

CUTERA INC
Form 10-Q
August 06, 2007
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 June 30, 2007

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)

77-0492262
(I.R.S. employer

identification no.)

Edgar Filing: CUTERA INC - Form 10-Q

(415) 657-5500

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is 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 July 31, 2007 was 13,323,118.

Table of Contents

CUTERA, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
PART I	
<u>FINANCIAL INFORMATION</u>	
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>	10
Item 3.	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	15
Item 4.	
<u>Controls and Procedures</u>	15
PART II	
<u>OTHER INFORMATION</u>	
Item 1.	
<u>Legal Proceedings</u>	15
Item 1A.	
<u>Risk Factors</u>	16
Item 2(c).	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 6.	
<u>Exhibits</u>	23
<u>Signatures</u>	24

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

	June 30,	December 31,
	2007	2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,411	\$ 11,800
Marketable investments	105,004	96,285
Accounts receivable, net	9,254	9,601
Inventories	6,717	5,220
Deferred tax asset	5,689	5,792
Other current assets	2,815	2,702
Total current assets	139,890	131,400
Property and equipment, net	1,471	1,029
Intangibles, net	1,328	1,446
Deferred tax asset, net of current portion	357	
Total assets	\$ 143,046	\$ 133,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,927	\$ 2,212
Accrued liabilities	13,191	13,675
Deferred revenue	4,167	3,514
Total current liabilities	19,285	19,401
Deferred rent	1,531	1,424
Deferred revenue, net of current portion	3,789	3,258
Income tax liability	988	60
Total liabilities	25,593	24,143
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock	14	13
Additional paid-in capital	90,036	86,242
Deferred stock-based compensation	(62)	(331)
Retained earnings	27,564	23,866
Accumulated other comprehensive loss	(99)	(58)

Edgar Filing: CUTERA INC - Form 10-Q

Total stockholders' equity	117,453	109,732
Total liabilities and stockholders' equity	\$ 143,046	\$ 133,875

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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Net revenue	\$ 23,873	\$ 24,395	\$ 47,130	\$ 45,152
Cost of revenue	7,910	7,768	15,691	13,579
Gross margin	15,963	16,627	31,439	31,573
Operating expenses:				
Sales and marketing	9,190	8,305	18,253	16,851
Research and development	1,923	1,552	3,671	2,859
General and administrative	2,900	4,248	5,918	8,623
Litigation settlement		18,391		18,391
Total operating expenses	14,013	32,496	27,842	46,724
Income (loss) from operations	1,950	(15,869)	3,597	(15,151)
Interest and other income, net	1,108	830	2,110	1,786
Income (loss) before income taxes	3,058	(15,039)	5,707	(13,365)
Provision (benefit) for income taxes	1,024	(5,990)	1,918	(5,423)
Net income (loss)	\$ 2,034	\$ (9,049)	\$ 3,789	\$ (7,942)
Net income (loss) per share:				
Basic	\$ 0.15	\$ (0.73)	\$ 0.28	\$ (0.64)
Diluted	\$ 0.14	\$ (0.73)	\$ 0.26	\$ (0.64)
Weighted-average number of shares used in per share calculations:				
Basic	13,610	12,444	13,413	12,352
Diluted	14,666	12,444	14,655	12,352

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)**

	Six Months Ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net income (loss)	\$ 3,789	\$ (7,942)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	454	413
Change in allowance for doubtful accounts	(31)	(4)
Provision for excess and obsolete inventories	184	32
Change in deferred tax asset	184	(4,584)
Stock-based compensation	2,788	1,997
Tax benefit from employee stock options	1,497	
Excess tax benefit related to stock-based compensation expense	(833)	
Changes in assets and liabilities:		
Accounts receivable	378	831
Inventories	(1,681)	(1,236)
Other current assets	(113)	(1,933)
Accounts payable	(285)	(36)
Accrued liabilities	(807)	1,279
Deferred rent	107	164
Deferred revenue	1,184	1,238
Income tax liability	(56)	
Net cash provided by (used in) operating activities	6,759	(9,781)
Cash flows from investing activities:		
Acquisition of property and equipment	(758)	(251)
Acquisition of intangibles	(20)	(1,170)
Proceeds from sales of marketable investments	18,669	11,460
Proceeds from maturities of marketable investments	17,253	47,405
Purchase of marketable investments, net	(44,682)	(52,210)
Net cash provided by (used in) investing activities	(9,538)	5,234
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	3,073	1,210
Repurchase of common stock	(2,516)	
Excess tax benefit related to stock-based compensation expense	833	
Net cash provided by financing activities	1,390	1,210
Net decrease in cash and cash equivalents	(1,389)	(3,337)
Cash and cash equivalents at beginning of period	11,800	5,260
Cash and cash equivalents at end of period	\$ 10,411	\$ 1,923

Edgar Filing: CUTERA INC - Form 10-Q

Non-cash disclosure of cash flow information:

Change in deferred stock-based compensation, net of terminations	\$ (8)	\$ (1,255)
--	--------	------------

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. Summary of Significant Accounting Policies

Description of Operations

Cutera, Inc., or Cutera or the Company, is a Delaware corporation headquartered in Brisbane, California. The Company is a medical device company specializing in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetic systems for practitioners worldwide. The Company offers easy-to-use products on three platforms - CoolGlide, Xeo and Solera - which enable dermatologists, plastic surgeons, gynecologists, primary care physicians, and other qualified practitioners to offer safe, effective and non- and minimally-invasive aesthetic treatments to their customers. The Company has wholly-owned subsidiaries in Australia, Canada, France, Germany, Japan, Spain, Switzerland and United Kingdom. The purpose of these subsidiaries is to market, sell and service the Company's products outside of the United States.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Unaudited Interim Financial Information

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, 2006 Condensed Consolidated Balance Sheet was derived from audited financial statements, but does not include all disclosures 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, 2006 filed with the Securities and Exchange Commission, or SEC, on March 16, 2007.

Use of Estimates

The preparation of the interim Condensed Consolidated Financial Statements in conformity with accounting principles generally accepted in the United States requires the Company's management to make estimates and assumptions that affect the amounts reported and disclosed in the financial statements and the accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, the Company evaluates their estimates, including those related to the accounts receivable and sales allowances, fair values of marketable investments, fair values of acquired intangible assets, useful lives of intangible assets and property and equipment, fair values of options to purchase the Company's common stock, recoverability of deferred tax assets, and effective income tax rates, among others. Management bases their estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

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, 2006 and have not changed significantly as of June 30, 2007, except for the following:

Accounting for Income Taxes

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement of Financial Accounting Standards, or SFAS, No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attributes for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and

Edgar Filing: CUTERA INC - Form 10-Q

transition. The Company adopted the provisions of FIN 48 effective January 1, 2007. Refer to Note 7 for further details of the impact of adoption.

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment of FASB Statement No. 115. This Statement permits an entity to choose to measure financial instruments and certain other items similar to financial instruments at fair value. All subsequent changes in fair value for the financial instrument would be reported in earnings. By electing the fair value option, an entity can also achieve consistent accounting for related assets and liabilities without having to apply complex hedge accounting. This Statement is effective January 1, 2008. The Company is currently evaluating the impact of adopting this standard on the consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS 157 in the quarter ended March 31, 2008. The Company is currently assessing the impact that SFAS 157 may have on its consolidated financial position, results of operations and cash flows.

Note 2. Balance Sheet Details

Cash, Cash Equivalents and Marketable Investments:

The Company considers all highly liquid investments, with an original maturity of three months or less at the time of purchase, to be cash equivalents. Investments in debt securities are accounted for as *available-for-sale* securities, carried at fair value with unrealized gains and losses reported in other comprehensive income, held for use in current operations and classified in current assets as *Marketable Investments*.

Table of Contents

The following is a summary of cash, cash equivalents and marketable investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Market Value
June 30, 2007 (in thousands)				
Cash and cash equivalents	\$ 10,411	\$	\$	\$ 10,411
Marketable investments	105,103		(99)	105,004
	\$ 115,514	\$	\$ (99)	\$ 115,415

	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Market Value
December 31, 2006 (in thousands)				
Cash and cash equivalents	\$ 11,800	\$	\$	\$ 11,800
Marketable investments	96,343		(58)	96,285
	\$ 108,143	\$	\$ (58)	\$ 108,085

Inventories:

Inventories consist of the following (in thousands):

	June 30, 2007	December 31, 2006
Raw materials	\$ 3,732	\$ 2,816
Finished goods	2,985	2,404
	\$ 6,717	\$ 5,220

Intangible Assets:

Intangible assets are principally comprised of a technology sublicense acquired in 2002; a patent sublicense acquired in 2006; and other intangibles. The components of intangible assets were as follows (in thousands):

	Gross Carrying Amount	June 30, 2007 Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 173	\$ 1,045
Technology sublicense	538	274	264
Other intangibles	185	166	19
Total	\$ 1,941	\$ 613	\$ 1,328

	Gross Carrying Amount	December 31, 2006 Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 104	\$ 1,114

Edgar Filing: CUTERA INC - Form 10-Q

Technology sublicense	538	247	291
Other intangibles	165	124	41
 Total	 \$ 1,921	 \$ 475	 \$ 1,446

For the six months ended June 30, 2007 and 2006, amortization expense for intangible assets was \$138,000 and \$103,000, respectively.

Based on intangible assets recorded at June 30, 2007, and assuming no subsequent additions to, or impairment of the underlying assets, the remaining estimated annual amortization expense is expected to be as follows (in thousands):

Fiscal year ending December 31:

2007 remainder	\$ 101
2008	202
2009	196
2010	192
2011	192
Thereafter	445
 Total	 \$ 1,328

Note 3. 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 June 30, 2007 and 2006, were as follows (in thousands):

	June 30, 2007	June 30, 2006
Balance at December 31, 2006 and 2005	\$ 6,652	\$ 3,117
Add: Payments received	4,012	2,948
Less: Revenue recognized	(2,821)	(1,702)
 Balance at June 30, 2007 and 2006	 \$ 7,843	 \$ 4,363

Costs incurred under service contracts during the three months ended June 30, 2007 and 2006 amounted to \$566,000 and \$449,000, respectively. For the six months ended June 30, 2007 and 2006, costs incurred under service contracts amounted to \$1,030,000 and \$851,000, respectively. All service contract costs are recognized as incurred.

Table of Contents**Note 4. Stock Repurchase Program and Stock-based Compensation****Stock Repurchase Program**

On May 15, 2007, the Company's Board of Directors approved a stock repurchase program under which the Company is authorized to use up to \$25 million to repurchase shares of its common stock. The Company entered into a pre-arranged Rule 10b5-1 trading plan with a broker to facilitate the repurchase of its shares. Acquisitions are made in accordance with the trading plan, at prevailing prices, subject to market conditions and other factors. Purchases under the trading plan may be modified at any time by giving the broker sixty days' notice. This repurchase program shall terminate at the earliest of: (i) the Company acquiring \$25 million worth of shares of its common stock, or (ii) May 15, 2008. The stock repurchased under the plan will be cancelled and returned to authorized share status.

During the quarter ended June 30, 2007, the Company used \$3.0 million to purchase 123,800 shares of its common stock at an average price of \$24.36. As of June 30, 2007, share repurchase transactions for \$500,000 had not been paid for as the trades had not yet settled.

Stock-based Compensation Expenses

The pre-tax stock-based compensation expense recognized during the three and six months ended June 30, 2007 and 2006 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Cost of sales	\$ 217	\$ 171	\$ 449	\$ 342
Sales and marketing	401	276	848	677
Research and development	156	201	363	360
General and administrative	671	263	1,128	618
Total stock-based compensation expense	\$ 1,445	\$ 911	\$ 2,788	\$ 1,997

Note 5. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is calculated by using the weighted-average number of common shares outstanding during the period increased to include 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 outstanding options, Employee Stock Purchase Plan, or ESPP, shares and restricted stock units is reflected in diluted net income (loss) per share by application of the treasury stock method, which includes consideration of stock-based compensation required by Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment (revised 2004)*, or SFAS 123(R), and SFAS No. 128, *Earnings 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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Numerator:				
Net income (loss) available to common stockholders - Basic and Diluted	\$ 2,034	\$ (9,049)	\$ 3,789	\$ (7,942)
Denominator:				
Weighted-average number of common shares outstanding used in computing basic net income (loss) per share	13,610	12,444	13,413	12,352

Edgar Filing: CUTERA INC - Form 10-Q

Dilutive potential common shares used in computing diluted net income (loss) per share	1,056		1,242	
Total weighted-average number of shares used in computing diluted net income (loss) per share	14,666	12,444	14,655	12,352

Anti-dilutive securities

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Options to purchase common stock	625	3,192	591	3,205
Restricted stock units		64		67

Table of Contents**Note 6. Comprehensive Income (Loss)**

Comprehensive income (loss) 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 (loss) that is excluded from net income (loss). The changes in components of other comprehensive income (loss) for the periods presented are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Net income (loss)	\$ 2,034	\$ (9,049)	\$ 3,789	\$ (7,942)
Unrealized loss on marketable investments	(54)	(1)	(41)	(39)
Comprehensive income (loss)	\$ 1,980	\$ (9,050)	\$ 3,748	\$ (7,981)

Note 7. Income Taxes

The interim effective income tax rate is based on management's best estimate of the annual effective income tax rate. The effective tax rates for the three and six months ended June 30, 2007 were 33% and 34%, respectively, and for the three and six months ended June 30, 2006 were 40% and 41%, respectively. These rates reflect applicable United States federal and state tax rates and the tax impact of foreign operations, offset primarily by research and development tax credits and tax exempt interest income. The higher effective tax rate for the three and six months ended June 30, 2006, compared with the same periods in 2007, was primarily attributable to the impact of the \$18.4 million litigation settlement expense that was included at the marginal rate of 39.75%; to the expiration of federal research and development tax credits; and the reduction of the section 199 deduction and Extraterritorial Income exclusion as a result of the net loss before income taxes that resulted from the inclusion of the \$18.4 million litigation settlement expense.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$1,799,000 and \$752,000 at June 30, 2007 and 2006, 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.

Impact of Adoption of FIN 48

The Company implemented the provisions of FIN 48 as of January 1, 2007 and recorded the cumulative effect of applying the provisions of the Interpretation as an adjustment to the Company's retained earnings balance as of January 1, 2007. The total amount of unrecognized tax benefits as of the date of adoption was approximately \$943,000. The Company reduced its January 1, 2007 retained earnings by approximately \$91,000.

Included in the balance of unrecognized tax benefits at January 1, 2007 were approximately \$542,000 of tax benefits that, if recognized, would affect the effective tax rate; and approximately \$401,000 of tax benefits that, if recognized, would result in an adjustment to deferred tax assets.

Accrued interest and penalties relating to the income tax on the unrecognized tax benefits as of June 30, 2007 and January 1, 2007 were approximately \$110,000 and \$93,000, respectively, with approximately \$17,000 being included as a component of provision for income taxes in the six months ended June 30, 2007.

In general, the Company's income tax returns are subject to examination by U.S. federal, state and foreign tax authorities for tax years 2002 forward. The Company does not expect that the amounts of unrecognized tax benefits will change significantly within the next 12 months.

Note 8. Commitments and Contingencies**Litigation**

Two securities class action lawsuits were filed against the Company and two of its executive officers in April 2007 and May 2007, respectively, in the U.S. District Court for the Northern District of California following declines in the Company's stock price. The plaintiffs claim to represent

Edgar Filing: CUTERA INC - Form 10-Q

purchasers of the Company's common stock from January 31, 2007 through May 7, 2007. The complaints generally allege that materially false statements and omissions were made regarding the Company's financial prospects, and seek unspecified monetary damages. The Company intends to defend these cases vigorously. Since the outcome of the litigation is unpredictable, and since the Company believes that a significant adverse result is not probable, no expense has been recorded with respect to the contingent liability associated with these matters. The Company retains director and officer liability insurance but there is no assurance that such insurance will cover the claims that are made or will insure the Company fully for all losses on covered claims.

Other Legal Matters

In addition to the foregoing lawsuits, the Company is named from time to time as a party to product liability and contractual lawsuits in the normal course of its business. As of June 30, 2007, the Company is not a party to any material pending litigation.

Facility Leases

The Company leases its office and manufacturing facility in Brisbane, California, and also leases offices in Japan, Switzerland and France under operating leases. These leases qualify for operating lease accounting treatment under SFAS No. 13, Accounting for Leases, and, as such, these facilities are not included on its Condensed Consolidated Balance Sheets.

The following is a schedule of operating leases payments (in thousands):

Fiscal Year Ending December 31,	
2007 remainder	\$ 546
2008	1,039
2009	1,076
2010	1,154
2011	1,307
Thereafter	2,970
Future minimum rental payments	\$ 8,092

Table of Contents**Warranty Obligations.**

The Company provides standard one to two year warranty coverage on its systems. Warranty coverage is for labor and parts necessary to repair the systems during the warranty period. The Company accounts for the estimated warranty cost as a charge to cost of revenue, when revenue is recognized. The estimated warranty cost is based on historical product performance and expenses to repair systems. Utilizing actual service records, the Company calculates the average service labor, overhead and parts expense per system and applies those averages to the actual units exposed to future warranty claims. The Company updates these estimates on a quarterly basis.

The following table provides the changes in the product warranty accrual for the six months ended June 30, 2007 and 2006 (in thousands):

	June 30, 2007	June 30, 2006
Balance at December 31, 2006 and 2005	\$ 3,055	\$ 2,043
Accruals for warranties issued during the period	2,361	2,694
Settlements made during the period	(2,676)	(2,096)
Balance at June 30, 2007 and 2006	\$ 2,740	\$ 2,641

Purchase Commitments.

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments were not material at June 30, 2007.

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, 2006 as contained in our annual report on Form 10-K filed with the SEC on March 16, 2007. 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 future financial performance, the planned expansion of and improvements in our sales force, distribution networks and customer base, the success of new product launches, future capital expenditures and requirements and the impact of exchange rate volatility. 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 16, 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 and expectations 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

The Management's Discussion and Analysis, or 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.

Edgar Filing: CUTERA INC - Form 10-Q

Critical accounting policies and estimates. This section describes the key accounting policies that are affected by critical accounting estimates.

Recent accounting pronouncements. This section describes the issuance and effect of new 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 Statements 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 June 30, 2007.

Executive Summary

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

Our corporate headquarters and U.S. operations are located in Brisbane, California, from where we conduct our manufacturing, warehousing, research, regulatory, sales, service, marketing and administrative activities. In the United States, we market, sell and service our products primarily through direct sales and service employees and through a distribution relationship with PSS World Medical Shared Services, Inc., a wholly owned subsidiary of PSS World Medical, or PSS, which has over 700 sales representatives serving physician offices throughout the United States. In addition, we also sell certain items, like Titan handpiece refills and marketing brochures, via the web.

International sales are generally made through a direct sales force and through independent sales representatives and distributors in over 30 countries. Outside the United States, we have a direct sales presence in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom.

Products. Our revenue is derived from the sale of products, product upgrades, service and Titan handpiece refills. Product revenue represents the sale of a system console that includes a universal graphic user interface, a laser and/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 to their system 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 prepaid service 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, which includes the replacement of the optical source after a set number of pulses has been performed.

Table of Contents

Significant Business Trends. We believe that our 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 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 dermatology and plastic surgeon specialties.

Generating service-, upgrade-, and Titan handpiece refill revenue from our growing installed base of customers.

During the six months ended June 30, 2007, compared to the same period in 2006, our total revenue increased by 4%, our U.S. revenue decreased by 1% and our international revenue increased by 17%. During the three months ended June 30, 2007, compared to the same period in 2006, our total revenue decreased by 2%, our U.S. revenue decreased by 8% and our international revenue increased by 10%. The decrease in U.S. revenue growth rates for the three and six months ended June 30, 2007, compared to the same periods in 2006, was primarily attributable to U.S. sales-productivity issues. The increase in the international revenue growth rate was primarily attributable to continuing investments we have been making toward building our international sales channels. These efforts have resulted in increased revenue from Australia, Canada, Japan and with our international-distributor network.

In the second quarter ended June 30, 2007, we started shipping a new product called Pearl. Pearl represents the first application of the 2790 nm wavelength for cosmetic dermatology, and is designed to provide a more-pronounced clinical outcome than non-invasive light-based treatments, with minimal patient downtime. Primarily due to upgrades to our multi-application Xeo systems and upgrades for our new Pearl product, our product upgrade revenue increased by 84% in the second quarter ended June 30, 2007, compared to the same period in 2006. We anticipate that, during the second half of 2007, many of our customers will upgrade their existing systems with Pearl, and many new customers will acquire Pearl as part of their purchase of multi-application Xeo systems. Partially due to this reason, and due to the continuing expansion of our sales force, we expect our upgrade and total revenue to increase during the second half of 2007.

For the six months ended June 30, 2007, our gross margin declined to 67%, compared to 70% in the same period of 2006. This percentage decrease was primarily attributable to \$963,000, or 2% of revenue, of higher patent royalty expense in the six months ended June 30, 2007, compared to the same period in 2006. We settled our patent litigation in the second quarter of 2006, and as a result, the first quarter of 2006 did not include patent royalty expense. The reduction in margin was also partially attributable to \$2.0 million of lower revenue in the six months ended June 30, 2007, compared to the same period in 2006, which resulted in reduced contributions to increased manufacturing and service costs. Given that our royalty expense will continue in the future, and that we expect our revenue to increase in the second half of 2007, we expect our gross margin to improve to approximately 68% to 70% of revenue in the second half of 2007.

General and administrative expenses for the six months ended June 30, 2007, compared to the same period in 2006, decreased by \$2.7 million or 31%. This decrease was primarily attributable to \$3.5 million of reduced legal expenses due to the patent litigation settlement in the second quarter of 2006. This reduction in expenses was partially offset by an increase in stock-based compensation expenses by \$510,000. In April and May 2007, two securities class action lawsuits were filed against us, respectively- see Part II, Item 1 Legal Proceedings. However, given that we retain director and officer liability insurance with a deductible, we expect the impact from this litigation to not be material for the remainder of 2007. As a percentage of total revenue, general and administrative expenses for the six months ended June 30, 2007 were at 12%. In the second half of 2007, we expect our general and administrative expenses to remain in the range of \$3.0 million to \$3.5 million per quarter.

Factors that May Impact Future Performance

Our industry is impacted by numerous competitive, regulatory and other significant factors. Our industry is highly competitive and our success depends on our ability to compete successfully. Additionally, the growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances 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. If we fail to compete effectively, fail to continue to develop new products and technologies, fail to obtain regulatory clearances, fail to protect our intellectual property, fail to produce our products cost effectively, or fail to market and distribute our products in a profitable manner, our

business could suffer. A detailed discussion of these and other factors that could impact our future performance are provided in Part II, Item 1A Risk Factors section.

Critical Accounting Policies and Estimates

The accounting policies that we consider to be critical, subjective, or requiring complex judgments 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, 2006 filed with the SEC on March 16, 2007. Other than the adoption of FIN 48, there have been no significant changes during the six months ended June 30, 2007 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, 2006.

Income Taxes We operate in multiple taxing jurisdictions, both within the United States and outside the United States. We have filed tax returns with positions that may be challenged by the tax authorities. These positions relate to, among others, deductibility of certain expenses, transfer pricing, expenses included in our research and development tax credit computations, as well as other matters. Although the outcome of tax audits is uncertain, in management's opinion, adequate provisions for income taxes have been made for potential liabilities resulting from such matters. We regularly assess the tax positions for such matters and include reserves for those differences in position. The reserves are utilized or reversed once the statute of limitations has expired and/or at the conclusion of the tax examination. We believe that the ultimate outcome of these matters will not have a material impact on our financial position, financial operations or liquidity. Effective January 1, 2007, we adopted FIN 48 (refer to Note 7).

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115. This Statement permits an entity to choose to measure financial instruments and certain other items similar to financial instruments at fair value. All subsequent changes in fair value for the financial instrument would be reported in earnings. By electing the fair value option, an entity can also achieve consistent accounting for related assets and liabilities without having to apply complex hedge accounting. This Statement is effective January 1, 2008. We are currently evaluating the impact of adopting this standard on the consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We will be required to adopt SFAS No. 157 in the quarter ended March 31, 2008 and are currently assessing the impact that this may have on our consolidated financial position, results of operations and cash flows.

Table of Contents**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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Consolidated Statement of Operations- Operating Ratios:				
Net revenue	100%	100%	100%	100%
Cost of revenue	33%	32%	33%	30%
Gross margin	67%	68%	67%	70%
Operating expenses:				
Sales and marketing	39%	34%	39%	38%
Research and development	8%	6%	8%	6%
General and administrative	12%	17%	12%	19%
Litigation settlement	%	76%	0%	41%
Total operating expenses	59%	133%	59%	104%
Income (loss) from operations	8%	(65)%	8%	(34)%
Interest and other income, net	5%	3%	4%	4%
Income (loss) before income taxes	13%	(62)%	12%	(30)%
Provision (benefit) for income taxes	4%	(25)%	4%	(12)%
Net income (loss)	9%	(37)%	8%	(18)%

Total Revenue

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
Revenue mix by geography:						
United States	\$ 15,124	(8)%	\$ 16,428	\$ 30,970	(1)%	\$ 31,337
International	8,749	10%	7,967	16,160	17%	13,815
Consolidated total revenue	\$ 23,873	(2)%	\$ 24,395	\$ 47,130	4%	\$ 45,152
<i>United States as a percentage of total revenue</i>	63%		67%	66%		69%
<i>International as a percentage of total revenue</i>	37%		33%	34%		31%
Revenue mix by product category:						
Products	\$ 17,694	(13)%	\$ 20,311	\$ 36,011	(5)%	\$ 37,867
Product upgrades	2,897	84%	1,573	4,819	78%	2,709
Service	2,060	47%	1,401	3,976	58%	2,522
Titan handpiece refills	1,222	10%	1,110	2,324	13%	2,054
Consolidated total revenue	\$ 23,873	(2)%	\$ 24,395	\$ 47,130	4%	\$ 45,152

During the three and six months ended June 30, 2007, compared to the same period in 2006, our U.S. revenue decreased by 8% and 1%, respectively, and our international revenue increased by 10% and 17%, respectively. The increase in international revenue growth was primarily

Edgar Filing: CUTERA INC - Form 10-Q

attributable to continuing investments we have been making toward building our international sales channel. These efforts have resulted in increased revenue from Canada, Japan, Australia and with our international-distributor network. The decrease in U.S. revenue growth in the second quarter and six months ended June 30, 2007, when compared to the same period in 2006, was primarily attributable to U.S. sales productivity issues identified at the start of the second quarter of 2007, and for which strategic initiatives have been implemented.

From a product category perspective, during the three and six months ended June 30, 2007, compared to the same period in 2006, our product revenue decreased by 13% and 5%, respectively. This was primarily attributable to U.S. sales productivity issues. Our upgrade revenue in the second quarter and six months ended June 30, 2007, compared to the same period in 2006, increased by 84% and 78%, respectively. This was primarily attributable to upgrades to our multi-application Xeo systems, and upgrades for our new product, Pearl. Our Service revenue also continued to grow due to the increasing installed base of customers purchasing extended service contracts. Growth in Titan handpiece refills reflected the continuing sales of the Titan product as well as an increased consumer demand for Titan procedures.

We anticipate that, during the second half of 2007, many of our customers will upgrade their existing systems with Pearl, and many new customers will acquire Pearl as part of their purchase of multi-application Xeo systems. Partially due to this reason, and also due to the continuing expansion of our sales force, we expect our upgrade and total revenue to increase during the second half of 2007.

Gross Margin

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
Gross margin	\$ 15,963	(4)%	\$ 16,627	\$ 31,439	0%	\$ 31,573
As a percentage of total revenue	67%		68%	67%		70%

Our cost of revenue consists primarily of material, labor, stock-based compensation, royalty expense, warranty and manufacturing overhead expenses. The decrease in gross margin in the second quarter of 2007 to 67%, compared to 68% in the same period in 2006, was primarily attributable to \$522,000 of lower revenue, which resulted in reduced contributions to increased manufacturing and service costs. For the six months ended June 30, 2007, our gross margin declined to 67%, compared to 70% in the same period in 2006. This decrease in margin rates was primarily attributable to \$963,000, or 2% of revenue, of higher patent royalty expenses in the six months ended June 30, 2007, compared to the same period in 2006. We settled our patent litigation in the second quarter of 2006, and as a result, the first quarter of 2006 did not include patent royalty expenses. In addition, the reduction in margin was partially attributable to \$2.0 million of lower revenue in the six months ended June 30, 2007, compared to the same period in 2006, which resulted in reduced contributions to increased manufacturing and service costs. Given that our royalty expense will continue in the future, and that we expect our revenue to increase in the second half of 2007, we expect our gross margin to improve to approximately 68% to 70% of revenue in the second half of 2007.

Table of Contents**Sales and Marketing**

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
Sales and marketing	\$ 9,190	11%	\$ 8,305	\$ 18,253	8%	\$ 16,851
As a percentage of total revenue	39%		34%	39%		38%

Sales and marketing expenses consist primarily of labor, stock-based compensation, expenses associated with customer-attended workshops and trade shows, and advertising. The increase in sales and marketing expenses in the three months ended June 30, 2007, compared to the same period in 2006, was primarily attributable to the continued investments made in expanding our international distribution network and in expanding our U.S. sales force. The primary contributors to the \$885,000 increase in sales and marketing expenses were higher employee-related expenses of \$534,000, due partially to increased headcount, and increased advertising and promotional expenses of \$354,000.

The increase in sales and marketing expenses in the six months ended June 30, 2007, compared to the same period in 2006, was primarily attributable to the continued investments made in expanding our international distribution network and in expanding of our U.S. sales force. The primary contributors to the \$1.4 million, or 8%, increase in sales and marketing expenses was higher employee-related expenses of \$1.1 million, due partially to increased headcount, and increased advertising and promotional expenses of \$329,000.

In the second half of 2007, primarily due to an increase in our personnel expenses that would result from the planned sales force expansion, we expect our sales and marketing expenses to increase in absolute dollar terms but decrease as a percentage of revenue, as revenue is expected to grow at a rate faster than the growth rate of expenses.

Research and Development (R&D)

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
Research and development	\$ 1,923	24%	\$ 1,552	\$ 3,671	28%	\$ 2,859
As a percentage of total revenue	8%		6%	8%		6%

R&D expenses consist primarily of labor, stock-based compensation, clinical, regulatory and material costs. In the three months ended June 30, 2007, R&D expenses increased by \$371,000 to 8% of total revenue. This increase was partially related to the research and development efforts associated with our new Pearl product released in the second quarter of 2007. The \$371,000 increase was primarily attributable to \$255,000 of higher material costs and \$126,000 of higher outside services related to clinical studies and product development activities.

During the six months ended June 30, 2007, compared to the same period in 2006, R&D expenses increased by \$812,000, or 28%, which was primarily attributable to higher employee-related expenses of \$191,000, \$379,000 of higher material costs and \$180,000 of higher outside services related to clinical studies and product development activities, including the development of our new Pearl product.

For the remainder of 2007, we will continue to invest our R&D efforts and perform clinical studies to gather additional data relating to our Pearl application, as well as continue developing other products, and we expect our R&D expenses to increase in the second half of 2007, compared with the first half of 2007. However, with the expected increase in revenue in the second half of 2007, we expect our R&D expenses to decrease as a percentage of revenue.

General and Administrative (G&A)

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
General and Administrative	\$ 2,900	(32)%	\$ 4,248	\$ 5,918	(31)%	\$ 8,623
As a percentage of total revenue	12%		17%	12%		19%

General and administrative expenses consist primarily of labor, stock-based compensation, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses. G&A expenses for the three months ended June 30, 2007, compared to the same period in 2006, decreased by \$1.3 million, or 32%, and were 12% of net revenue. This decrease was primarily attributable to decreased legal expenses of

Edgar Filing: CUTERA INC - Form 10-Q

approximately \$2.0 million, primarily relating to the patent litigation, which was settled in the second quarter of 2006. This was partially offset by an increase in stock compensation charges of \$409,000. In April and May 2007, two securities class action lawsuits were filed against us- see Part II, Item 1 Legal Proceedings. However, given that we retain director and officer liability insurance with a deductible, we expect the impact from this litigation to be not material for the remainder of 2007.

General and administrative expenses for the six months ended June 30, 2007, compared to the same period in 2006, decreased by \$2.7 million or 31%. This decrease was primarily attributable to \$3.5 million of reduced legal expenses due to the patent litigation settlement in the second quarter of 2006. This reduction in expenses was partially offset by an increase in stock-based compensation expenses by \$510,000.

In the second half of 2007, we expect our G&A expenses to remain in the range of \$3.0 million to \$3.5 million per quarter.

Interest and Other Income, Net

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	% Change	2006	2007	% Change	2006
Interest and other income, net	\$ 1,108	34%	\$ 830	\$ 2,110	18%	\$ 1,786

The increase in interest and other income, net, in the three and six months ended June 30, 2007, compared to the same period in 2006, was primarily attributable to improved tax-exempt interest yields on investments and an increased amount invested. Our cash, cash equivalents and marketable investment balances was at \$115.4 million as of June 30, 2007 compared with \$82.0 million as of June 30, 2006.

Table of Contents**Provision (benefit) for Income Taxes**

(Dollars in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	Change	2006	2007	Change	2006
Income (loss) before income taxes	\$ 3,057	\$ 18,096	\$ (15,039)	\$ 5,707	19,072	\$ (13,365)
Provision (benefit) for income taxes	1,024	7,014	(5,990)	1,918	7,341	(5,423)
Effective tax rate	33%		40%	34%		41%

Our effective tax rate reflects applicable United States federal and state tax rates and the tax impact of foreign operations, offset primarily by research and development tax credits and tax exempt interest income.

Liquidity and Capital Resources

Liquidity is the measurement of our ability to meet potential cash requirements, fund the planned expansion of our operations and acquire businesses. Our sources of cash include operations, marketable investments, stock option exercises and employee stock purchases. We actively manage our cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet our daily needs.

Cash, Cash Equivalents and Marketable Investments

The following table summarizes our cash, cash equivalents and marketable securities (in thousands):

	June 30, 2007	December 31, 2006	Increase/ (Decrease)
Cash and cash equivalents	\$ 10,411	\$ 11,800	\$ (1,389)
Marketable investments	105,004	96,285	\$ 8,719
Total	\$ 115,415	\$ 108,085	\$ 7,330

The net increase in cash, cash equivalents and marketable investments of \$7.3 million in the six months ended June 30, 2007 was primarily a result of \$6.8 million of cash generated by operations, \$3.1 million of cash generated from the exercise of common stock option exercises and employee stock purchases and \$833,000 for excess tax benefits on employee stock option exercises, which were partially offset by \$2.5 million used to repurchase our common stock and \$758,000 used to purchase property and equipment. As of June 30, 2007, we believe we have sufficient cash resources for at least the next twelve months to meet our anticipated needs for working capital, capital expenditures and the \$22.0 million of shares of our common stock that may be repurchased pursuant to our stock repurchase program.

Cash Flows

(Dollars in thousands)	Six Months Ended June 30,	
	2007	2006
Net cash flow provided by (used in):		
Operating activities	\$ 6,759	\$ (9,781)
Investing activities	(9,538)	5,234
Financing activities	1,390	1,210
Net decrease in cash and cash equivalents	\$ (1,389)	\$ (3,337)

Net Cash Provided by Operating Activities

Edgar Filing: CUTERA INC - Form 10-Q

We generated net cash from operating activities of \$6.8 million in the six months ended June 30, 2007, compared to \$9.8 million used in operating activities for the same period in 2006. Of the \$6.8 million generated from operations in the six months ended June 30, 2007, \$3.8 million was generated by net income adjusted for non-cash related items of \$4.2 million, net, (primarily \$2.8 million of stock-based compensation and \$664,000, net, of tax benefit from stock option exercises) and \$1.2 million was generated by an increase in deferred revenue due primarily to an increase in customers purchasing prepaid service contracts. This was partially offset by \$1.7 million of cash used to increase inventories, in preparation for the higher anticipated product shipments in the second half of 2007, and \$807,000 used to reduce our accrued liabilities balance, which resulted partially from increased revenue in the fourth quarter of 2006.

For the six months ended June 30, 2006, net cash used in operations was \$9.8 million. This was primarily attributable to a net loss of \$7.9 million, adjusted for non-cash related items of \$2.1 million, net, (primarily \$2.0 million add back for stock-based compensation expenses, offset by an increase in deferred tax assets by \$4.6 million. The increase in deferred tax assets was primarily attributable to the tax benefit associated with the \$18.4 million litigation settlement expense recorded in the second quarter ended June 30, 2006). In addition, we used \$1.9 million due to a \$2.4 million overpayment of the estimated patent litigation settlement in June 2006. These uses of cash in the six months ended June 30, 2006 were offset partially by the cash generated from an increase in accrued liabilities of \$1.3 million, due partially to unpaid legal bills associated with the patent litigation, and an increase in deferred revenue of \$1.2 million, due primarily to increased sales of extended service contracts.

Net Cash Provided by (Used in) Investing Activities

We used \$9.5 million of cash in investing activities for the six months ended June 30, 2007. This was primarily attributable to \$8.8 million of net purchases of marketable investments, which was partially offset by \$758,000 used to purchase property and equipment primarily for R&D and purchase of a trade show booth.

For the six months ended June 30, 2006, net cash provided by investing activities was \$5.2 million, which was primarily attributable to \$6.7 million from the proceeds of sales and maturities of marketable investments, offset by \$1.2 million used to purchase a patent license and \$251,000 used to purchase property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2007 was \$1.4 million. This was primarily attributable to \$3.1 million cash generated from the issuance of stock pursuant to our stock option and stock purchase plans and \$833,000 from the excess tax benefits related to the option exercises. This was partially offset by \$2.5 million used to repurchase and retire shares of our common stock pursuant to our stock repurchase program approved by our Board of Directors on May 15, 2007. During the six months ended June 30, 2006, \$1.2 million was generated by financing activities relating to the issuance of stock pursuant to our stock option and stock purchase plans.

Table of Contents**Contractual Cash Obligations**

The following summarizes our contractual obligations as of June 30, 2007 for minimum lease payments related to facility leases in California, Japan, Switzerland and France:

	Payments Due by Period (in thousands)				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases	\$8,092	\$1,106	\$2,135	\$2,594	\$2,257
FIN 48 Income Tax Liability					

As of June 30, 2007, we have included in our condensed consolidated balance sheet \$108,000 in Accrued Liabilities and \$988,000 in long-term Income Tax Liability with respect to unrecognized tax benefits and accrued interest. As of June 30, 2007, the settlement period for our income tax liabilities cannot be determined, however, it is not expected to be due within the next twelve months.

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 June 30, 2007 would have potentially declined by \$913,200.

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

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

ITEM 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures***

Attached as exhibits to this Quarterly Report are certifications of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (Exchange Act). This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications, and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

The Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in the Rules 13a-15(e) and 15d-15(e) under the Exchange Act) (Disclosure Controls) as of the end of the period covered by this Report required by Exchange Act Rules 13a-15(b) or 15d-15(b). The controls evaluation was conducted under the supervision and with the participation of the Company's management, including the CEO and CFO. Based on this evaluation, the CEO and our CFO have concluded that as of the end of the period covered by this report the Company's disclosure controls and procedures were effective at a reasonable assurance level.

Definition of Disclosure Controls

Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in the Company's reports filed under the Exchange Act, such as this Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed to reasonably assure that such information is accumulated and communicated to the Company's management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. The Company's Disclosure Controls include components of its internal control over financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the U.S. To the extent that components of the Company's internal control over financial reporting are included within its Disclosure Controls, they are included in the scope of the Company's annual controls evaluation.

Limitations on the Effectiveness of Controls

The Company's management, including the CEO and CFO, does not expect that the Company's disclosure controls or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only 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. Because of 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 the Company 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 were no changes in the Company's internal control over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Two securities class action lawsuits were filed against us and two of our executive officers in April 2007 and May 2007, respectively, in the U.S. District Court for the

Table of Contents

Northern District of California following declines in our stock price. The plaintiffs claim to represent purchasers of our common stock from January 31, 2007 through May 7, 2007. The complaints generally allege that materially false statements and omissions were made regarding our financial prospects, and seeks unspecified monetary damages. We intend to defend these cases vigorously. Since the outcome of this litigation is unpredictable, and since we believe that a significant adverse result for us is not probable, no expense has been recorded with respect to the contingent liability associated with these matters. We retain director and officer liability insurance but there is no assurance that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims.

ITEM 1A. RISK FACTORS

Our first quarter 2007 revenue and earnings, and the revised guidance that we gave on May 7, 2007 for our 2007 fiscal year, were below the earlier guidance provided to the investment community on January 31, 2007. The initiatives that we are implementing in an effort to improve our revenue and income could be unsuccessful, and the instability we may experience while attempting to improve sales productivity could harm our business and may further depress the price of our stock.

During the six months ended June 30, 2007, compared to the same period in 2006, our total revenue increased by 4%, our international revenue increased by 17%, and our U.S. revenue decreased by 1%. This significant decrease in U.S. revenue growth was primarily attributable to:

Reduced sales productivity of our junior sales representatives.

Reduced revenue from PSS World Medical and other national accounts.

Higher-than-expected turnover of sales representatives.

In an effort to improve our revenue and income levels, we have implemented several strategic initiatives, including the following:

The junior-sales program has been discontinued.

We have dedicated additional sales representatives to work closely with, and increase the focus and attention on, our PSS relationship.

We plan to expand our North American direct sales force.

We believe these initiatives should improve our revenue and income. However, these initiatives may not be successful for several reasons: they may lead to employee turnover; there are no assurances that we can hire and train new sales employees; and our efforts to improve our sales productivity may result in instability to our operations, causing harm to our business and a further decline in our stock price.

Two securities class action lawsuits were filed against us in April and May 2007, respectively, based upon the decreases in our stock price following the announcement of our preliminary first quarter 2007 revenue and earnings, and the announcement of our revised 2007 guidance. Defending ourselves against these class action lawsuits could distract management and harm our business.

Two class action lawsuits were filed against us following declines in our stock price in the spring of 2007. We will incur legal costs as a result of this litigation. We retain director and officer liability insurance but there can be no guarantee that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims. This litigation may distract our management and consume resources that would otherwise have been directed toward running our business. Each of these factors could harm 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.

Edgar Filing: CUTERA INC - Form 10-Q

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

intellectual property protection;

product performance;

product pricing;

quality of customer support;

success and timing of new product development and introductions; and

Table of Contents

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, business 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. Our competitors could form strategic alliances with other companies to develop products and solutions that effectively compete with our products. For example, Palomar and Syneron have each entered into agreements with Proctor and Gamble for the proposed development of home-use aesthetic devices. And Syneron entered into an agreement with Obagi Medical Products to study the effects of using Obagi's skin care products during treatments with Syneron aesthetic devices. Business combinations and alliances by our competitors could increase competition, which could harm our business.

Competition among providers of laser and other energy-based devices for the aesthetic market is characterized by rapid innovation, and we must continuously develop or acquire new products or our revenue 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 could decline as our customers and prospects purchase our competitors' products.

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

We have created products to apply our technology to hair removal, treatment of veins, skin rejuvenation, treatment of pigmented lesions and treatment of wrinkles. Currently, these applications represent the majority of laser and other energy-based aesthetic procedures. To be successful in the future, we must develop and acquire new and innovative aesthetic applications, identify new markets for our existing technology, and develop and acquire new technology from various platforms. To successfully expand our product offerings, we must, among other things:

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

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

sell our products to a broad customer base;

identify new markets and alternative applications for our technology;

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

Edgar Filing: CUTERA INC - Form 10-Q

satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, we have introduced at least one new product. 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. Even with a significant investment in research and development, we may be unable to continue to develop or acquire new products and technologies annually, or at all, which could adversely affect our projected growth rate.

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 energy-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;

the cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser- or other energy-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.

Table of Contents

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.

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 Shared Services, Inc., or PSS, a wholly-owned subsidiary of PSS World Medical. PSS sales representatives work in coordination with our sales force to locate new customers for our products throughout the United States. For the year ended December 31, 2006, approximately 15% of our revenue came from PSS. For the three months ended March 31, 2007, revenue from PSS transactions was below what we had anticipated. We have dedicated additional sales representatives to work closely with, and increase the focus and attention on, our PSS relationship, but it may take time for the increase in resources to result in an improvement in revenue from our PSS relationship. In addition, we can provide no assurances that the increased focus on PSS will translate into increased revenue for us. Further, if PSS does not perform adequately under the arrangement, or terminates our relationship, it may have a material adverse effect on our business, financial condition and results of operations.

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

We provide guidance to the investment community regarding our anticipated future operating performance, both for the coming quarters and fiscal year. 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, on January 31, 2007, we indicated that we expected revenue for the first quarter of 2007 to be \$26 million and revenue for 2007 to be \$126 million. Actual revenue for the first quarter of 2007 was \$23.3 million, and we have since lowered our guidance for 2007 to \$110 million. If in the future 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 again decline significantly.

The price of our common stock may fluctuate substantially.

The public market price of our common stock has in the past fluctuated substantially and may continue to do so in the future. The market price for our common stock could be affected by a number of factors, including:

quarterly variations in our, or our competitors', results of operations;

changes in earnings estimates or guidance, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates;

the announcement of new products or service enhancements by us or our competitors;

the announcement of the departure of a key employee or executive officer;

regulatory developments or delays concerning our, or our competitors', products;

the initiation of litigation by us or one of our competitors; and

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors. Actual or perceived instability in our stock price could reduce demand from potential buyers of our stock, thereby causing our stock price to decline.

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

Our competitors or other patent holders may assert that our present or future 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 selling the applicable 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 June 30, 2007, we had eight issued U.S. patents. Some of our 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.

Table of Contents

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 and our business could be adversely affected.

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 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, but there are no assurances as to when, or whether, we will ever obtain such clearances. In the event that we do not obtain additional FDA clearances, our ability to market Titan in the United States and revenue derived therefrom, including revenue from both Titan unit sales and hand piece 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 FDA clearances or approvals for our products, our ability to market and sell them 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, 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 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. 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.

Table of Contents

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 quarter ended June 30, 2007, approximately 37% of our revenue was derived from international customers, which is 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 underperform, we may be unable to increase or maintain our level of international revenue. We will need to expand the territories in which we sell our products and attract additional international distributors to grow our business. 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.

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 could adversely affect our ability to sell our products, and therefore 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 potential customers may opt against purchasing laser and other energy-based products due to the cost of, or inability to, procure insurance coverage. The unavailability of insurance coverage for our customers and prospects could adversely affect our ability to sell our products, and that could harm our financial condition.

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

Federal regulations allow us to sell our products to or on the order of licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states, by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We and our distributors generally offer but do not require product training to the purchasers or operators of our products. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedures. 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 our business, and, in the event these result in product liability litigation, distract management and subject us to liability, including legal expenses.

Table of Contents

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. In addition, 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 insurance coverage, or we have product liability claims in excess of our insurance coverage, claims would be paid out of cash reserves, thereby harming our financial condition, operating results and profitability.

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 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; and,

delay in supplier deliveries.

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

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

Edgar Filing: CUTERA INC - Form 10-Q

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 twelve 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 inventories, which would

Table of Contents

increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventories, 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.

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

Most of our revenue in the United States is derived from sales to customers outside of the core dermatologist and plastic surgeon specialties, such as family practitioners, primary care physicians, gynecologists and medi-spas. Continuing to achieve further penetration into this new market is a material assumption of our growth strategy. Demand for our products in the non-core market could be weakened by several factors including poor financial performance of businesses introducing aesthetic procedures to their practice or medi-spas, reduced patient demand for alternative treatments and services being provided by non-core practitioners and an increase in malpractice lawsuits against non-core practitioners. If we do not achieve anticipated demand for our products in the non-core market, our expected revenue growth may not be achieved.

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. We do not have a succession plan in place for each of our officers and key employees. 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 critical factors 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include a report by our management on our internal control over financial reporting in each of our Annual Reports on Form 10-K. Such reports contain 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 such internal control was effective.

Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, and take up a significant amount of management's time and resources. Though we have not historically identified any significant deficiency or material weakness in our internal control over financial reporting, if we are ever unable to assert that our internal control over financial reporting is effective for any given period, our stock price may decline and it could have an adverse effect on our business.

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

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

While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any acquisitions or collaborative projects.

Edgar Filing: CUTERA INC - Form 10-Q

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.

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 changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, unanticipated decreases in the amount of revenue or earnings in countries with low statutory tax rates, changes in the valuation of our deferred tax assets and liabilities, future levels of research and development spending, deductions for employee stock option exercises being different to what we projected, and changes in overall levels of income before taxes.

Table of Contents

The quarterly royalty payments under our patent license with Palomar are subject to an annual audit. Any material adjustments from this audit could result in a material adverse effect on our business and our stock price.

We pay royalties to Palomar after each fiscal quarter for applicable product sales made in that quarter. These royalty amounts are subject to an annual review by an independent public accountant hired by Palomar. The independent public accountant's interpretation of the applicable royalty rate for any new products, or combination of products, and the net revenue for which to calculate the royalty, could be different from ours. In the event that the independent public accountant's assessment of the accuracy of our estimated royalty payments to Palomar is materially different from our calculations, we could owe a higher amount to Palomar than we accrued for, and would then have to report it as an additional expense in our financial statements for the applicable period. This could result in a material adverse effect on our business and stock price.

Stock-based compensation expense adjustments could adversely affect our reported financial results, which could cause the price of our stock to decline.

As of January 1, 2006, we adopted SFAS 123(R), which requires us to measure and record stock-based compensation expense using a fair value method, which can adversely affect our results of operations by increasing our cost by the amount of such stock-based compensation charges. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the input of highly subjective assumptions, which 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. Actual stock-based compensation expenses that are significantly higher than our expectations would materially decrease our net income and adversely affect our reported financial results, which could cause the price of our stock to decline and harm our business.

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 currently anticipate paying cash dividends on our common stock. 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 investment will only occur if our stock price appreciates.

ITEM 2(c). UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs *	Millions of Dollars
				Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
June 1 -30, 2007	123,800	\$ 24.36	123,800	\$ 21,984

* On May 15, 2007, the Company's Board of Directors approved a stock repurchase program under which the Company is authorized to use up to \$25 million to repurchase shares of its common stock. The Company entered into a pre-arranged, Rule 10b5-1 trading plan with a broker to facilitate the repurchase of its shares. Acquisitions are made in accordance with the trading plan, at prevailing prices, subject to market conditions and other factors. Purchases under the trading plan may be modified at any time by giving the broker sixty days' notice. This repurchase program shall terminate at the earliest of: (i) the Company acquiring \$25 million worth of its stock, or (ii) May 15, 2008. The stock repurchased under the plan will be cancelled and returned to authorized share status.

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

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

Table of Contents

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) 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, in the city of Brisbane, State of California, on the 6th day of August, 2007.

CUTERA, INC.

/S/ RONALD J. SANTILLI
Ronald J. Santilli

Chief Financial Officer and Executive Vice President

(Principal Financial and Accounting Officer and
Authorized Signatory)