expenses the cost of the restricted stock unit awards, which is determined to be the fair market value of the shares at the date of grant, ratably over the period during which the restrictions lapse - generally four years from the grant date. As of March 31, 2006, there were no restricted stock units vested.

Activity under the 1998 Stock Plan and 2004 Equity Incentive Plan is summarized as follows:

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in \$ millions)*
Balances, December 31, 2003	223,550	3,791,913	\$ 2.83		
Additional shares reserved	1,750,000				
Options granted	(699,375)	699,375	\$ 13.34		
Options exercised		(319,643)	\$ 2.20		
Options forfeited	223,217	(223,217)	\$ 9.96		
Balances, December 31, 2004	1,497,392	3,948,428	\$ 4.39		
Additional shares reserved	547,860				
Options granted	(682,625)	682,625	\$ 18.03		
Restricted stock units granted	(71,500)				
Options exercised		(1,197,949)	\$ 4.65		
Options forfeited	188,495	(188,495)	\$ 8.74		
Balances, December 31, 2005	1,479,622	3,244,609	\$ 6.91		
Additional shares reserved	610,674				
Options granted	(72,000)	72,000	\$ 26.03		
Options exercised		(121,193)	\$ 4.58		
Options forfeited	49,100	(49,100)	\$ 14.58		
Restricted stock units forfeited	1,500				
Balances, March 31, 2006	2,068,896	3,146,316	\$ 7.32	6.18	\$ 62
Vested and exercisable as of March 31, 2006		2,013,575	\$ 2.80	4.80	\$ 49

Edgar Filing: CUTERA INC - Form 10-Q

* Based on the closing stock price of the Company's common stock of \$27.12 on March 31, 2006.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the first quarter of fiscal 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2006. This amount changes based on the fair market value of the Company's stock. Total intrinsic value of options exercised for the three months ended March 31, 2006 was \$2.7 million. Total fair value of options vested and expensed was \$739,000, net of tax, for the three months ended March 31, 2006. The Company issues new shares upon the exercise of options and restricted stock units.

As a result of adopting the fair value recognition provisions of SFAS 123(R), the impact to the Condensed Consolidated Financial Statements for the three months ended March 31, 2006 from stock-based compensation is as follows (*in thousands, except per share data*):

Table of Contents

	Three Months Ended March 31, 2006
Stock-based compensation expense by award type:	
Employee stock options granted at their intrinsic value	\$ (705)
Employee stock options granted below their deemed intrinsic fair value prior to the Company's initial public offering	(142) ⁽¹⁾
Employee stock purchase plan	(150)
Restrictive stock unit	(89) ⁽¹⁾
Total stock-based compensation	(1,086)
Tax effect on stock-based compensation at the Company's marginal tax rate	347
Effect on net income	\$ (739)
Effect on net income per share:	
Basic	\$ (0.06)
Diluted	\$ (0.05)
Effect on cash flows:	
Reclass of excess tax benefit related to stock-based compensation expense	
Cash flows from operating activities	\$ (999)
Cash flows from financing activities	\$ 999
Change in deferred stock-based compensation	
Due to reversal of unamortized deferred stock-based compensation upon adoption	\$ (1,237)
Due to reversal of unamortized deferred stock-based compensation for terminations of employee stock options granted below their deemed intrinsic fair value prior to the Company's initial public offering	(18) ⁽¹⁾
	\$ (1,255)

(1) This amount would also have been recorded under the provisions of APB 25, prior to the adoption of FAS 123(R). As of January 1, 2006, the Company had an unrecorded deferred stock-based compensation balance related to stock options and restricted stock unit awards of \$9.9 million before estimated forfeitures. In the Company's pro forma disclosures prior to the adoption of SFAS 123(R), the Company accounted for forfeitures when they actually occurred. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised if necessary in subsequent periods if actual forfeitures differ from those estimates. Under SFAS 123(R), the Company estimated that \$503,000 of the unrecorded deferred stock-based compensation amount as of January 1, 2006 will not be recognized due to forfeitures.

During the quarter ended March 31, 2006, the Company granted options for 72,000 shares of common stock with an estimated total grant-date fair value of \$1.3 million. Of this amount, the Company estimates that the amount of unrecorded deferred stock-based compensation relating to awards not expected to vest due to forfeiture is \$36,000. As of March 31, 2006, the unrecognized compensation cost related to non-vested stock options and restricted stock unit awards was \$8.6 million and will be recognized using the straight-line attribution method over an estimated weighted-average amortization period of 2.3 years.

During the quarter ended March 31, 2006, the Company estimated the grant date fair value of ESPP stock to be \$8.01 per share and recorded the forecasted expense for the quarter ended March 31, 2006 of \$150,000. As of March 31, 2006, the unrecognized compensation cost related to ESPP options was \$158,000 and will be recognized using the straight-line attribution method over 0.6 years.

Valuation Assumptions

Edgar Filing: CUTERA INC - Form 10-Q

The Company estimates the fair value of employee stock options and ESPP using a Black-Scholes option-pricing model, consistent with the provisions of SFAS 123(R), SAB 107, and the Company's prior period pro forma disclosures of net earnings, including stock-based compensation (determined under a fair value method as prescribed by SFAS 123). The fair value of each option grant and each stock issuance under the

Table of Contents

ESPP were estimated on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Three Months Ended	
	March 31,	March 31,
	2006	2005
Employee stock options:		
Expected dividend yield	0%	0%
Risk-free interest rate	4.22%	3.4%
Expected volatility	76%	67%
Expected life (in years)	6.1	4.0
Employee stock purchase plan options:		
Expected dividend yield	0%	0%
Risk-free interest rate	3.89%	1.87%
Expected volatility	50%	52%
Expected life (in years)	0.8	0.5

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The expected stock price volatility is based on a combination of the Company's historical volatility combined with the weighted average of the volatility of other similar companies in the same industry. The Company believes this is more reflective and a better indicator of the expected future volatility, than using an average of a comparable market index or of a comparable company in the same industry. Due to the Company's recent IPO, the expected term of options granted in the quarter ended March 31, 2006 was derived from the short-cut method described in SEC's SAB No. 107. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Note 3. Net Income Per Share

The following table sets forth the computation of basic and diluted net income and the weighted average number of shares used in computing basic and diluted net income per share (in thousands):

	Three Months Ended	
	March 31,	
	2006	2005
Numerator:		
Net income available to common stockholders - Basic and Diluted	\$ 1,107	\$ 1,486
Denominator:		
Weighted-average number of common shares outstanding used in computing basic net income per share	12,257	11,093
Dilutive potential common shares used in computing diluted net income per share	1,917	2,439
Total weighted-average number of shares used in computing diluted net income per share	14,174	13,532

Anti-dilutive securities

The following outstanding options (prior to the application of 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

Edgar Filing: CUTERA INC - Form 10-Q

	March 31,	
	2006	2005
Options to purchase common stock	309	1

Table of Contents**Note 4. Inventory**

Inventory consists of the following (in thousands):

	March 31, 2006	December 31, 2005
Raw materials	\$ 3,498	\$ 3,071
Finished goods	3,186	2,174
	\$ 6,684	\$ 5,245

Note 5. Warranty and Service Contracts*Warranty reserve*

The Company has a direct field service organization in the United States, Canada, Switzerland, Germany, Australia and Japan that provides service for its products in these countries. The Company has third party service providers in all other locations. The Company generally provides a warranty with its products, depending on the type of product. After the warranty period, maintenance and support are offered on a service contract basis or on a time and materials basis. The Company currently provides for the estimated cost to repair or replace products under warranty at the time of sale. The warranty reserve activity for the three months ended March 31, 2006 and 2005, was as follows (in thousands):

	March 31, 2006	March 31, 2005
Balance at December 31, 2005 and 2004	\$ 2,043	\$ 1,850
Add: Accruals for warranties issued in 2006 and 2005	1,178	553
Less: Settlements made during the period	(876)	(553)
Balance at March 31, 2006 and 2005	\$ 2,345	\$ 1,850

Deferred service contract revenue

Service contract revenue is recognized on a straight-line basis over the period of the applicable service contract. The deferred service contract revenue balances as of March 31, 2006 and December 31, 2005, were as follows (in thousands):

	March 31, 2006	March 31, 2005
Balance at December 31, 2005 and 2004	\$ 3,117	\$ 1,906
Add: Payments received	1,441	559
Less: Revenue recognized	(786)	(482)
Balance at March 31, 2006 and 2005	\$ 3,772	\$ 1,983

Costs incurred under service contracts during the three months ended March 31, 2006 and 2005, amounted to \$402,000 and \$188,000, respectively. All service contract costs are recognized as incurred.

Note 6. Comprehensive Income

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

Table of Contents

	Three Months Ended	
	March 31, 2006	2005
Net income	\$ 1,107	\$ 1,486
Unrealized loss on marketable investments	(38)	(13)
Comprehensive income	\$ 1,069	\$ 1,473

Note 7. Income Tax

The interim effective income tax rate is based on management's best estimate of the annual effective income tax rate. The effective tax rate for the three months ended March 31, 2006 and 2005 was 34% and 30%, respectively. These rates reflect applicable United States federal and state tax rates and the tax impact of foreign operations offset by research and development tax credits in the three months ended March 31, 2005, tax exempt interest income and deductions for disqualifying incentive stock option exercises.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$590,000 and \$217,000 at March 31, 2006 and 2005, respectively, are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to various foreign countries.

Note 8. Contingencies

In February 2002, Palomar Medical Technologies (Palomar) filed a lawsuit against the Company in the United States District Court, District of Massachusetts. The plaintiff alleges that by making, using, selling or offering for sale the Company's CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, the Company is willfully and deliberately infringing U.S. Patent No. 5,735,844. This patent concerns a method and apparatus for removing hair with light energy. Massachusetts General Hospital (MGH) later joined the lawsuit as an additional plaintiff, since Palomar is the exclusive licensee, and MGH is the owner, of the patent at issue in the lawsuit. Palomar and MGH are seeking to enjoin the Company from selling products found to infringe the patent, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. The Company is defending the action vigorously, claiming that its products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, the Company has filed a counterclaim alleging that the patent should be declared unenforceable because of inadequate disclosures made to the U.S. Patent and Trademark Office by the plaintiffs during that patent's prosecution with the U.S. Patent and Trademark Office. The litigation is active, and the court has set a trial date for May 30, 2006.

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

The Company responded by filing a motion to dismiss this second lawsuit on the grounds of lack of jurisdiction, and by filing complaints for declaratory relief against these plaintiffs in California and Delaware. On May 5, 2006, the court in Massachusetts denied that motion, likely subjecting the subject matter of that second lawsuit to the jurisdiction of that court. The Company believes that it has meritorious defenses of non-infringement and invalidity in these actions.

Since the outcome of this litigation is unpredictable, and since management believes that a significant adverse result for the Company is not probable, no expense has been recorded with respect to the contingent liability associated with this matter. If the Company does not prevail, it may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. The Company could also be ordered to stop selling any products that perform hair removal. The Company may also be required to pay substantial amounts, including ongoing royalty payments, in the event that the

Table of Contents

parties enter into a settlement agreement. Most of the Company's products include an application for hair removal.

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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Caution Regarding Forward-Looking Statements

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, 2005 as contained in our annual report on Form 10-K filed with the SEC on March 16, 2006. This quarterly report, including the following sections, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. These statements include, but are not limited to, 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 Part II, Item 1A Risk Factors commencing on page 21, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this report. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-Q.

Introduction

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

Executive summary. This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.

Critical accounting policies and estimates. This section describes the key accounting policies that are affected by critical accounting estimates. In addition, it includes a summary of recent accounting pronouncements that may be applicable to us.

Results of operations. This section provides our analysis and outlook for the significant line items on our consolidated statement of operations.

Liquidity and capital resources. This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of March 31, 2006.

Executive Summary

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

Table of Contents

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research, regulatory, sales, marketing and administrative activities. Outside the United States, we have a direct sales presence in Australia, Canada, France, Germany, Japan, Spain, Switzerland and the United Kingdom. As of March 31, 2006, we had 78 direct sales employees worldwide, a global network of distributors located in more than 25 countries, and a distributor relationship in the United States with PSS World Medical. PSS's Physician Sales and Service business operates medical supply distribution service centers with approximately 700 sales representatives serving physician offices in all 50 of the United States.

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

Significant Business Trends. We believe that revenue growth has been and will continue to be primarily attributable to the following:

Investments made in our global sales and marketing infrastructure, including the expansion of our sales force and improved productivity, to increase our market penetration in an expanding aesthetic laser market.

Continuing introduction of new aesthetic products and applications.

Marketing to physicians outside the core dermatologist and plastic surgeon specialties, including the medi-spa market. During the three months ended March 31, 2006, compared to the same period in 2005, net revenue, increased by \$5.6 million or 37%. On a geographical basis, for the three months ended March 31, 2006, compared to the same period in 2005, our U.S. revenue increased by \$4.5 million, or 44%, and our international revenue increased by \$1.1 million, or 23%. We experienced stronger U.S growth, versus international growth, due primarily to our increased sales and marketing efforts and our higher concentration of direct sales employees in the United States.

Due to our patent litigation set for trial on May 30, 2006 see Part II, Item 1 Legal Proceedings our general and administrative expenses were significantly higher than the same period in 2005. In the quarter ended June 30, 2006, due to the preparation for the upcoming Palomar trial, we expect our general and administrative expenses to further increase over the expenses incurred in the quarter ended March 31, 2006. After the trial is completed, anticipated for June 2006, we expect our general and administrative expenses to be approximately 9-11% of revenue in the second half of 2006.

Factors that May Impact Future Performance. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances and compliance for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. Our industry is subject to extensive government regulation, including the regulation by the United States Food and Drug Administration. Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other factors that could impact our future performance are provided in Part II, Item 1A Risk Factors section below.

Table of Contents

Critical Accounting Policies and Estimates

The accounting policies that we consider to be our most critical (those that are most important to the portrayal of our financial condition and results of operations and that require our most difficult, subjective or complex judgments), the effects of those accounting policies applied and the judgments made in their application are summarized in *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2005 filed with SEC on March 16, 2006. Other than the adoption of SFAS 123(R), there have been no significant changes during the three months ended March 31, 2006 to the items that we disclosed as our critical accounting policies and estimates in our Annual Report on Form 10-K for the year ended December 31, 2005.

Stock-Based Compensation Expense

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), using the modified prospective transition method, and therefore have not restated prior periods' results. Under this method we recognize compensation expense for all stock-based payments granted after January 1, 2006, and prior to but not yet vested as of January 1, 2006, in accordance with SFAS 123(R). Under the fair value recognition provisions of SFAS 123(R), we recognize stock-based compensation net of an estimated forfeiture rate and only recognize compensation cost for those shares expected to vest on a straight-line basis over the requisite service period of the award. Prior to SFAS 123(R) adoption, we accounted for stock-based payments under APB 25 and accordingly, recognized compensation expense for options that were granted at an exercise price below their deemed fair market value and for restricted stock units granted to employees.

Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the input of various highly-subjective assumptions, including the expected life of the stock-based payment awards, our stock price volatility and the expected forfeiture rate of our options. Management determined the expected stock price volatility assumption based on a combination of the Company's historical volatility combined with the weighted average of the volatility of other similar companies in the same industry. We believe this is more reflective and a better indicator of the expected future volatility, than using an average of a comparable market index or of a comparable company in the same industry. Due to the Company's recent IPO, the expected term of options granted in the quarter ended March 31, 2006 was derived from the short-cut method described in SEC's SAB No. 107. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. See Note 1 and 2 to the Condensed Consolidated Financial Statements for a further discussion on stock-based compensation.

Recent Pronouncements

In May 2005, the Financial Accounting Standards Board, or FASB, issued SFAS 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. SFAS 154 requires retrospective application to prior period financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 also requires that retrospective application of a change in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle should be recognized in the period of the accounting change. SFAS 154 further requires a change in depreciation, amortization, or depletion method for long-lived, non-financial assets to be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The impact of adopting SFAS 154 has not had a material impact on our financial condition or results of operations.

Table of Contents

In November 2005, the FASB issued FASB Staff Position (FSP) FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments (FSP 115-1), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 is required to be applied to reporting periods beginning after December 15, 2005. The adoption of FSP 115-1 has not had a material impact on our results of operations and financial condition.

Results of Operations

The following table sets forth selected consolidated financial data for the periods indicated, expressed as a percentage of net revenue.

	Three Months Ended March 31,	
	2006	2005
Revenue mix by geography:		
Revenue from United States customers	72%	69%
Revenue from International customers	28%	31%
	100%	100%
Revenue mix by product category:		
Products	85%	83%
Product upgrades	5%	11%
Service	5%	5%
Titan refills	5%	1%
	100%	100%
Net revenue	100%	100%
Cost of revenue	28%	27%
Gross profit	72%	73%
Operating expenses:		
Sales and marketing	41%	38%
Research and development	6%	8%
General and administrative	21%	15%
Total operating expenses	68%	61%
Income from operations	3%	12%
Interest and other income, net	5%	2%
Income before income taxes	8%	14%
Provision for income taxes	3%	4%
Net income	5%	10%

Three months ended March 31, 2006 and March 31, 2005***Net Revenue***

Edgar Filing: CUTERA INC - Form 10-Q

Revenue is derived primarily from the sale of products, product upgrades, service related to our products and Titan handpiece refills. For the three months ended March 31, 2006, compared to the same period in 2005, net revenue increased by \$5.6 million, or 37%, from \$15.1 million to \$20.8 million. This was the result of a \$4.9 million, or 39%, increase in product revenue; a \$371,000, or 49%, increase in service revenue; and an \$802,000, or 565%, increase in revenue from Titan handpiece refills. These increases were partially offset by a decline in upgrade revenue, which for the three months ended March 31, 2006, when

Table of Contents

compared to the same period in 2005, decreased \$458,000 or 29%. This was primarily due to an increase in the number of customers choosing to purchase new systems from our Solera family of products instead of upgrading their existing systems.

With respect to the geographical source of the \$5.6 million increase in net revenue, \$4.5 million was attributable to higher U.S. revenue and \$1.1 million was attributable to higher international revenue. The primary contributors to this revenue growth were the continued expansion of our direct sales force, with our domestic sales force growing at a quicker pace than our international sales force.

Cost of Revenue

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the three months ended March 31, 2006, compared to the three months ended March 31, 2005, cost of revenue increased by \$1.8 million, or 45%, from \$4.0 million to \$5.8 million. Cost of revenue as a percentage of revenue, increased from 27% for the three months ended March 31, 2005, to 28% for the three months ended March 31, 2006. This increase in cost of revenue as a percentage of net revenue, was primarily attributable to higher stock-based compensation expenses resulting from the adoption of FAS 123(R).

Sales and Marketing

Sales and marketing expenses consist primarily of personnel cost, including costs associated with employee stock-based compensation effective January 1, 2006, and expenses associated with customer-attended workshops, trade shows and advertising. For the three months ended March 31, 2006, compared to the same period in 2005, sales and marketing expenses increased by \$2.7 million, or 47%, from \$5.8 million to \$8.5 million. This increase was primarily attributable to approximately \$1.4 million of higher personnel expenses associated primarily with the increased expenses relating to higher headcount; \$534,000 of higher marketing expenses attributable to increased trade show expenses; and \$350,000 of higher employee stock-based compensation expenses. As a percentage of net revenue, sales and marketing expenses increased from 38% in the three months ended March 31, 2005, to 41% in the three months ended March 31, 2006. This increase was primarily attributable to an increase in world wide direct sales headcount, increased marketing related activities and higher stock-based compensation expense. For the remainder of 2006, we estimate that sales and marketing expenses will increase in absolute dollar terms, but decrease as a percentage of revenue.

Research and Development

Research and development expenses consist primarily of personnel cost, including costs associated with employee stock-based compensation effective January 1, 2006, clinical, regulatory and material costs. For the three months ended March 31, 2006, compared to the three months ended March 31, 2005, research and development expenses increased by \$121,000, or 10%, from \$1.2 million to \$1.3 million. This increase was primarily attributable to \$162,000 of higher personnel expense, due partly to increased headcount; \$55,000 of higher stock-based compensation expense; which was offset by a decrease in outside service costs of \$81,000. As a percentage of net revenue, research and development expenses decreased from 8% in the three months ended March 31, 2005, to 6% in the three months ended March 31, 2006 due to the higher net revenue in the period ended March 31, 2006. For the remainder of 2006, we expect research and development expenses to decrease as a percentage of net revenue.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including costs associated with employee stock-based compensation effective January 1, 2006, legal and accounting fees and other general and administrative expenses. For the three months ended March 31, 2006, compared to the same period in 2005, general and administrative expenses increased by \$2.1 million, or 89%. This increase was primarily attributable to \$1.0 million of higher legal expenses, due mainly to the Palomar litigation; \$339,000 of higher accounting, tax and audit fees, due primarily to the costs of complying with the requirements of Section 404 of the Sarbanes-Oxley Act; and \$113,000 of higher stock-based compensation expense. As a percentage of net revenue, general and administrative expenses increased from 15%, for the three months ended March 31, 2005, to 21% for the three months ended March 31, 2006. As our patent litigation is set for trial on May 30, 2006 see Part II, Item 1 Legal Proceedings our general and administrative expenses for the quarter ended June 30, 2006 are expected to increase over the quarter ended March 31, 2006.

Table of Contents***Interest and Other Income, Net***

For the three months ended March 31, 2006, compared to the same period in 2005, interest and other income increased \$670,000. This increase was primarily attributable to higher tax-exempt interest income, resulting from higher yields in the three months ended March 31, 2006, compared to the three months ended March 31, 2005, and an increase in the average cash and marketable investments balance.

Provision for Income Taxes

Provision for income taxes for the three months ended March 31, 2006, compared to the same period in 2005, decreased by \$69,000. The effective tax rate for the three months ended March 31, 2006 was 34%, compared to 30% for the same period in 2005. The increase in the effective tax rate in 2006, compared to 2005, was primarily attributable to the expiration of the law relating to the granting of federal research and development credits; due to non tax-deductibility of stock-based compensation expense for ESPP and international options; and because we have fully utilized the benefit from disqualifying dispositions of incentive stock options that can reduce our effective tax rate.

Liquidity and Capital Resources***Net Cash Provided by Operating Activities***

For the three months ended March 31, 2006, net cash provided by operations was \$2.1 million. This was primarily attributable to net income of \$1.1 million; add back for non-cash stock based compensation of \$1.1 million; cash provided from tax benefits related to employee stock options exercised of \$1.0 million; and accounts payable of \$1.0 million for unpaid legal and audit related fees. This was offset by cash used for inventory of \$1.4 million to support anticipated shipments and a broader product offering in our first fiscal quarter of 2006.

For the three months ended March 31, 2005, net cash provided by operations was \$1.6 million. This was attributable primarily to net income of \$1.5 million; realization of deferred taxes for employee stock option resulting from the reduction of income taxes payable of \$553,000; add backs for the non-cash amortization of deferred stock-based compensation of \$426,000; and a reduction in accounts receivable of \$757,000 due to collections of the cyclically high revenue generated in December 2004. This was offset by cash used to increase inventories by \$989,000 for the planned ramp-up of production for the Solera tabletop products released in the fourth quarter of 2004; and a reduction in accrued liabilities of \$659,000 resulting from the settlement of the year-end accrued liabilities.

Net Cash Provided by (Used in) Investing Activities

For the three months ended March 31, 2006, we used \$6.0 million, net, for primarily purchasing tax-exempt marketable investments.

Net cash provided by investing activities was \$210,000 for the three months ended March 31, 2005, which was primarily due to net proceeds from the sale and maturities of marketable investments of \$340,000, offset by \$130,000 used to purchase property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2006, was \$ 1.6 million. This was attributable to proceeds from the issuance of stock through our stock option and employee stock purchase plans of \$556,000; and the inclusion of \$1.0 million of excess tax benefits from stock-based compensation expense, which was categorized in financing activities starting this fiscal quarter as required by SFAS 123(R). Under SFAS 123(R), the excess tax benefit from stock-based compensation recorded in the prior period before the adoption of SFAS 123(R) remain categorized in operating activities.

Net cash provided by financing activities for the three months ended March 31, 2005, was \$ 1.4 million and was attributable to proceeds from the issuance of stock through our stock option and employee stock purchase plans.

Table of Contents

As of March 31, 2006, we had cash, cash equivalents and marketable investments of \$95.5 million, which we believe are sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

As disclosed in Note 8 to the Notes to Condensed Consolidated Financial Statements – Contingencies, we are involved in patent litigation with Palomar Medical Technologies, Inc. Since the outcome of this litigation is unpredictable, and since management believes that a significant adverse result for us is not probable, no expense has been recorded with respect to the contingent liability associated with this matter. If we do not prevail in this litigation, we could be ordered to pay substantial damages, which could adversely impact the working capital available for use in future operations. We may also be required to pay substantial amounts, including ongoing royalty payments, in the event that the parties enter into a settlement agreement. See Part II, Item 1A – Risk Factors – relating to this litigation. Our expense projections for the quarter ended June 30, 2006 include significant spending on this continued litigation as the matter approaches trial on May 30, 2006.

Contractual Cash Obligations

The following table discloses aggregate information about our contractual obligations for minimum lease payments related to facility leases, net of sub-lease income in 2006, and the periods in which these payments are due as of March 31, 2006.

Contractual Obligations	Total	Payments Due by Period (\$ 000 s)			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases	\$8,744	\$880	\$1,696	\$2,218	\$3,950

Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of March 31, 2006, and December 31, 2005, we were not involved in any unconsolidated transactions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies, municipal bonds and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity (interest reset date for auction-rate securities and variable rate demand notes) of generally less than eighteen months. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of March 31, 2006 would have potentially declined by \$363,000.

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 partly due to our sales and operating expenses being predominantly denominated in foreign currencies and we do not maintain significant foreign currency cash balances. We cannot assure 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.

Table of Contents

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management evaluated, with the participation of the Chief Executive Officer and the Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Inherent Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within us have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting. There was no change in our internal control over financial reporting that occurred during our first fiscal quarter of fiscal 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In February 2002, Palomar Medical Technologies filed a lawsuit against us in the United States District Court, District of Massachusetts. A trial date has been set for May 30, 2006. The plaintiff alleges that by making, using, selling or offering for sale our CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, we are willfully and deliberately infringing U.S. Patent No. 5,735,844. This patent concerns a method and apparatus for removing hair with light energy. Massachusetts General Hospital later joined the lawsuit as an additional plaintiff, since Palomar is the exclusive licensee, and MGH is the owner, of the patent at issue in the lawsuit. Palomar and MGH are seeking to enjoin us from selling products found to infringe the patent, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. We are defending the action vigorously, asserting that our products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, we have filed a counterclaim alleging that the patent should be declared unenforceable because of inadequate disclosures made to the U.S. Patent and Trademark Office by the plaintiffs during that patent's prosecution with the U.S. Patent and Trademark Office. This matter is set for trial on May 30, 2006.

In April 2005, the plaintiffs filed a second lawsuit in this same court, alleging that by making, using, selling or offering for sale products that utilize pulsed-light technology for hair removal, we are willfully and

Table of Contents

deliberately infringing U.S. Patent Nos. 5,735,844 and 5,595,568. The plaintiffs are seeking to enjoin us from selling our products found to infringe those patents, and to obtain compensatory and treble damages, reasonable costs and attorney's fees, and other relief as the court deems just and proper. We have responded by filing a motion to dismiss this second lawsuit on the grounds of lack of jurisdiction, and by filing complaints for declaratory relief against these plaintiffs in California and Delaware. On May 5, 2006, the court in Massachusetts denied that motion, likely subjecting the subject matter of that second lawsuit to the jurisdiction of that court.

We believe that we have meritorious defenses of non-infringement and invalidity in these actions. However, litigation is unpredictable and we may not prevail in successfully defending or asserting our position. If we do not prevail, we may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. We could also be ordered to stop selling any products that perform hair removal. We may also be required to pay substantial amounts, including ongoing royalty payments, in the event that the parties enter into a settlement agreement. Most of our products include an application for hair removal.

ITEM 1A. RISK FACTORS

Unfavorable results in our intellectual property litigation with Palomar Medical Technologies may result in significant decline to our stock price.

Since February 2002, we have been involved in litigation with one of our public company competitors, Palomar Medical Technologies, which alleges that the manufacture, use and sale of our products for laser hair removal infringe a certain United States patent. Public announcements concerning this litigation that are unfavorable to us have in the past resulted, and may in the future result, in significant declines in our stock price. For example, on December 13, 2005, the date of the public announcement of the denial of our motion for summary judgment, our stock price declined 34.4%. The parties are now preparing for trial, which is expected to start on May 30, 2006. An adverse ruling or judgment in this matter could cause our stock price to decline. Additionally, if the parties settle the litigation, we may be required to pay substantial amounts, including ongoing royalty payment, which could have a material adverse impact on our operating results and could cause our stock price to decline.

Even if we prevail in this litigation, we do not believe that will end the dispute with Palomar. It is likely that the party who loses at the trial court level will file an appeal. Additionally, in 2005, we became involved in a second litigation against Palomar concerning our products that use pulsed light technology for hair removal, and whether these products infringe two United States patents. Consequently, even following a favorable determination in the litigation set for trial, we expect our stock to be subject to volatility from the Palomar dispute.

Our intellectual property litigation with Palomar is costly and may prevent us from selling many of our products and generating anticipated revenue.

If we do not prevail in our action against Palomar, we may be ordered to pay substantial damages for past sales (including compensatory and treble damages) and an ongoing royalty for future sales of products found to infringe. We could also be ordered to stop selling any products that are found to infringe. Most of our products include an application for laser-based hair removal, the alleged infringing application. If found liable, we do not know whether we could redesign our products to avoid future infringement with respect to this application. Consequently, we could have to remove the infringing application. Alternatively, we could seek a license to the technology from Palomar, but they have indicated publicly that they will not give us a license.

Litigation with Palomar 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 or judgment. Whether or not we are successful in the pending lawsuits, litigation consumes substantial amounts of or financial resources and diverts management's attention away from our core business. See Item 1 Legal Proceedings. Similar to our quarter ended March 31, 2006, we believe the cost of the Palomar litigation will be substantial in our second quarter ended June 30, 2006 as the matter approaches and enters the trial stage on May 30, 2006.

Table of Contents

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

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

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

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

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and products. At March 31, 2006, we had six issued U.S. patents, some 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, Palomar, and Syneron as well as private companies such as Reliant Technologies and Thermage. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. We also face competition from medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include sclerotherapy, a procedure

Table of Contents

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:

intellectual property protection;

product performance;

product pricing;

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 perform a variety of applications, may diminish over time, as companies successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue will decline as our customers purchase our competitors' products.

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

Table of Contents

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

develop or acquire new products that either add to or significantly improve our current products;

convince our target customers that our new products or product upgrades would be an attractive revenue-generating addition to their practices;

sell our products to non-traditional customers;

identify new markets and alternative applications for our technology;

protect our existing and future products with defensible intellectual property; and

satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, we have introduced at least one new product and a corresponding upgrade to our existing products. Historically, these introductions have been a significant component of our financial performance. Our business strategy is based, in part, on our expectation that we will continue to make annual product introductions that we can sell to new customers and to existing customers as upgrades. In the future, we plan to invest between 6-7% of net revenue in our research and development department. Even with a significant investment in research and development, we may be unable, however, to continue to develop new products and technologies annually, or at all, which could adversely affect our projected growth rate.

If our public guidance or our future operating performance does not meet investor expectations, our stock price could decline.

We provide guidance to the investing community regarding our anticipated future operating performance, both for the coming quarter and fiscal year-end. Our business typically has a short sales cycle, we do not have significant backlog of orders at the start of a quarter, and our ability to sell our products successfully is subject to many uncertainties, as discussed herein. In light of those factors, it is difficult for us to estimate with accuracy our future results. In the past, our actual performance had turned out to be significantly different from our prior guidance. For example, at the beginning of 2005, we indicated that we expected our 2005 revenue to increase by 25% over 2004. Actual 2005 growth was higher, at 44% over 2004. Earlier this year, we stated publicly that we expected our revenue to grow 25% in 2006, compared to 2005 and we have since increased that guidance to 30%. As we stated at the time, such expectations are subject to numerous risks and uncertainties which could make actual results differ materially, either higher or lower. If our actual results do not meet our public guidance, or our results or guidance as to the future were to be below the expectations of third party financial analysts, our stock price could decline significantly.

If we fail to obtain clearance from the U.S. Food and Drug Administration to market our Titan product for additional indications, our revenue from this product may be adversely affected.

Our Titan product, introduced in 2004, is a material component of our growth strategy. We currently have FDA clearance to market Titan in the United States for deep dermal heating. The FDA has denied our initial 510(k) application to market Titan for wrinkle reduction on the basis that Titan is not substantially equivalent to predicate devices for the treatment of wrinkles. We are continuing to seek a clearance from the FDA to market Titan for additional indications, but there are no assurances as to when, or whether, we will ever obtain such a clearance. We cannot promote or advertise our Titan product in the United States for any indications other than deep dermal heating until we receive additional FDA clearances. In the event that we do not obtain additional FDA clearances, our ability to market Titan in the United States and

Table of Contents

revenue derived therefrom, including revenue from both Titan unit sales and handpiece refills, may be adversely affected.

If we fail to obtain or maintain necessary FDA 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 FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or labeling claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. In the event that we do not obtain additional FDA clearances, our ability to market future products or applications in the United States and revenue derived therefrom may be adversely affected.

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

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

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;

withdrawing 510(k) clearance or pre-market approvals that have already been granted; and

criminal prosecution.

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

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

Table of Contents

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.

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

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

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, which could have a material adverse effect on our business and growth strategy.

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

For the three months ended March 31, 2006, approximately 28% of our revenue was derived from international customers, which are a material component of our growth strategy. We depend on third-party distributors and a relatively new direct sales operation to sell our products internationally, and if these distributors or direct sales personnel under-perform, we may be unable to increase or maintain our level of international revenue. We will need to attract additional international distributors to grow our business and expand the territories in which we sell our products. Distributors may not accept our business or 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 engage distributors in particular geographic areas, we may not realize projected international revenue growth. Additionally, we expect to expand our direct sales force in Europe and Asia. If we are unable to hire, retain and obtain satisfactory performance from such additional personnel, our revenue from international operations may be adversely affected.

Table of Contents

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

difficulties in staffing and managing our foreign operations;

difficulties in penetrating markets in which our competitors' products are more established;

reduced protection for intellectual property rights in some countries;

export restrictions, trade regulations and foreign tax laws;

fluctuating foreign currency exchange rates;

foreign certification and regulatory requirements;

lengthy payment cycles and difficulty in collecting accounts receivable;

customs clearance and shipping delays;

political and economic instability;

lack of awareness of our brand in international markets; 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 of or 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.

Edgar Filing: CUTERA INC - Form 10-Q

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,

Table of Contents

and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

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, thereby 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.

Table of Contents

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

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

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

loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

increased cost of our warranty program due to product repair or replacement;

inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal action.

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

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

We keep limited materials and components on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to nine months in advance and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand. If we overestimate our component and material requirements, we will have excess inventory, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of our products to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

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

Continued expansion of the global market for laser- and other light-based aesthetic procedures is a material assumption of our growth strategy. Most procedures performed using our products are elective procedures not reimbursable through government or private health insurance, with the costs 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;

Table of Contents

the cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser- or other light-based technologies and treatments which use pharmaceutical products;

the success of our sales and marketing efforts; and

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

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

Lack of demand for our products in the medi-spa market would harm our anticipated revenue growth.

An increasing portion of our revenue is derived from sales to customers in the medi-spa market, which is comprised of physicians offering aesthetic treatments in a spa environment. Achieving further penetration into this new market is a material assumption of our growth strategy. Demand for our products in the medi-spa market could be weakened by factors including poor financial performance of medi-spa businesses, reduced patient demand for aesthetic treatments in a spa environment, price sensitivity of medi-spa patients and demand for alternative treatments and services in the medi-spa setting. If we do not achieve anticipated demand for our products in the medi-spa market, our expected revenue growth may not be achieved.

If PSS World Medical fails to perform to our expectations, we may fail to achieve anticipated operating results.

We have a distribution agreement with PSS World Medical, which operates medical supply distribution service centers with approximately 700 sales representatives serving physician offices in all 50 states of the United States. PSS World Medical sales representatives work in coordination with our sales force to locate new potential customers for our products. For the year ended December 31, 2005, approximately 16% of our revenue was from PSS.

If PSS World Medical does not perform adequately under the arrangement, or terminates our relationship, which it can do at any time upon 90 days notice, it may have a material adverse effect on our business, financial condition, results of operations or future cash flows.

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

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

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

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

Table of Contents

With effect from January 1, 2006, we, like other companies, have adopted SFAS 123(R) that requires us to measure and record stock-based compensation expense using the fair value method, which adversely affects our results of operations by increasing our cost by the amount of such stock-based compensation charges. In the year ending December 31, 2006, we estimate that the adoption of FAS 123(R) will increase our cost of goods sold and operating expenses by approximately \$4.5 million. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of valuation assumptions and the related tax effect.

Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the input of highly subjective assumptions, including the expected life of the stock-based payment awards, our stock price volatility and the expected forfeiture rate of our options. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period.

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

Beginning with the annual report for our fiscal year ended on December 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 required us to include a report by our management on our internal control over financial reporting. Such report contained an assessment by management of the effectiveness of our internal control over financial reporting as of the end of our fiscal year and a statement as to whether or not such internal control is effective. Also included in our Annual Report on Form 10-K was an opinion by our Independent Registered Public Accounting Firm of management's assessment of such internal control.

Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, the commitment of time and operational resources and the diversion of management's attention. Though management did not identify any material weaknesses in our internal control over financial reporting during the year ended December 31, 2005, if we are unable to assert that our internal control over financial reporting is effective as of our fiscal year end in 2006 and future years, our business may be harmed.

Our effective income tax rate may vary significantly.

Unanticipated changes in our tax rates could affect our future results of operations. Our future effective tax rates could be unfavorably affected by changes in tax laws or the interpretation of tax laws, by unanticipated decreases in the amount of revenue or earnings in countries with low statutory tax rates, by changes in the valuation of our deferred tax assets and liabilities, future levels of research & development spending, deductions for employee stock option exercises being different to what we projected, and changes in overall levels of income before taxes.

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.

Table of Contents

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

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

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

a classified board of directors;

advance notice requirements to stockholders for matters to be brought at stockholder meetings;

a supermajority stockholder vote requirement for amending certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws;

limitations on stockholder actions by written consent; and

the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

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

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

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

Item 6. Exhibits

Exhibit No.	Description
3.2 ⁽¹⁾	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 ⁽¹⁾	Bylaws of the Registrant.
4.1 ⁽²⁾	Specimen Common Stock certificate of the Registrant.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Edgar Filing: CUTERA INC - Form 10-Q

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

- (1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.
- (2) Incorporated by reference from our Annual Report on Form 10-K filed with the SEC on March 25, 2005.

Table of Contents

SIGNATURE

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

CUTERA, INC.

/s/ Ronald J. Santilli
Ronald J. Santilli

Chief Financial Officer

(Principal Financial Officer and

Authorized Signatory)

Date: May 10, 2006