

CUTERA INC
Form 10-Q
November 03, 2008
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 September 30, 2008

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)

Edgar Filing: CUTERA INC - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)
3240 Bayshore Blvd., Brisbane, California 94005
(Address of principal executive offices)
(415) 657-5500
(Registrant's telephone number, including area code)

77-0492262
(I.R.S. employer
identification no.)

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, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

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

The number of shares of Registrant's common stock issued and outstanding as of October 24, 2008 was 12,779,692.

Table of Contents

CUTERA, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
PART I. <u>FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
PART II. <u>OTHER INFORMATION</u>	19
Item 1. <u>Legal Proceedings</u>	19
Item 1A. <u>Risk Factors</u>	19
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
Item 3. <u>Defaults Upon Senior Securities</u>	27
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	27
Item 5. <u>Other Information</u>	27
Item 6. <u>Exhibits</u>	27
<u>Signature</u>	27

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

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,683	\$ 11,054
Marketable investments	71,662	88,510
Accounts receivable, net	6,486	10,692
Inventories	8,753	7,533
Deferred tax asset	7,938	8,058
Other current assets	2,322	1,955
Total current assets	123,844	127,802
Property and equipment, net	1,378	1,361
Long term investments	11,028	7,429
Intangible assets, net	1,076	1,227
Deferred tax asset, net of current portion	814	834
Total assets	\$ 138,140	\$ 138,653
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,120	\$ 2,350
Accrued liabilities	10,030	13,587
Deferred revenue	6,518	4,971
Total current liabilities	18,668	20,908
Deferred rent	1,695	1,639
Deferred revenue, net of current portion	5,652	5,593
Income tax liability	1,367	1,160
Total liabilities	27,382	29,300
Commitments and contingencies (Note 8)		
Stockholders equity:		
Common stock	13	13
Additional paid-in capital	79,166	74,871
Retained earnings	31,645	34,279
Accumulated other comprehensive income (loss)	(66)	190
Total stockholders equity	110,758	109,353

Edgar Filing: CUTERA INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 138,140	\$ 138,653
--	------------	------------

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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net revenue	\$ 19,110	\$ 28,143	\$ 65,482	\$ 75,273
Cost of revenue	7,823	9,607	25,313	25,298
Gross profit	11,287	18,536	40,169	49,975
Operating expenses:				
Sales and marketing	8,076	10,586	28,786	28,839
Research and development	1,828	1,764	5,617	5,435
General and administrative	2,583	3,078	8,547	8,996
Total operating expenses	12,487	15,428	42,950	43,270
Income (loss) from operations	(1,200)	3,108	(2,781)	6,705
Interest and other income, net	733	1,096	2,491	3,206
Other-than-temporary impairment of long term investments	(2,372)		(2,372)	
Income (loss) before income taxes	(2,839)	4,204	(2,662)	9,911
Provision (benefit) for income taxes	(86)	1,112	(28)	3,031
Net income (loss)	\$ (2,753)	\$ 3,092	\$ (2,634)	\$ 6,880
Net income (loss) per share:				
Basic	\$ (0.22)	\$ 0.24	\$ (0.21)	\$ 0.52
Diluted	\$ (0.22)	\$ 0.22	\$ (0.21)	\$ 0.48
Weighted-average number of shares used in per share calculations:				
Basic	12,780	13,026	12,762	13,283
Diluted	12,780	13,970	12,762	14,422

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)**

	Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net income (loss)	\$ (2,634)	\$ 6,880
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	3,983	4,305
Tax benefit from employee stock options	49	2,408
Excess tax benefit related to stock-based compensation expense		(1,863)
Depreciation and amortization	671	681
Other-than-temporary impairment of long term investments	2,372	
Change in deferred tax asset	140	267
Other	89	196
Changes in assets and liabilities:		
Accounts receivable	4,057	(1,885)
Inventories	(1,159)	(1,532)
Other current assets	220	(361)
Accounts payable	(230)	(473)
Accrued liabilities	(3,557)	893
Deferred rent	56	162
Deferred revenue	1,606	2,518
Income tax liability	207	(340)
Net cash provided by operating activities	5,870	11,856
Cash flows from investing activities:		
Acquisition of property and equipment	(538)	(881)
Proceeds from sales of marketable investments	49,969	48,643
Proceeds from maturities of marketable investments	18,150	26,558
Purchase of marketable and long term investments	(58,085)	(66,960)
Other		(14)
Net cash provided by investing activities	9,496	7,346
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	263	3,511
Repurchase of common stock		(25,000)
Excess tax benefit related to stock-based compensation expense		1,863
Net cash provided by (used in) financing activities	263	(19,626)
Net increase (decrease) in cash and cash equivalents	15,629	(424)
Cash and cash equivalents at beginning of period	11,054	11,800
Cash and cash equivalents at end of period	\$ 26,683	\$ 11,376

Non-cash disclosure of cash flow information:

Change in deferred stock-based compensation, net of terminations	\$	\$	(9)
--	----	----	-----

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 and Principles of Consolidation.

Cutera, Inc. (Cutera or the Company) is a global provider of laser and other light-based aesthetic systems for practitioners worldwide. The Company designs, develops, manufactures, and markets the CoolGlide, Xeo and Solera product platforms for use by physicians and other qualified practitioners to allow its customers to offer safe and effective aesthetic treatments to their customers.

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries in Australia, Canada, France, Japan, Spain, Switzerland and United Kingdom that market, sell and service its products outside of the United States. The Condensed Consolidated Financial Statements include the accounts of the Company and its subsidiaries. All inter-company transactions and balances 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, 2007 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, or GAAP. 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, 2007 filed with the Securities and Exchange Commission, or SEC, on March 13, 2008.

Use of Estimates

The preparation of interim Condensed Consolidated Financial Statements in conformity with GAAP 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 and long term 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, 2007 and have not changed significantly as of September 30, 2008, except for the following:

Fair Value Measurements

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157, as it relates to financial assets and financial liabilities. In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which delayed the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. This standard is now the single source in GAAP for the definition of fair value, except for the fair value of leased property as defined in SFAS No. 13, *Accounting for Leases*. SFAS 157 establishes a fair value hierarchy that distinguishes

Edgar Filing: CUTERA INC - Form 10-Q

between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under SFAS 157 are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value. The following section describes the valuation methodologies used by the Company to measure different financial instruments at fair value, including an indication of the level in the fair value hierarchy in which each instrument is generally classified.

At September 30, 2008, the Company held \$13.4 million (par value), with an estimated fair value of \$11.0 million, of AAA to Aa3 rated municipal bonds with an auction interest rate reset feature, known as auction rate securities, or ARS. The ARS held by the Company are guaranteed either by the Federal Family Education Loan Program or the Maine Education Loan Authority, and were issued for the purpose of financing student loans. ARS have historically traded at par and are redeemable at

Table of Contents

par plus accrued interest at the option of the issuer. Interest is typically paid at the end of each auction period or semi-annually. Until February 2008, the market for the Company's ARS was highly liquid. Since February 2008, a substantial number of auctions failed, meaning that there was not enough demand to sell all of the securities that holders desired to sell at auction. The immediate effect of a failed auction is that such holders cannot sell the securities at auction and the interest rate on the security generally resets to a maximum interest rate. In the case of funds invested by the Company in ARS which are the subject of a failed auction, the Company may not be able to access the funds without a loss of principal, unless a future auction of these investments is successful or the issuer redeems the security. As of September 30, 2008, the Company has classified its ARS investment balance as long term investments because of the Company's belief that it could take more than one year before they are readily marketable. The Company has also modified its current investment strategy and increased its investments in more liquid money market funds.

At September 30, 2008, observable market information was not available to determine the fair value of the Company's ARS investments. Therefore, the Company estimated their fair values using valuation models that relied on Level 3 inputs including those that are based on expected cash flow streams and collateral values, assessments of counterparty credit quality, default risk underlying the security, market discount rates and overall capital market liquidity. The valuation of the Company's ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the Company's valuation in the future include changes to credit ratings of the securities, as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. These financial instruments are classified within Level 3 of the fair value hierarchy.

As of September 30, 2008, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 24,728	\$	\$	\$ 24,728
Short term marketable investments:				
Available-for-sale securities		71,662		71,662
Long term investments:				
Available-for-sale ARS			11,028	11,028
Total assets at fair value	\$ 24,728	\$ 71,662	\$ 11,028	\$ 107,418

The table presented below summarizes the change in carrying value associated with Level 3 financial assets, which represents our investment in ARS and classified as long term investments, for the three and nine months ended September 30, 2008 (in thousands):

	Three Months Ended September 30,	Nine Months Ended September 30,
Balance at June 30, 2008 and December 31, 2007	\$ 11,478	\$
Transfers into Level 3		13,400
Sales, settlements and purchases, net, during the period		
Total gains or losses (realized or unrealized)		
Included in earnings (other-than-temporary impairment of non-current ARS investments)	(2,372)	(2,372)
Transferred from other comprehensive loss	1,922	
Balance at September 30, 2008	\$ 11,028	\$ 11,028

In accordance with the guidance provided in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and SEC Staff Accounting Bulletin (SAB) Topic 5M, *Accounting for Noncurrent Marketable Equity Securities* the Company determines when an investment is other-than-temporarily impaired by performing quarterly reviews of its investments. If the cost of an investment exceeds its fair value, in making the judgment of whether there has been an other-than-temporary impairment, the Company considers available quantitative and qualitative evidence, including, among other factors, the Company's intent and ability to hold the investment to recovery, the duration and extent to which the fair value is less than cost, specific adverse conditions related to the financial health of and business outlook for the investee and

Edgar Filing: CUTERA INC - Form 10-Q

rating agency actions. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Since February 2008, due to the lack of liquidity experienced in the global credit and capital markets, and specifically in the ARS market, the Company's ARS have experienced failed auctions and the estimated market values continue to decline. As a result, as of September 30, 2008 the Company concluded that the previously unrealized loss on their ARS investments was other-than-temporary and therefore recognized approximately \$2.4 million as an impairment of long term investments, with a corresponding decrease in *Accumulated Other Comprehensive Loss*, during the third quarter ended September 30, 2008.

Recent Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not expect SFAS 162 to have a material impact on its Consolidated Financial Statements.

In April 2008, the FASB issued FASB Staff Position, or FSP, FAS 142-3, *Determination of the Useful Life of Intangible Assets*, or FSP FAS 142-3. FSP FAS 142-3 removes the requirement of SFAS 142, *Goodwill and Other Intangible Assets* for an entity to consider, when determining the useful life of an acquired intangible asset, whether the intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions associated with the intangible asset. FSP FAS 142-3 replaces the previous useful-life assessment criteria with a requirement that an entity considers its own experience in renewing similar arrangements. If the entity has no relevant experience, it would consider market participant assumptions regarding renewal. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of adopting FSP FAS 142-3.

In February 2008, the FASB issued FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, to partially defer SFAS 157. FSP 157-2 defers the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008. The Company is currently evaluating what impact the adoption of the provisions of FSP 157-2 will have on its Consolidated Financial Statements.

Table of Contents

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, (SFAS 141R). This issuance retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control. SFAS 141R is effective for the Company beginning January 1, 2009. Though this pronouncement is not expected to have an effect on the Company's consolidated financial position, annual results of operations or cash flows, if it were to acquire another entity, it would be required to account for it in accordance with this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, (SFAS 160). This issuance amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS 160 is effective for the Company beginning January 1, 2009. Though this pronouncement is not expected to have an effect on the Company's consolidated financial position, annual results of operations or cash flows, if it were to acquire another entity, it would be required to account for it in accordance with this pronouncement.

Note 2. Balance Sheet Details***Cash and Cash Equivalents, Marketable Investments and Long Term 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 (loss), held for use in current operations and classified in current assets as Marketable investments and in long term assets as Long term investments.

The following is a summary of cash and cash equivalents, marketable investments and long term investments:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
September 30, 2008 (in thousands)				
Cash and cash equivalents:				
Cash and money market funds	\$ 16,501	\$	\$	\$ 16,501
Municipal bonds	10,178	4		10,182
Total cash and cash equivalents	26,679	4		26,683
Marketable debt investments in municipal securities	71,732	107	(177)	71,662
Long term investments in ARS	11,028			11,028
	\$ 109,439	\$ 111	\$ (177)	\$ 109,373

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
December 31, 2007 (in thousands)				
Cash and cash equivalents:				
Cash and money market funds	\$ 6,405	\$	\$	\$ 6,405
Municipal bonds	4,649			4,649
Total cash and cash equivalents	11,054			11,054
Marketable debt investments:				
Municipal securities	74,229	190		74,419
ARS	14,091			14,091
Total marketable debt investments:	88,320	190		88,510
Long term investments in ARS	7,429			7,429

Edgar Filing: CUTERA INC - Form 10-Q

\$ 106,803 \$ 190 \$ \$ 106,993

Inventories:

Inventories consist of the following (in thousands):

	September 30, 2008	December 31, 2007
Raw materials	\$ 4,984	\$ 3,313
Finished goods	3,769	4,220
	\$ 8,753	\$ 7,533

Edgar Filing: CUTERA INC - Form 10-Q

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):

	September 30, 2008		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 345	\$ 873
Technology sublicense	538	342	196
Other intangibles	185	178	7
 Total	 \$ 1,941	 \$ 865	 \$ 1,076

Table of Contents

	December 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 241	\$ 977
Technology sublicense	538	302	236
Other intangibles	185	171	14
Total	\$ 1,941	\$ 714	\$ 1,227

For the nine months ended September 30, 2008 and 2007, amortization expense for intangible assets was approximately \$151,000 and \$188,000, respectively.

Based on intangible assets recorded at September 30, 2008, 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:

2008 remainder	\$ 51
2009	196
2010	192
2011	192
2012	158
2013	138
Thereafter	149
Total	\$ 1,076

Note 3. Stock-based Compensation and Stock Repurchase Program*Stock-based Compensation Expenses*

The pre-tax stock-based compensation expense recognized during the three and nine months ended September 30, 2008 and 2007 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of revenue	\$ 222	\$ 225	\$ 648	\$ 674
Sales and marketing	440	419	1,290	1,268
Research and development	170	209	443	571
General and administrative	494	664	1,602	1,792
Total stock-based compensation expense	\$ 1,326	\$ 1,517	\$ 3,983	\$ 4,305

Stock Repurchase Program

During the nine months ended September 30, 2007, the Company repurchased 1,107,856 shares of its common stock at an average price of \$22.57 for a total of \$25.0 million. The stock repurchased under the plan was cancelled and returned to authorized share status.

Note 4. Net Income (Loss) Per Share

Edgar Filing: CUTERA INC - Form 10-Q

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 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, shares and restricted stock units is reflected in diluted net income per share by application of the treasury stock method, which includes consideration of stock-based compensation required by SFAS No. 123(R), *Share-Based Payment (revised 2004)*, and SFAS No. 128, *Earnings Per Share*.

For periods presented with a net loss available to common stockholders, diluted net loss per common share is the same as basic net loss per common share, as the effect of the potential common stock equivalents is anti-dilutive and as such is excluded from the calculations of the diluted net loss per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Numerator:				
Net income (loss) available to common stockholders	Basic and Diluted			
	\$ (2,753)	\$ 3,092	\$ (2,634)	\$ 6,880
Denominator:				
Weighted-average number of common shares outstanding used in computing basic net income (loss) per share	12,780	13,026	12,762	13,283
Dilutive potential common shares used in computing diluted net income (loss) per share		944		1,139
Total weighted-average number of shares used in computing diluted net income (loss) per share	12,780	13,970	12,762	14,422

Anti-dilutive securities

The following number of weighted shares outstanding, 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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Options to purchase common stock	3,160	969	2,812	735
Restricted stock units	13		21	
Employee stock purchase plan shares	31	18	63	18
	3,204	987	2,896	753

Table of Contents**Note 5. 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 September 30, 2008 and September 30, 2007, were as follows (in thousands):

	September 30, 2008	September 30, 2007
Balance at December 31, 2007 and 2006	\$ 10,564	\$ 6,652
Add: Payments received	7,987	6,996
Less: Revenue recognized	(6,381)	(4,468)
Balance at September 30, 2008 and 2007	\$ 12,170	\$ 9,180

Costs incurred under service contracts during the nine months ended September 30, 2008 and 2007, amounted to \$3.4 million and \$1.6 million respectively. All service contract costs are recognized as incurred.

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 gain (loss) on marketable and long term 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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net income (loss)	\$ (2,753)	\$ 3,092	\$ (2,634)	\$ 6,880
Unrealized gain (loss) on marketable and long term investments	(639)	157	(2,628)	116
Recognized loss on non-current ARS included in earnings	2,372		2,372	
Comprehensive income (loss)	\$ (1,020)	\$ 3,249	\$ (2,890)	\$ 6,996

Note 7. Income Taxes

The interim effective income tax rate reflects applicable United States federal and state tax rates and the tax impact of foreign operations, reduced primarily by research and development tax credits (U.S. federal income tax credits in 2007 but not in the nine months ended September 30, 2008) and tax exempt interest income. The interim effective income tax rate is based on management's best estimate of the annual effective income tax rate. The decrease in the effective tax rate for the three and nine months ended September 30, 2008, to 3% and 1%, compared to 26% and 31% for the same periods in 2007, respectively, was primarily attributable to tax exempt interest income being a larger percentage of the lower projected pre-tax income for fiscal year 2008, compared to fiscal year 2007.

With respect to the \$2.4 million impairment charge for ARS investments recognized in the third quarter ended September 30, 2008, the Company treated this for income tax purposes as a discrete item in the quarter. Given this impairment charge is a capital loss, the Company recorded a deferred tax asset but because it did not believe it is more likely than not realizable, it recorded a valuation allowance against the deferred tax asset. As a result, there was no effect on the Company's total tax provision for the quarter and nine months ended September 30, 2008 for this charge.

The Emergency Economic Stabilization Act of 2008, which contains the Tax Extenders and Alternative Minimum Tax Relief Act of 2008, was signed into law on October 3, 2008. Under the Act, the research credit was retroactively extended for amounts paid or incurred after December 31, 2007 and before January 1, 2010. The effects of the change in the tax law will be recognized in the Company's fourth quarter 2008, which is the quarter in which the law was enacted. The Company is still assessing the impact of this new legislation but does not expect

the effect to its fourth quarter provision for income taxes to be material.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$2.0 million and \$1.5 million at September 30, 2008 and 2007, 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.

As of September 30, 2008, the Company had included in its Condensed Consolidated Balance Sheet \$1.4 million in long term income tax liability with respect to unrecognized tax benefits and accrued interest. In general, the Company's income tax returns are subject to examination by U.S. federal tax authorities for tax years 2005 onward and by various U.S. state and foreign tax authorities for tax years 2002 onward. The Company is currently under audit by the Internal Revenue Service for federal income tax years ended December 31, 2005 and 2006. In addition, other state and international tax authorities audit the Company's tax returns from time to time. The Company has reserved for potential adjustments to its provision for income taxes that may result from examinations by, or any negotiated agreements with, these tax authorities, and it believes that the final outcome of these examinations or agreements will not have a material effect on its results of operations. If events occur which indicate payment of these amounts is unnecessary, the reversal of the liabilities would result in the recognition of tax benefits in the period it determines the liabilities are no longer necessary. If the Company's estimates of the federal, state, and foreign income tax liabilities are less than the ultimate assessment, a further charge to expense would result. As of September 30, 2008, the Company does not expect any unrecognized tax benefits to be paid within the next twelve months, nor can it make a reliable estimate when cash settlement with a taxing authority may occur.

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

Table of Contents

Court for the Northern District of California following declines in the Company's stock price. The plaintiffs claim to represent 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. On November 1, 2007, the Court ordered the two cases consolidated. On December 17, 2007, the plaintiffs filed a consolidated, amended complaint, and on January 31, 2008, the Company filed a motion to dismiss that complaint. On September 30, 2008, in response to the Company's motion, the Court issued an order dismissing the plaintiffs' amended complaint without prejudice, and allowed the plaintiffs thirty days to file a second amended complaint. On October 28, 2008, the plaintiffs filed a Notice Of Intention Not to File A Second Amended Consolidated Complaint. No final judgment has yet been entered in this case, and, upon entry of such a judgment, plaintiffs may choose to appeal the Court's prior order dismissing their first amended complaint. The Company intends to continue to defend this case vigorously, regardless of the stage of litigation. The Company retains director and officer liability insurance, though 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. Since the outcome of this litigation is unpredictable and not reasonably estimable, and since the Company does not believe that a significant adverse result is probable, no expense has been recorded with respect to the contingent liability associated with this matter.

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against the Company in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, Ltd., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that the Company violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, the Company removed the case to federal court in the Northern District of Illinois, and filed its response to the complaint on February 29, 2008. Although the Company is continuing to investigate the number of facsimiles transmitted during the period for which the plaintiff seeks class certification and the number of these facsimiles that were unsolicited within the meaning of the TCPA, the Company expects that the number of unsolicited facsimiles could be large and potential liability may be substantial as a result. The Company retains general liability insurance, with one insurer covering the first two years of the four-year period preceding the lawsuit, and a second insurer covering the latter two years of that four-year period. The first carrier has agreed to defend the Company subject to a reservation of rights. The second carrier has declined coverage. The Company intends to defend this case vigorously, including the plaintiff's allegations seeking class certification, and regardless of the stage of litigation. Since the outcome of this litigation is unpredictable and not reasonably estimable, and since the Company does not believe that a significant adverse result is probable, no expense has been recorded with respect to the contingent liability associated with this matter.

Other Legal Matters

In addition to the foregoing lawsuits, the Company is named from time to time as a party to product liability and other lawsuits in the normal course of its business. As of September 30, 2008, the Company is not a party to any other 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. The following is a schedule of non-cancellable operating lease payments (in thousands):

Fiscal Year Ending December 31,	
2008 (remainder)	\$ 350
2009	1,407
2010	1,314
2011	1,317
2012	1,429
2013	1,545
Future minimum rental payments	\$ 7,362

Warranty Obligations.

Edgar Filing: CUTERA INC - Form 10-Q

The Company provides standard one-year or two-year warranty coverage on its systems. Warranty coverage provided is for labor and parts necessary to repair the systems during the warranty period. The Company accounts for the estimated warranty cost of the standard warranty coverage as a charge to costs of revenue when revenue is recognized. The estimated warranty cost is based on historical product performance. Utilizing actual service records, the Company calculates the average service hours and parts expense per system, and applies the actual labor and overhead rates to determine the estimated warranty charge. The Company updates these estimated charges every quarter.

Edgar Filing: CUTERA INC - Form 10-Q

The following table provides the changes in the product warranty accrual for the nine months ended September 30, 2008 and 2007 (in thousands):

	September 30, 2008	September 30, 2007
Balance at December 31, 2007 and 2006	\$ 2,725	\$ 3,055
Accruals for warranties issued during the period	3,735	3,667
Settlements made during the period	(4,263)	(4,044)
Balance at September 30, 2008 and 2007	\$ 2,197	\$ 2,678

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 mutually agreed upon between the parties. This forecast time-horizon can vary among different suppliers. The Company's open inventory purchase commitments were not material at September 30, 2008.

Income Taxes

The Company is currently under audit for the years ended December 31, 2005 and 2006 by the Internal Revenue Service. In addition, other state and international tax authorities audit the Company's tax returns from time to time. The Company has reserved for potential adjustments to its provision for income taxes that may result from examinations by, or any negotiated agreements with, these tax authorities, and it believes that the final outcome of these examinations or agreements will not have a material effect on its results of operations. If events occur which indicate payment of these amounts is unnecessary, the reversal of the liabilities would result in the recognition of tax benefits in the period the Company determines the liabilities are no longer necessary. If the Company's estimates of the federal and state income tax liabilities are less than the ultimate assessment, a further charge to expense would result. As of September 30, 2008, the Company does not expect any unrecognized tax benefits to be paid within the next twelve months, nor can it make a reliable estimate when cash settlement with a taxing authority may occur.

Table of Contents

Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, the Company has entered into indemnification agreements with each of its directors and executive officers. In 2007, two of the Company's executive officers were named as defendants in securities class action litigation—see *Litigation* section above. The Company's exposure under its various indemnification obligations, including those under the indemnification agreements with its directors and executive officers, is unknown since the outcome of that securities litigation is unpredictable and the amount that could be payable thereunder is not reasonably estimable, and since other indemnification obligations involve future claims that may be made against the Company. The Company has not accrued or paid any amounts for any such indemnification obligations. However, the Company may record charges in the future as a result of these potential indemnification obligations, including those related to the securities class action litigation.

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, 2007 as contained in our annual report on Form 10-K filed with the SEC on March 13, 2008. This quarterly report, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the ability to grow our business, increase our revenue, manage expenses, generate additional cash, return to profitability, develop and commercialize existing and new products and applications, and improve the performance of our worldwide sales and distribution network, and to the outlook regarding long term prospects. 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 19, 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.

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 September 30, 2008.

Executive Summary

Edgar Filing: CUTERA INC - Form 10-Q

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 for practitioners worldwide. We offer products on three platforms CoolGlide, Xeo and Solera for use by physicians and other qualified practitioners to allow our customers to offer safe and effective aesthetic treatments to their customers.

Our corporate headquarters and U.S. operations are located in Brisbane, California. We conduct our manufacturing, warehousing, research, regulatory, sales, service, marketing and administrative activities from this facility. 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 hand piece refills and marketing brochures, through the internet.

International sales are generally made through direct sales employees and through a worldwide distributor network 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, Upgrades, Service and Titan hand piece refills. Product revenue represents the sale of a system which consists of one or more hand pieces and a console that incorporates a universal graphic user interface, a laser and/or other light-based module, control system software and high voltage electronics. However, depending on the application, the laser or other light-based module is sometimes contained in the hand piece, such as with our Pearl and Pearl Fractional products, instead of in the console. We offer our customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications as their practice grows. This enables customers to upgrade their systems whenever they want and provides us with a source of recurring revenue, which we classify as Upgrade revenue. Service revenue relates to amortization of pre-paid service contract revenue and receipts for services on out-of-warranty products. Titan hand piece refill revenue is associated with our Titan hand piece, which requires replacement of the optical source after a set number of pulses have been used.

Significant Business Trends. We believe that our ability to grow revenue has been, and will continue to be, primarily dependent on the following:

Investments made in our global sales and marketing infrastructure.

Continuing introduction of new aesthetic products and applications.

Continuing customer demands for our products.

Marketing to physicians in the core dermatology and plastic surgeon specialties as well as outside those specialties.

Generating service and Titan hand piece refill revenue from our growing installed base of customers.

Table of Contents

For the three and nine months ended September 30, 2008, compared to the same periods in 2007, our U.S. revenue decreased by 46% and 30%, respectively. We believe that the current market conditions may be causing our non-core physician prospects to defer a purchasing decision at this time, even though most of these physicians may not be limited by credit barriers. Further, we believe that a segment of our business – those aesthetic practices that operate in settings that are not medical offices – are being particularly affected by the economic environment and may be finding it more difficult to obtain credit financing. This may be resulting in them delaying their purchase decisions. Also, FDA clearance for our Pearl product was received in early 2007, which allowed us to begin shipping our Pearl product in June 2007 and provided significant Upgrade revenue for the third quarter of 2007. In contrast, our Pearl Fractional product started shipping at the end of the third quarter of 2008, which resulted in lower Upgrade revenue in that period.

For the three and nine months ended September 30, 2008, compared to the same period in 2007, our international revenue decreased by 8% and increased by 18%, respectively. The decrease in international revenue for the three months ended September 30, 2008, compared to the same period in 2007, was primarily due to difficult economic conditions. The increase in the first nine months of international revenue, compared to the same period in 2007, was primarily attributable to the continuing investments in developing our global infrastructure. These efforts resulted in increased revenue from several of our geographic locations, including Europe and emerging global markets.

For the three and nine months ended September 30, 2008, our gross margin declined to 59% and 61%, respectively, compared to 66% in the same periods of 2007. This decrease in gross margin was primarily attributable to:

Higher service and Titan refill revenue, as a percentage of total revenue, which have a lower gross margin than our Product and Upgrade revenue categories;

Increased level of international distributor business, which has slightly lower gross margins than our direct business; and

Lower than expected overall revenue, which reduced the leverage of our manufacturing and service department expenses and was dilutive to our gross margin percentage in the short term.

Sales and marketing expenses for the three months ended September 30, 2008, compared to the same period in 2007, decreased by \$2.5 million, primarily due to reduced marketing and sales costs in North America, resulting from a reduction in head count and lower sales commission expenses. Sales and marketing expense for the nine months ended September 30, 2008, compared to the same period in 2007, remained flat. As a percentage of revenue, sales and marketing expenses for the three and nine months ended September 30, 2008, increased to 42% and 44%, respectively, compared to 38% in the same periods in 2007. This increase in sales and marketing expenses as a percentage of revenue was primarily attributable to lower than-expected U.S. revenue.

Our general and administrative expenses for the three and nine months ended September 30, 2008, compared to the same periods in 2007, decreased 16% and 5%, respectively, but increased slightly as a percentage of revenue due to lower levels of revenue.

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 in this Form 10-Q.

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, 2007 filed with SEC on March 13, 2008. There have been no significant changes during the nine months ended

Edgar Filing: CUTERA INC - Form 10-Q

September 30, 2008 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, 2007, except for the items discussed below.

Fair Value Measurements

With effect from January 1, 2008, we adopted the fair value measurement provisions of Statement of Financial Accounting Standards, or SFAS, No. 157 *Fair Value Measurements*. This statement does not require any new fair value measurements. More specifically, SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and sets out a fair value hierarchy, which ranks the quality and reliability of the information used to determine fair value. SFAS No. 157 was effective January 1, 2008 for financial assets and liabilities and will be effective January 1, 2009 for non-financial assets and liabilities. For details on the adoption of SFAS No. 157 for financial assets and liabilities, see Note 1 *Summary of Significant Accounting Policies* to our Condensed Consolidated Financial Statements. We are currently evaluating the effect, if any, of the adoption of this statement for non-financial assets and liabilities on our financial condition and results of operations.

At September 30, 2008, total financial assets measured and recognized at fair value were \$109.4 million and of these assets, \$11.0 million, or 10%, were financial assets that were measured and recognized using significant unobservable inputs (Level 3). These assets were AAA to Aa3 rated municipal bonds, with an auction interest rate reset feature, known as auction rate securities (ARS). There were no non-financial assets or liabilities measured at fair value as of September 30, 2008.

The ARS held in our investment portfolio, were guaranteed either by the Federal Family Education Loan Program (FFELP) or the Maine Education Loan Authority (MELA), and were issued for the purpose of financing student loans. ARS have historically traded at par and are redeemable at par plus accrued interest at the option of the issuer. Interest is typically paid at the end of each auction period. Until February 2008, the market for our ARS portfolio was highly liquid. Starting in February 2008, a substantial number of auctions failed, meaning that there was not enough demand to sell all of the securities that holders desired to sell at auction. The immediate effect of a failed auction is that such holders cannot sell the securities at auction and the interest rate on the security generally resets to a maximum interest rate. In the case of funds invested by us in ARS which are the subject of a failed auction, we may not be able to access the funds without a loss of principal, unless a future auction of these investments are successful or the issuers redeem the securities. As of September 30, 2008, all of our ARS investment balance is classified as long term investments because of our belief that it could take more than one year before they are readily marketable. In addition, we also modified our current investment strategy and increased our investments in more liquid money market funds.

Given observable ARS market information was not available to determine the fair value of our ARS portfolio, we compared the fair value of our securities to a model using the discount rate adjustment technique as well as transaction data and bid-ask spread data for other similar illiquid securities from a secondary market. In determining the fair value using the discount rate adjustment technique, there were several significant assumptions, including:

Projected interest income (2.85% to 4.08%) and principal payments through the legal maturity of the securities.

Market risk adjusted discount rate, which was based on the one month London Inter-Bank Offered Rate of 3.93% as of September 30, 2008, adjusted for an expected yield premium of approximately 200 basis points to compensate for the current lack of liquidity resulting from failing auctions for such securities.

Table of Contents

No default or credit risk adjustments to the discount rate, given the ARS in our portfolio were all AAA to Aa3 rated by a nationally recognized rating agency, collateralized by student loans and repayment of the underlying obligations is guaranteed by either a U.S. federal or municipal government institution.

While our valuation model was based on both Level 2 (credit quality and interest rates) and Level 3 inputs, we determined that the Level 3 inputs were the most significant to the overall fair value measurement, particularly the estimates of risk adjusted discount rates. For definitions of Level 2 and Level 3 inputs see *Note 1 Summary of Significant Accounting Policies* of the Condensed Consolidated Financial Statements in Part I, Item I of this Form 10-Q. Based on the results of our fair value measurement, the net carrying value of our ARS as of September 30, 2008 was \$11.0 million, which was classified as Long term investments on our Condensed Consolidated Balance Sheet.

The valuation of the ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the valuation of our ARS portfolio in the future include: changes to credit ratings of the securities, as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

We determine if an investment is other-than-temporarily impaired by performing quarterly reviews of our portfolio of investments. If the cost of an investment exceeds its fair value, in making the judgment of whether there has been an other-than-temporary impairment, we consider available quantitative and qualitative evidence, including, among other factors, our intent and ability to hold the investment to maturity, the duration and extent to which the fair value is less than cost, specific adverse conditions related to the financial health of and business outlook for the investee and rating agency actions. Once a decline in fair value is determined to be other-than-temporary, we record an impairment charge to our statement of operations and a new cost basis in the investment is established.

Since February 2008, due to the lack of liquidity experienced in the global credit and capital markets, and specifically in the ARS market, our ARS have experienced failed auctions and the estimated market values continue to decline. As a result, as of September 30, 2008 we concluded that the previously unrealized loss on our ARS investments was other-than-temporary and therefore recognized approximately \$2.4 million as an impairment of long term investments, with a corresponding decrease in *Accumulated Other Comprehensive Loss*, during the third quarter ended September 30, 2008.

The valuation of our investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact its valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, liquidity and ongoing strength and quality of credit markets. If the current market conditions deteriorate further, or the anticipated recovery in market values does not occur, we may be required to record additional impairment charges in future quarters.

We continue to monitor the market for ARS and consider its impact, if any, on the fair value of our ARS investments.

Recent Accounting Pronouncements

For a full description of recent accounting pronouncements, including the respective expected dates of adoption and effects on results of operations and financial condition see *Note 2 Summary of Significant Accounting Policies - Recent Accounting Pronouncement* of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Consolidated Statement of Operations- Operating Ratios:				
Net revenue	100%	100%	100%	100%
Cost of revenue	41%	34%	39%	34%
Gross margin	59%	66%	61%	66%

Edgar Filing: CUTERA INC - Form 10-Q

Operating expenses:				
Sales and marketing	42%	38%	44%	38%
Research and development	10%	6%	9%	7%
General and administrative	13%	11%	13%	12%
Total operating expenses	65%	55%	66%	57%
Income (loss) from operations				
Interest and other income, net	3%	4%	4%	4%
Other-than-temporary impairment on long term investments	(12)%	0%	(3)%	0%
Income (loss) before income taxes				
Provision (benefit) for income taxes	(1)%	4%	0%	4%
Net income (loss)				
	(14)%	11%	(4)%	9%

Net Revenue

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Revenue mix by geography:						
United States	\$ 9,498	(46)%	\$ 17,747	\$ 34,266	(30)%	\$ 48,717
International	9,612	(8)%	10,396	31,216	18%	26,556
Consolidated total revenue	\$ 19,110	(32)%	\$ 28,143	\$ 65,482	(13)%	\$ 75,273
<i>United States as a percentage of total revenue</i>	<i>50%</i>		<i>63%</i>	<i>52%</i>		<i>65%</i>
<i>International as a percentage of total revenue</i>	<i>50%</i>		<i>37%</i>	<i>48%</i>		<i>35%</i>
Revenue mix by product category:						
Products	\$ 12,920	(34)%	\$ 19,633	\$ 46,610	(16)%	\$ 55,644
Product Upgrades	1,948	(61)%	5,019	6,333	(36)%	9,839
Service	2,920	25%	2,333	8,311	32%	6,308
Titan handpiece refills	1,322	14%	1,158	4,228	21%	3,482
Consolidated total revenue	\$ 19,110	(32)%	\$ 28,143	\$ 65,482	(13)%	\$ 75,273

Table of Contents

For the three and nine months ended September 30, 2008, compared to the same periods in 2007, our U.S. revenue decreased by 46% and 30%, respectively. We believe that the current market conditions may be causing our non-core physician prospects to defer a purchasing decision at this time, even though most of these physicians may not be limited by credit barriers. Further, we believe that a segment of our business – those aesthetic practices that operate in settings that are not medical offices – are being particularly affected by the economic environment and may be finding it more difficult to obtain credit financing. This may be resulting in them delaying their purchase decisions. Also, FDA clearance for our Pearl product was received in early 2007, which allowed us to begin shipping our Pearl product in July 2007 and provided significant Upgrade revenue for the third quarter of 2007. In contrast, our Pearl Fractional product started shipping at the end of the third quarter of 2008, which resulted in lower Upgrade revenue in that period.

For the three and nine months ended September 30, 2008, compared to the same period in 2007, our international revenue decreased by 8% and increased by 18%, respectively. The decrease in international revenue for the three months ended September 30, 2008, compared to the same period last year, was primarily due to difficult economic conditions in some of our overseas markets. The increase in international revenue for the nine months ended September 30, 2008, compared to the same period in 2007, was primarily attributable to the continuing investments in developing our global infrastructure. These efforts have resulted in increased revenue from several of our geographic locations, including Europe and emerging global markets.

For the three and nine months ended September 30, 2008, compared to the same periods in 2007, our Product revenue decreased by 34% and 16%, respectively. This reflects slower revenue growth in the U.S. due to an uncertain worldwide economy, partially offset by higher international sales of our multi-application Xeo and CoolGlide products. Our Upgrade revenue in the third quarter and nine months ended September 30, 2008, compared to the same periods in 2007, decreased by 61% and 36%, respectively. This decrease was primarily attributable to reduced Upgrade revenue from our Pearl product, which accounted for significant Upgrade revenue in the third quarter of 2007. In contrast, our Pearl Fractional product started shipping at the end of the third quarter of 2008, which resulted in lower Upgrade revenue in that period.

Our service revenue increased by 25% and 32% in the three and nine months ended September 30, 2008, compared to the same periods in 2007, due primarily to a larger installed base of customers who are eligible to purchase extended service contracts. However, our sequential service revenue growth rates are declining as a result of fewer customers electing to purchase service contracts. We believe this reduced customer demand for service contracts is due to the challenging economic environment. Our Titan hand piece refills revenue increased 14% and 21% in the three and nine months ended September 30, 2008, compared to the same periods in 2007, due primarily to an increase in the installed base and grater utilization. Although we experienced modest growth when compared to year-ago periods, we have experienced flat sequential revenue in this category during the past four quarters. This revenue trend indicates a declining utilization level which we believe is caused by a softening economy.

Gross Profit

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Gross Profit	\$ 11,287	(39)%	\$ 18,536	\$ 40,169	(20) %	\$ 49,975
As a percentage of total revenue	59%		66%	61%		66%

Our cost of revenue consists primarily of material, labor, stock-based compensation, royalty expense, warranty and manufacturing overhead expenses. For the three and nine months ended September 30, 2008, our gross margin declined to 59% and 61%, respectively, compared to 66% in the same periods of 2007. This decrease in gross margin was primarily attributable to:

Higher service and Titan refill revenue, as a percentage of total revenue, which have a lower gross margin than our Product and Upgrade revenue categories;

Increased level of international distributor business, which has slightly lower gross margins than our direct business; and

Lower than expected overall revenue, which reduced the leverage of our manufacturing and service department expenses and was dilutive to our gross margin percentage in the short term.

Sales and Marketing

Edgar Filing: CUTERA INC - Form 10-Q

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Sales and marketing	\$ 8,076	(24)%	\$ 10,586	\$ 28,786	%	\$ 28,839
As a percentage of total revenue	42%		38%	44%		38%

Sales and marketing expenses consist primarily of labor, stock-based compensation, expenses associated with customer-attended workshops and trade shows, and advertising. In the three months ended September 30, 2008, compared to the same period in 2007, sales and marketing expenses decreased by \$2.5 million, and in the nine months ended September 30, 2008, compared to the same period in 2007, our sales and marketing expenses remained relatively flat. The decrease in expenses in the third quarter of 2008, compared to the same period in 2007, was primarily attributable to \$1.8 million of lower personnel expenses for North America, resulting from a reduction in head count and lower sales commission expenses. In the nine months ended September 2008, compared to the same period in 2007, expenses remained flat as lower sales and marketing expense in North America were more than offset by higher expenses in international sales and marketing. As a percentage of revenue, sales and marketing expenses for the three and nine months ended September 30, 2008, increased to 42% and 44%, respectively, compared to 38% in the respective periods of 2007. This increase was primarily attributable to lower-than-expected revenue in the United States.

Research and Development (R&D)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Research and development	\$ 1,828	4%	\$ 1,764	\$ 5,617	3%	\$ 5,435
As a percentage of total revenue	10%		6%	9%		7%

Research and development expenses consist primarily of labor, stock-based compensation, clinical, regulatory and material costs. In the three and nine months ended

Table of Contents

September 30, 2008, R&D expenses increased slightly from the same periods in the prior year and were 10% and 9% of net revenue, respectively, compared to 6% and 7% in the same periods in 2007. The slight increase in R&D expenses was a result of \$139,000 and \$217,000 of higher consultant fees incurred in the three and nine months ended September 30, 2008, compared to the same periods in 2007, respectively. This increase in R&D expenses as a percentage of revenue was primarily attributable to lower-than-expected revenue in the United States

General and Administrative (G&A)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
General and Administrative	\$ 2,583	(16)%	\$ 3,078	\$ 8,547	(5)%	\$ 8,996
As a percentage of total revenue	13%		11%	13%		12%

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. In the three and nine months ended September 30, 2008, compared to the respective periods in 2007, G&A expenses decreased by \$495,000 and \$449,000, respectively. The decrease in G&A expenses in the three and nine months ended September 30, 2008, compared to the same periods in 2007, was primarily attributable to lower personnel related expenses of \$517,000 and \$845,000, partially offset by higher professional consulting fees related to legal, accounting and tax related matters of \$108,000 and \$628,000, respectively. The increase in G&A expenses as a percentage of revenue was primarily attributable to lower-than-expected revenue in the United States.

In April and May 2007, two securities class action lawsuits were filed against us and were later consolidated into one lawsuit. Given that we retain director and officer liability insurance with a deductible, this litigation is not expected to have a material impact on our general and administrative expenses in the fourth quarter of 2008. In addition, in January 2008, a TCPA class action lawsuit was filed against us. We have not accrued for any potential liability associated with these lawsuits. For additional details relating to these lawsuits see Part II, Item 1 Legal Proceedings.

Interest and Other Income, Net

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Interest and other income, net	\$ 733	(33)%	\$ 1,096	\$ 2,491	(22)%	\$ 3,206

Interest and other income, net, decreased by 33% and 22% in the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, due primarily to reduced tax-exempt interest yields resulting primarily from the federal reserve cutting interest rates in 2008 and 2007.

Other-Than-Temporary Impairment of Long Term Investments

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	% Change	2007	2008	% Change	2007
Other-than-temporary impairment of long term investments	\$ 2,372	100%	\$	\$ 2,372	100%	\$

As explained in detail in the *Critical Accounting Policies and Estimates* section above, in the third quarter ended September 30, 2008, we recognized a \$2.4 million impairment charge relating to our non-current investments in ARS.

Provision for Income Taxes

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	Change	2007	2008	Change	2007
Income (loss) before income taxes	\$ (2,839)	\$ (7,043)	\$ 4,204	\$ (2,662)	(12,573)	\$ 9,911

Edgar Filing: CUTERA INC - Form 10-Q

Provision (benefit) for income taxes	(86)	(1,198)	1,112	(28)	(3,059)	3,031
Effective tax rate	3%		26%	1%		31%

Our interim effective income 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 (U.S. federal income tax credits in 2007 but not in 2008) and tax exempt interest income. The interim effective income tax rate is based on our best estimate of the annual effective income tax rate. The decrease in the effective tax rate for the three and nine months ended September 30, 2008, to 3% and 1%, respectively, compared to 26% and 31% for the same periods in 2007, respectively, was primarily attributable to tax exempt interest income being a larger percentage of the lower projected pre-tax income for fiscal year 2008, compared to fiscal year 2007.

With respect to the \$2.4 million impairment charge for ARS investments recognized in the third quarter ended September 30, 2008, we treated this for income tax purposes as a discrete item in the quarter. Given this impairment charge is a capital loss, we recorded a deferred tax asset but because we did not believe it is more likely than not realizable, we recorded a valuation allowance against the deferred tax asset. As a result, there was no effect on our total tax provision for the quarter and nine months ended September 30, 2008 for this charge.

The Emergency Economic Stabilization Act of 2008, which contains the Tax Extenders and Alternative Minimum Tax Relief Act of 2008, was signed into law on October 3, 2008. Under the Act, the research credit was retroactively extended for amounts paid or incurred after December 31, 2007 and before January 1, 2010. The effects of the change in the tax law will be recognized in our fourth quarter 2008 provision, which is the quarter in which the law was enacted. We do not expect the research credit that will be available to reduce our fourth quarter provision to be material.

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, long term 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 and Cash Equivalents, Marketable Investments and Long Term Investments Summary

The following table summarizes our cash and cash equivalents, marketable investments and long term investments (in thousands):

	September 30, 2008	December 31, 2007	Increase/ (Decrease)
Cash and cash equivalents	\$ 26,683	\$ 11,054	\$ 15,629
Marketable investments	71,662	88,510	\$ (16,848)
Long term investments	11,028	7,429	3,599
Total cash and cash equivalents, marketable investments and long term investments	\$ 109,373	\$ 106,993	\$ 2,380

Table of Contents**Cash Flows**

(Dollars in thousands)	Nine Months Ended September 30,	
	2008	2007
Net cash flow provided by (used in):		
Operating activities	\$ 5,870	\$ 11,856
Investing activities	9,496	7,346
Financing activities	263	(19,626)
Net increase (decrease) in cash and cash equivalents	\$ 15,629	\$ (424)

Cash Flows from Operating Activities

We generated net cash from operating activities of \$5.9 million for the nine months ended September 30, 2008, which was primarily attributable to:

\$4.7 million generated from net loss of \$2.6 million after adjusting for non-cash related items primarily consisting of \$4.0 million of stock-based compensation, other-than-temporary impairment of long term investments of \$2.4 million, depreciation and amortization of \$671,000, and other items of \$278,000, net;

\$4.1 million of cash generated from the collection of the higher accounts receivable balance as of December 31, 2007;

\$1.6 million of cash generated due to an increase in deferred revenue resulting primarily from higher service contract revenue; offset by

\$3.6 million used to pay down the higher year-end accrued liabilities relating primarily to personnel expenses of \$410,000, net reduction of \$1.1 million of the income tax payable due to the payment of the 2007 year-end income tax liability, net reduction of \$1.0 million of royalty accrual, and \$528,000 relating to the reduction in accrued warranty costs due primarily to fewer units remaining under warranty;

\$1.2 million cash used as a result of the increase in inventories due to the lower than expected revenue in the first nine months of 2008 and to ramp up production for our new Pearl Fractional product that started shipping in September 2008.

We generated net cash from operating activities of \$11.9 million in the nine months ended September 30, 2007, which was primarily attributable to:

\$6.9 million generated by net income adjusted for non-cash related items of \$6.0 million, net, (primarily \$4.3 million of stock-based compensation, \$681,000 of depreciation and amortization and \$545,000, net, of tax benefit from stock option exercises);

\$2.5 million generated by an increase in deferred revenue, due primarily to an increase in customers purchasing prepaid service contracts; offset by

Edgar Filing: CUTERA INC - Form 10-Q

\$1.9 million used to increase accounts receivable because a large percentage of our third quarter revenue shipped in the last month of the quarter; and

\$1.5 million of cash used to increase inventories, in preparation for the higher anticipated product shipments in the fourth quarter of 2007.

Cash Flows from Investing Activities

We generated \$9.5 million of cash from investing activities in the nine months ended September 30, 2008, which was primarily generated from:

\$68.1 million in net proceeds from the sales and maturities of marketable investments due to an attempt to reduce our exposure to the auction rate and variable rate demand note markets during the nine months ended September 30, 2008; offset by

\$58.1 million of cash used to purchase marketable and long term investments; and

\$538,000 cash used to purchase property and equipment primarily for the research and development function.

We generated \$7.3 million of cash in investing activities for the nine months ended September 30, 2007. This was primarily attributable to:

\$75.2 million in net proceeds from the sales and maturities of marketable investments due partly to fund the \$25 million share repurchase program; offset by

\$67.0 million of cash used to purchase marketable and long term investments; and

\$881,000 cash used to purchase property and equipment primarily for the research, development and manufacturing operations.

Cash Flows from Financing Activities

Net cash provided by financing activities in the nine months ended September 30, 2008 was \$263,000, which resulted from the proceeds of the issuance of stock through our stock option and employee stock purchase plans.

Net cash used by financing activities in the nine months ended September 30, 2007 was \$19.6 million, which was primarily attributable to \$25.0 million used to repurchase shares of our common stock pursuant to our stock repurchase program, partially offset by \$3.5 million of cash generated from the issuance of stock pursuant to our stock option and stock purchase plans and \$1.9 million of cash generated from the excess tax benefits related to the option exercises.

Adequacy of cash resources to meet future needs

We have cash, cash equivalents, marketable investments and long term investments of \$109.4 million as of September 30, 2008. Of this amount, we have \$11.0 million invested in student loan ARS that were rated AAA to Aa3 by a major credit rating agency and are either commercially insured or guaranteed by the FFELP or MELA. These securities were classified under the caption of "Long term investments" in the Condensed Consolidated Balance Sheet as auctions for these securities have been failing since February 2008 due to the current overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security prospectus, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our ARS into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. Based on our ability to access our cash, cash equivalents and other short term marketable investments and our expected operating cash flows, we do not anticipate the current lack of liquidity on these investments will affect our ability to operate our business as usual over the next twelve months.

Table of Contents**Contractual Cash Obligations**

The following summarizes our contractual obligations as of September 30, 2008 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	\$ 7,362	\$ 1,429	\$ 2,631	\$ 2,916	\$ 386
Income Tax Liability					

As of September 30, 2008, we have included in our Condensed Consolidated Balance Sheet \$1.4 million in long term income tax liability with respect to unrecognized tax benefits and accrued interest. As of September 30, 2008, we do not expect any unrecognized tax benefits to be paid within the next twelve months, nor can we make a reliable estimate when cash settlement with a taxing authority may occur. As a result, this amount is not included in the contractual obligations table above.

Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of September 30, 2008, we were not involved in any unconsolidated transactions.

Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, we have entered into indemnification agreements with each of our directors and executive officers. In 2007, two of our executive officers were named as defendants in securities class action litigation see Part II, Item 2 Legal Proceedings. Our exposure under the various indemnification obligations, including those under the indemnification agreements with our directors and executive officers, is unknown since the outcome of the securities litigation is unpredictable and the amount that could be payable thereunder is not reasonably estimable, and since other indemnification obligations involve future claims that may be made against us. We have not accrued or paid any amounts for any such indemnification obligations. However, we may record charges in the future as a result of these potential indemnification obligations, including those related to the securities class action litigation.

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 ARS 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 September 30, 2008 would have potentially declined by \$670,000.

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. To date, our exposure to exchange rate volatility has not been significant. 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 United States. 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.

Table of Contents***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 error 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 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 seek unspecified monetary damages. On November 1, 2007, the Court ordered the two cases consolidated. On December 17, 2007, the plaintiffs filed a consolidated, amended complaint, and on January 31, 2008, we filed a motion to dismiss that complaint. On September 30, 2008, in response to our motion, the Court issued an order dismissing the plaintiffs' amended complaint without prejudice, and allowed the plaintiffs thirty days to file a second amended complaint. On October 28, 2008, the plaintiffs filed a Notice Of Intention Not to File A Second Amended Consolidated Complaint. No final judgment has yet been entered in this case, and, upon entry of such a judgment, plaintiffs may choose to appeal the Court's prior order dismissing their first amended complaint. We intend to continue to defend this case vigorously, regardless of the stage of litigation. Although we retain director and officer liability insurance, 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. Since the outcome of this litigation is unpredictable and is not reasonably estimable, and since we do not believe that a significant adverse result for us is probable, no expense has been recorded with respect to the contingent liability associated with this matter.

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against us in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, Ltd., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that we violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, we removed the case to federal court in the Northern District of Illinois, and filed our response to the complaint on February 29, 2008. Although we are continuing to investigate the number of facsimiles transmitted during the period for which the plaintiff seeks class certification and the number of these facsimiles that were unsolicited within the meaning of the TCPA, we expect that the number of unsolicited facsimiles could be large and potential liability may be substantial as a result. We retain general liability insurance, with one insurer covering the first two years of the four-year period preceding the lawsuit, and a second insurer covering the latter two years of that four-year period. The first carrier has agreed to defend us subject to a reservation of rights. The second carrier has declined coverage. We intend to defend this case vigorously, including the plaintiff's allegations seeking class certification, regardless of the stage of litigation. Since the outcome of this litigation is unpredictable and not reasonably estimable, and since we do not believe that a significant adverse result is probable, no expense has been recorded with respect to the contingent liability associated with this matter.

ITEM 1A. RISK FACTORS

We are entering into a difficult economic period, and the uncertainty in the economy may increase stock price volatility, reduce customer demand for our products, and cause potential customers to delay their purchase decisions.

Current economic conditions have been unstable, and we may be entering, or already in, a global recession. In times of economic uncertainty or global recession individuals often reduce the amount of money that they spend on aesthetic procedures. This economic uncertainty may increase the volatility of our stock price, may reduce consumer demand for the elective procedures that are performed with our products, may cause potential customers to delay their capital equipment purchases, and may make it more difficult for potential customers to obtain credit financing necessary to purchase our products, each of which can have a material adverse effect on our revenue, profitability and business.

The initiatives that we are implementing in an effort to improve our sales productivity, revenue and income could be unsuccessful, which could harm our business and may further depress the price of our stock.

In an effort to improve our revenue and income levels, we have implemented during 2008 several strategic initiatives focusing on our worldwide sales and marketing infrastructure and product introductions.

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; and our efforts to improve our sales productivity, marketing efforts and product launches generally may result in instability to our operations, causing harm to our business and a further decline in our stock price.

We have new sales professionals in our sales team. If we are unable to effectively train, retain and manage these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Some of the sales professionals on our sales team have been in their respective roles for about a year or less. Our experience is that new sales professionals are at higher risk for employee turnover and generally take two to three quarters to achieve effective productivity levels. Our success largely depends on our ability to manage and improve the productivity levels of our sales professionals and worldwide distribution network. If we fail to manage, or do not improve the productivity of, any material part of that network, including the North American sales team, this could lead to reduced revenue and employee turnover, which could materially harm our business. If we experience significant levels of attrition among our sales professionals or our sales managers, our revenue and profitability may be adversely affected as a result.

Table of Contents

Lack of demand for our products in any of our markets would harm our anticipated revenue growth.

Most of our products are marketed to established dermatology and plastic surgeon medical offices, as well as the non-traditional businesses, such as family practitioners, primary care physicians, gynecologists, and non-medical models. Our most recent product introductions, Pearl and Pearl Fractional, are targeted at dermatology and plastic surgery offices. Continuing to achieve and maintain penetration into each of our markets is a material assumption of our growth strategy.

Demand for our products in any of our markets could be weakened by several factors including poor financial performance of market segments introducing aesthetic procedures to their businesses, reduced patient demand for elective aesthetic procedures, failure to build and maintain relationships with opinion leaders within the various market segments and an increase in malpractice lawsuits. If we do not achieve anticipated demand for our products in each of our market segments, our revenue may be adversely impacted.

To successfully market and sell our products internationally, we must address many issues that are unique to our overseas business.

Our international revenue represented approximately 50% and 48% of our revenue for the three and nine months ended September 30, 2008, respectively, in contrast to 37% and 35% for the three and nine months ended September 30, 2007, respectively. Increasing our percentage of revenue from international customers is a material component of our growth strategy. We depend on third-party distributors and a 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 if we are unable to engage distributors in particular geographic areas, we may not be able to realize international revenue growth. Additionally, if we are unable to retain and obtain satisfactory performance from our international direct sales 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;

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;

Edgar Filing: CUTERA INC - Form 10-Q

Lack of awareness of our brand in international markets;

Preference for locally-produced products; and

Reduced protection for intellectual property rights in some countries;

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

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

Our industry is subject to intense competition. 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, Sciton and several other companies. Additional competitors may enter the market, and we are likely to compete with new companies in the future. 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;

Table of Contents

Success and timing of new product development and introductions; and

Development of successful distribution channels, both domestically and internationally.

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

In addition, some of our current and potential competitors have significantly greater financial, research and development, 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. For example, Thermage announced a plan to acquire Reliant, and that planned merger is expected to close by the end of 2008. To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of performance, brand name, service and price, and this is difficult to do in a crowded market. 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. 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 and successfully introduce them or our revenue may decline.

Some of our competitors release new products more often and more successfully than we do. For example, in the second half of 2007, revenue from sales of our new Pearl product to new customers did not meet our expectations, although revenue from sales of Pearl upgrades to existing customers grew significantly. We believe that, to increase revenue from sales of new products and related upgrades, we need to continue developing our clinical support and increasing market awareness of the benefits of those new products. If we fail to successfully commercialize any of our products, our business could be harmed.

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 hand pieces 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 and skin rejuvenation, including the treating of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and pigmented lesions. Currently, these applications represent the majority of laser and other energy-based aesthetic procedures. To continue growing 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 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

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;

Table of Contents

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;

Consumer confidence and disposable income, which may be impacted by political and macroeconomic conditions, such as recession, continuing increases in energy and food prices, high unemployment rates, increased interest rates and subprime mortgage failures; and

The education of our customers and patients on the benefits and uses of our products, compared to competitors' products and technologies.

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, which could have a material adverse effect on our business, financial condition, revenue and result of operations.

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. PSS sales professionals work in coordination with our sales force to locate new customers for our products throughout the United States. For the years ended December 31, 2007 and 2006, approximately 14% and 15% of our revenue came from PSS, respectively. Although we have dedicated additional sales professionals to work closely with, and increase the focus and attention on, our PSS relationship, 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.

We may incur substantial expenses if our practices are shown to have violated the Telephone Consumer Protection Act, and defending ourselves against the related litigation could distract management and harm our business

A class action lawsuit was filed against us in January 2008 alleging violations under the federal Telephone Consumer Protection Act and related Illinois state laws. We will incur legal costs as a result of this litigation. Although we retain general liability insurance, one carrier has denied coverage, and the other has agreed to defend us subject to a reservation of rights. There can be no guarantee that any such insurance will cover the claims that are made, or will insure us for losses on covered claims.

We have not recorded a liability related to this lawsuit. However, we may determine in the future that an accrual is required, and we may be required to pay damages in respect of this lawsuit, any of which could materially and adversely affect our results of operations, cash flows and financial condition. Regardless of the outcome, this lawsuit may cause us to incur significant expenses, consume resources and divert the attention of our management and key personnel from our business operations. Each of these factors could harm our business.

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 this litigation 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. On November 1, 2007, the court ordered the two cases consolidated. We will incur legal costs as a result of this litigation. Although we retain director and officer liability insurance, 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 operating our business. Each of these factors could harm our business.

We hold auction-rate securities (ARS) in our portfolio of investments. Due to failed auctions for some of our auction rate investments since February 2008, we are unable to readily liquidate our ARS into cash, future earnings could be reduced if we have to take an impairment charge, our business could be harmed and our stock price could decline significantly as a result.

Edgar Filing: CUTERA INC - Form 10-Q

We invest our excess cash primarily in money market funds and in highly liquid debt instruments of the U.S. government and its agencies, U.S. municipalities, and in bonds of high-quality corporate issuers. At September 30, 2008, we had marketable securities of \$71.7 million and \$11.0 million of ARS, which are classified under the caption of Long term investments in the Condensed Consolidated Balance Sheets. These ARS provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days though auctions for some of the securities are held every 360 days. However, since February 2008, auctions for each of our investments in ARS have failed due to the current overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our ARS into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument.

If in the future we are unable to liquidate our investments in ARS, or there are further other-than-temporary impairments in their market value, our future earnings would be reduced, our business could be harmed and our stock price could decline significantly as a result.

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 and we may incur significant legal, accounting and banking fees in connection with such a transaction. In addition, if we purchase a company that is not profitable, our cash balances may be reduced or depleted, to fund such company's business. We do not have any experience as a team 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 could be dilutive to our stockholders.

Table of Contents

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 material acquisitions or collaborative projects.

The price of our common stock may fluctuate substantially. We have a limited number of shares of common stock outstanding, a large portion of which is held by a small number of investors, which could result in the increase in volatility of our stock price.

As of June 30, 2008, approximately 56% of our outstanding shares of common stock were held by ten institutional investors. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

Sales of large blocks of our common stock, including sales by our executive officers, directors and our large institutional investors;

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

Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' 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 own or will obtain patents that they may claim 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. In addition, 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.

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.

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 September 30, 2008, we had ten 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.

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 or maintain necessary FDA clearances for our products and indications, if clearances for future products and indications are delayed or not issued, if there are federal or state level regulatory changes or if we are found to have violated applicable FDA marketing rules, 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 there from may be adversely affected.

Table of Contents

Medical devices may be marketed in the United States only for the indications for which they are approved or cleared by the FDA. For example, we have FDA clearance to market our Titan product in the United States only for deep dermal heating, and are therefore prevented from promoting or advertising Titan in the United States for any other indications. If we fail to comply with these regulations, it could result in enforcement action by the FDA which could lead to such consequences as warning letters, adverse publicity, criminal enforcement action and/or third-party civil litigation, each of which could adversely affect us.

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. If we fail to comply with applicable regulatory requirements, it 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, it 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.

Edgar Filing: CUTERA INC - Form 10-Q

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. We may not be able to obtain additional 510(k) clearance or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearance would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability.

We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearance or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

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

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

Table of Contents

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 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.

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 could 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;

Edgar Filing: CUTERA INC - Form 10-Q

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.

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;

Table of Contents

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 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.

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 are 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.

Our profit margins may vary over time.

Our profit margins may be adversely affected by a number of factors, including decreases in our shipment volume, reductions in, or obsolescence of, our inventory, shifts in our product mix and increased expenses associated with repairing defective products covered by our warranty program. In addition, the competitive market environment in which we operate may adversely affect pricing for our products. Because we own most of our manufacturing capacity, a significant portion of our operating costs are fixed. If we experience a decrease in shipment volume, or have to reduce our pricing to remain competitive, or experience a greater than expected failure rate for any of our products, our gross and operating margins will be adversely impacted.

We are subject to fluctuations in the exchange rate of the U.S. dollar and foreign currencies.

We do not actively hedge our exposure to currency rate fluctuations. While we transact business primarily in U.S. Dollars, and a significant proportion of our revenue is denominated in U.S. Dollars, a portion of our costs and revenue is denominated in other currencies, such as the

Edgar Filing: CUTERA INC - Form 10-Q

Euro, Japanese Yen, Australian Dollar, Canadian Dollar and British Pound Sterling. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our net income (loss).

We are exposed to fluctuations in the market values of our portfolio investments and in interest rates.

Our investment portfolio consists of both high investment grade corporate and municipal securities that have a maximum effective maturity of up to two years. In addition to bonds, we have investments in ARS whose interest rates reset generally every 35 days though auctions for some of the ARS are held every 360 days. The longer the duration of a security, the more susceptible it is to changes in market interest rates and bond yields. As yields increase, those securities with a lower yield-at-cost show a mark-to-market unrealized loss. For example, assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of September 30, 2008 would have potentially decreased by \$670,000, resulting in an unrealized loss that would subsequently adversely impact our earnings. As a result, changes in the market interest rates will affect our future net income (loss).

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;

Table of Contents

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

Limitations on stockholder actions by written consent; and

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

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

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

We have never paid cash dividends on our common stock and do not 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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We did not sell any equity securities during the period covered by this report.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.2 ⁽¹⁾	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 ⁽¹⁾	Bylaws of the Registrant.
4.1 ⁽²⁾	Specimen Common Stock certificate of the Registrant.
10.14 ⁽³⁾	Cutera, Inc. 2004 Equity Incentive Plan, as amended by its Board of Directors on April 25, 2008.

Edgar Filing: CUTERA INC - Form 10-Q

- 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 with the SEC on March 25, 2005.
- (3) Incorporated by reference from our Definitive Proxy Statement on Form 14A filed with the SEC on April 28, 2008.

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 3rd day of November, 2008.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

**Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)**

INDEX TO EXHIBITS

Exhibit No.	Description
3.2 ⁽¹⁾	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 ⁽¹⁾	Bylaws of the Registrant.
4.1 ⁽²⁾	Specimen Common Stock certificate of the Registrant.
10.14 ⁽³⁾	Cutera, Inc. 2004 Equity Incentive Plan, as amended by its Board of Directors on April 25, 2008.
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 with the SEC on March 25, 2005.
- (3) Incorporated by reference from our Definitive Proxy Statement on Form 14A filed with the SEC on April 28, 2008.