

CUTERA INC  
Form 10-Q  
November 01, 2010

---

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, 2010

OR

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

For the transition period to .

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

(415) 657-5500  
(Registrant's telephone number, including area code)

Edgar Filing: CUTERA INC - Form 10-Q

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 26, 2010 was 13,607,421.

---

CUTERA, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
PART I FINANCIAL INFORMATION	
Item 1. <u>Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Operations</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	19
PART II OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	21
Item 1A <u>Risk Factors</u>	21
Item 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3. <u>Defaults Upon Senior Securities</u>	32
Item 4 <u>[Removed and Reserved]</u>	32
Item 5 <u>Other Information</u>	32
Item 6 <u>Exhibits</u>	32
<u>Signature</u>	33

---

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## CUTERA, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	September 30, 2010	December, 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$21,703	\$22,829
Marketable investments	69,154	76,780
Accounts receivable, net	3,024	3,327
Inventories	7,144	6,408
Deferred tax asset	204	175
Other current assets and prepaid expenses	2,855	2,785
<b>Total current assets</b>	<b>104,084</b>	<b>112,304</b>
Property and equipment, net	624	847
Long-term investments	6,683	7,275
Intangibles, net	685	829
Deferred tax asset, net of current portion	97	97
<b>Total assets</b>	<b>\$ 112,173</b>	<b>\$ 121,352</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$1,701	\$1,081
Accrued liabilities	5,821	9,048
Deferred revenue	5,757	6,160
<b>Total current liabilities</b>	<b>13,279</b>	<b>16,289</b>
Deferred rent	1,504	1,493
Deferred revenue, net of current portion	1,302	1,968
Income tax liability	566	749
<b>Total liabilities</b>	<b>16,651</b>	<b>20,499</b>
<b>Commitments and Contingencies (Note 8)</b>		
Stockholders' equity:		
Common stock	14	13
Additional paid-in capital	89,296	85,248

Edgar Filing: CUTERA INC - Form 10-Q

Retained earnings	8,016	17,254
Accumulated other comprehensive loss	(1,804 )	(1,662 )
Total stockholders' equity	95,522	100,853
Total liabilities and stockholders' equity	\$112,173	\$121,352

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

- 1 -

---

## CUTERA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net revenue	\$ 12,092	\$ 12,171	\$ 38,058	\$ 38,266
Cost of revenue	5,661	4,910	16,825	15,976
Gross profit	6,431	7,261	21,233	22,290
Operating expenses:				
Sales and marketing	5,799	5,112	18,612	18,186
Research and development	1,871	1,684	4,831	4,922
General and administrative	2,352	2,121	7,338	8,257
Litigation settlement	-	-	-	850
Total operating expenses	10,022	8,917	30,781	32,215
Loss from operations	(3,591 )	(1,656 )	(9,548 )	(9,925 )
Interest and other income, net	132	288	439	1,398
Loss before income taxes	(3,459 )	(1,368 )	(9,109 )	(8,527 )
Provision for income taxes	-	12,126	129	9,159
Net loss	\$(3,459 )	\$(13,494 )	\$(9,238 )	\$(17,686 )
Net loss per share:				
Basic and Diluted	\$(0.25 )	\$(1.01 )	\$(0.68 )	\$(1.33 )
Weighted-average number of shares used in per share calculations:				
Basic and Diluted	13,589	13,382	13,512	13,274

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

## CUTERA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2010	2009
<b>Cash flows from operating activities:</b>		
Net loss	\$(9,238 )	\$(17,686 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Stock-based compensation	3,670	3,396
Tax deficit from stock-based compensation		(2 )
Depreciation and amortization	560	664
Provision for excess and obsolete inventories	217	247
Provision for doubtful accounts receivable	(91 )	550
Gain on sale of marketable investments	74	103
Change in deferred tax asset	(29 )	10,540
<b>Changes in assets and liabilities:</b>		
Accounts receivable	394	2,607
Inventories	(953 )	1,796
Other current assets and prepaid expenses	1,613	469
Accounts payable	620	(478 )
Accrued liabilities	(3,058 )	(1,686 )
Deferred rent	(158 )	(46 )
Deferred revenue	(1,069 )	(3,039 )
Income tax liability	(183 )	(570 )
Net cash used in operating activities	(7,631 )	(3,135 )
<b>Cash flows from investing activities:</b>		
Acquisition of property and equipment	(193 )	(98 )
Proceeds from sales of marketable investments	38,800	20,794
Proceeds from maturities of marketable investments	34,135	10,560
Purchase of marketable investments	(66,617 )	(30,795 )
Net cash provided by investing activities	6,125	461
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options and employee stock purchase plan	380	436
Net cash provided by financing activities	380	436
Net decrease in cash and cash equivalents	(1,126 )	(2,238 )
Cash and cash equivalents at beginning of period	22,829	36,540
Cash and cash equivalents at end of period	\$21,703	\$34,302

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





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 medical device company engaged in the design, development, manufacture, marketing and servicing of laser and other energy-based aesthetics systems for practitioners worldwide. The Company offers aesthetic systems on three platforms—Xeo, CoolGlide, and Solera. The Xeo and Solera platforms offer multiple hand pieces and applications, which allow customers to upgrade their systems (Upgrades revenue). In addition to systems and upgrades revenue, the Company generate revenue from the sale of extended warranty contracts, labor and materials for products that are out of warranty, Titan hand piece refills, and the distribution of third party dermal filler and cosmeceuticals in Japan.

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.

Business Segment

In accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 280 guidance on disclosures about segments of an enterprise and related information, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. Our chief decision maker, as defined under the FASB's ASC 280 guidance, is a combination of the Chief Executive Officer; and the Executive Vice President and Chief Financial Officer. To date, the Company has viewed its operations, managed its business, and used one measurement of profitability for the one operating segment – the sale of aesthetic medical equipment and services, and distribution of cosmeceuticals and dermal filler products, to qualified medical practitioners. In addition, substantially all of the Company's long-lived assets are located in one facility in the United States. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's operating segment.

Unaudited Interim Financial Information

The financial information filed 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, 2009 Condensed Consolidated Balance Sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America (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, 2009 filed with the Securities and Exchange Commission, or SEC, on March 15, 2010.

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 Condensed Consolidated Financial Statements and the accompanying notes. Actual results could differ materially

from those estimates. On an ongoing basis, the Company evaluates these estimates, including those related to warranty obligation, sales commission, accounts receivable and sales allowances, provision for excess and obsolete inventories, fair values of marketable and long-term investments, fair values of acquired intangible assets, useful lives of intangible assets and property and equipment, recoverability of deferred tax assets, and effective income tax rates, among others. Management bases these 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, 2009 filed with the SEC on March 15, 2010, and have not changed significantly as of September 30, 2010.

#### Recent Accounting Updates

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, "Multiple-Deliverable Revenue Arrangements a Consensus of the FASB Emerging Issues Task Force" an update to ASC Topic 605, "Revenue Recognition." This update requires the allocation of consideration among separately identified deliverables contained within an arrangement, based on their related selling prices. This update will be effective for annual reporting periods beginning January 1, 2011. The Company is currently evaluating the impact of this update on its financial position, results of operations, cash flows, and disclosures.

TABLE OF CONTENTS

In January 2010, the FASB issued ASU No. 2010-06, “Improving Disclosures about Fair Value Measurements” an update to ASC Topic 820, “Fair Value Measurements and Disclosures.” This update requires an entity to: (i) disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for the transfers and (ii) present separate information for Level 3 activity pertaining to gross purchases, sales, issuances, and settlements. This guidance became effective for us in the quarter ended March 31, 2010, except that the disclosure on the roll forward activities for Level 3 fair value measurements will become effective for us with the reporting period beginning January 1, 2011. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on our financial statements.

## 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 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 (in thousands):

	Amortized Cost	September 30, 2010		Fair Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Cash and cash equivalents	\$21,703	\$—	\$—	\$21,703
Marketable investments- debt securities	69,086	79	(11 )	69,154
Long-term investments in auction rate securities	8,325	—	(1,642 )	6,683
Total cash and cash equivalents, marketable investments and long-term investments	\$99,114	\$79	\$(1,653 )	\$97,540
	Amortized Cost	December 31, 2009		Fair Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Cash and cash equivalents	\$22,829	\$—	\$—	\$22,829
Marketable investments:				
Municipal securities	76,512	182	(14 )	76,680
Auction rate securities	100	—	—	100
Total marketable investments	76,612	182	(14 )	76,780
Long-term investments in auction rate securities	8,875	—	(1,600 )	7,275
Total cash and cash equivalents, marketable investments and long-term investments	\$108,316	\$182	\$(1,614 )	\$106,884

## Fair Value of Financial Instruments:

Fair value is defined 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. The fair value hierarchy distinguishes 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 are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- 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.

TABLE OF CONTENTS

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.

As of September 30, 2010, 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	\$20,061	\$—	\$—	\$20,061
Securities available for sale:				
Marketable investments—debt securities	—	69,154	—	69,154
Long-term investments—auction rate securities	—	—	6,683	6,683
Total assets at fair value	\$20,061	\$69,154	\$6,683	\$95,898

The Company's Level 1 financial assets are money market funds and highly liquid debt instruments of U.S. federal and municipal governments and their agencies with stated maturities of three months or less from the date of purchase, whose fair values are based on quoted market prices. The Company's Level 2 financial assets are highly liquid debt instruments of U.S. federal and municipal governments and their agencies as well as corporate bonds issued with a Federal Deposit Insurance Corporations (FDIC) guarantee under the U.S. Treasury Department's Temporary Liquidity Guarantee Program (TLGP). These securities have stated maturities of greater than three months, whose fair values are obtained from readily-available pricing sources for the identical underlying security that may, or may not, be actively traded.

At September 30, 2010, observable market information was not available to determine the fair value of the Company's Auction Rate Securities (ARS) investments. Therefore, the fair value is based on 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 valuations 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.

The table presented below summarizes the change in carrying value of the Company's financial assets (in thousands):

	Level 1	Level 2	Level 3	Total
Beginning balance, January 1, 2010	\$19,346	\$76,780	\$7,275	\$103,401
Total gains or losses:				
Included in earnings (or changes in net assets)	1	(75 )	—	(74 )
Included in other comprehensive loss	(31 )	(27 )	(42 )	(100 )
Purchases, issuance, sales and settlements (net)	745	(7,524 )	(550 )	(7,329 )
Ending balance, September 30, 2010	\$20,061	\$69,154	\$6,683	\$95,898

Other Current Assets and Prepaid Expenses:

Other current assets and prepaid expenses consist of the following (in thousands):

September	December
30,	31,
2010	2009

Edgar Filing: CUTERA INC - Form 10-Q

Tax receivable	\$1,526	\$1,517
Deposits	661	737
Prepaid expense	668	531
Total	\$2,855	\$2,785

Inventories:

Inventories consist of the following (in thousands):

	September 30, 2010	December 31, 2009
Raw materials	\$4,299	\$3,775
Finished goods	2,845	2,633
Total	\$7,144	\$6,408

Intangible Assets:

Intangible assets comprise a patent sublicense acquired from Palomar in 2006, a technology sublicense acquired in 2002 and an

TABLE OF CONTENTS

other intangible asset acquired in 2007. The components of intangible assets were as follows (in thousands):

	September 30, 2010		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$1,218	\$(620)	\$598
Technology sublicense	538	(451)	87
Total	\$1,756	\$(1,071)	\$685

	December 31, 2009		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$1,218	\$(517)	\$701
Technology sublicense	538	(410)	128
Other intangible	20	(20)	—
Total	\$1,776	\$(947)	\$829

Amortization expense for intangible assets was \$144,000 for the nine months ended September 30, 2010 and \$148,000 for the nine months ended September 30, 2009.

Based on intangible assets recorded at September 30, 2010, 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,	
2010 (remainder)	\$48
2011	192
2012	158
2013	138
2014	138
Thereafter	11
Total	\$685

### Note 3. Warranty and Service Contract

#### Warranty Obligations

The Company historically provided a standard one-year or two-year warranty coverage on its systems. Beginning in September 2009, the Company changed its warranty policy to a one-year standard warranty on all 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. To determine the estimated warranty reserve, the Company utilizes actual service records to calculate the average service expense per system and applies this to the equivalent number of units exposed under warranty. 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, 2010 and 2009 (in thousands):

	September 30,	
	2010	2009
Beginning Balance	\$1,049	\$1,916
Add: Accruals for warranties issued during the period	2,058	1,402
Less: Settlements made during the period	(2,447 )	(2,229 )
Ending Balance	\$660	\$1,089

Deferred Service Contract revenue

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

The following table provides changes in deferred service contract revenue for the nine months ended September 30, 2010 and 2009 (in thousands):

	September 30,	
	2010	2009
Beginning Balance	\$8,128	\$11,665
Add: Payments received	6,004	4,643
Less: Revenue recognized	(7,210 )	(7,682 )
Ending Balance	\$6,922	\$8,626

Costs incurred under service contracts were \$3.2 million for the nine months ended September 30, 2010 and \$3.5 million for the nine months ended September 30, 2009 and are recognized as incurred.

Note 4. Stock-based Compensation Expense

Total pre-tax stock-based compensation expense by department recognized during the three and nine months ended September 30, 2010 and 2009 was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2010	2009	2010	2009
Cost of revenue	\$191	\$161	\$566	\$568
Sales and marketing	214	250	476	817
Research and development	316	116	904	364
General and administrative	360	368	1,724	1,647
Total stock-based compensation expense	\$1,081	\$895	\$3,670	\$3,396

Note 5. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the year. 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.

Weighted Average Shares Outstanding

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



	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Numerator:</b>				
Net loss – Basic and Diluted	\$(3,459 )	\$(13,494 )	\$(9,238 )	\$(17,686 )
<b>Denominator:</b>				
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per share	13,589	13,382	13,512	13,274

**Anti-dilutive securities**

The following number of shares outstanding, prior to the application of the treasury stock method, were excluded from the computation of diluted net 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,	
	2010	2009	2010	2009
Options to purchase common stock	3,484	2,846	3,110	2,769
Restricted stock units	72	-	40	7
Employee stock purchase plan shares	23	29	45	63
Total	3,579	2,875	3,195	2,839

**Note 6. Income Taxes**

The Company's income tax provision for the three and nine months ended September 30, 2010 is primarily related to income taxes of the Company's non U.S. operations. The Company's income tax provision for the three and nine months ended September 30, 2009 reflects applicable United States federal and state income tax and the tax impact of non-U.S. operations, reduced primarily by tax exempt interest income and research and development (R&D) tax credit. The Company recorded an

TABLE OF CONTENTS

income tax provision of less than \$1,000 during the three months ended September 30, 2010 and \$129,000 during the nine months ended September 30, 2010. The Company recorded an income tax provision of \$12.1 million during the three months ended September 30, 2009 and \$9.2 million during the nine months ended September 30, 2009.

The Company utilizes the asset and liability method of accounting for income taxes, under which deferred taxes are determined based on the temporary differences between the financial statement and tax basis of assets and liabilities using tax rates expected to be in effect during the years in which the basis differences reverse. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. In evaluating the ability to recover deferred tax assets, the Company considered available positive and negative evidence giving greater weight to its recent cumulative losses and its ability to carryback losses against prior taxable income and lesser weight to its projected financial results due to the challenges of forecasting future periods. The Company also considered, commensurate with its objective verifiability, the forecast of future taxable income including the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. At the end of the third quarter of 2009, changes in previously anticipated expectations necessitated a valuation allowance against the U.S. operations historical excess tax benefits to be recognized in that quarter since they were no longer more likely than not realizable. Under current tax laws, this valuation allowance will not limit the Company's ability to utilize federal and state deferred tax assets provided it can generate sufficient future taxable income.

As of the end of the second quarter of 2010, there were no material changes to either the nature or the amounts of the uncertain tax positions previously determined and disclosed pursuant to FASB ASC Topic 740, at the end of 2009.

## Note 7. Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss	\$(3,459 )	\$(13,494 )	\$(9,238 )	\$(17,686 )
Net change in unrealized gain (loss), on available-for-sale-securities	(54 )	(105 )	(142 )	1,635
Change in income tax effect on unrealized gain (loss) on available-for sale-securities	—	(66 )	—	1
Comprehensive loss	\$(3,513 )	\$(13,665 )	\$(9,380 )	\$(16,050 )

## Note 8. Commitments and Contingencies

## Facility Leases

The Company leases its Brisbane, California, office and manufacturing facility under a non-cancelable operating lease. In August 2010, the Company renegotiated its lease and extended it for another four year term which expires December 31, 2017. In addition, the Company has leased office facilities in certain international countries, including: Japan, Switzerland, France, and Spain. As of September 30, 2010, the Company was committed to minimum lease payments for facilities and other leased assets under long-term non-cancelable operating leases as follows (in thousands):

Fiscal Year Ending December 31,	
2010 (remainder)	\$469
2011	1,652
2012	1,498
2013	1,278
2014	1,232
Thereafter	3,922
Future minimum rental payments	\$10,051

#### Purchase Commitments

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments were not material at September 30, 2010.

#### 2009 Restructuring Charges

## TABLE OF CONTENTS

In accordance with FASB ASC 420-10-50 and SAB Topic 5.P.4, the Company recognized a total of \$976,000 in restructuring charges during the year ended December 31, 2009. These benefits were provided to then current employees that were involuntarily terminated under the terms of one-time benefit arrangements during the year. The Company implemented three reduction-in-force (RIF) programs in 2009: January 2009, May 2009 and August 2009. In general, the company-wide RIF programs specifically targeted positions that were directly impacted by the business slow down, such as sales, customer relations, manufacturing, and service. All employees terminated under these programs were notified within the quarter the severance and benefit expenses were recognized. The Company did not exit, dispose, terminate, or relocate any business activities and it did not materially change either the scope of, or the manner in which it conducted business following the headcount reductions. The Company incurred severance and benefits expenses accrued under one-time benefit arrangements of \$96,000 for the three months and \$976,000 for the nine months ended September 30, 2009, and the severance liability was \$14,000 at September 30, 2009. There were no remaining obligations associated with the 2009 RIF at December 31, 2009.

### Litigation

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against the Company in January 2008. In the third quarter of 2009, following negotiations between the parties, the parties entered into a settlement agreement that would resolve the case on a class-wide basis. On April 6, 2010, the Court gave its final approval for the settlement. Under the terms of the settlement, the Company paid a total of \$950,000 in exchange for a full release of facsimile-related claims. The Company included \$850,000 in its 2009 Condensed Consolidated Statements of Operations for the cost of the settlement, net of the administrative expenses recovered from its insurance carrier.

### Other Legal Matters

In addition to the foregoing lawsuits, the Company is named from time to time as a party to product liability and contractual lawsuits in the normal course of its business. As of September 30, 2010, the Company was not a party to any material pending litigation other than those described above in the "Litigation" section.

### 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 entered into indemnification agreements with each of its directors and executive officers. The Company's exposure under its various indemnification obligations, including those under the indemnification agreements with its directors and executive officers, is unknown since 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 to date.

### Note 9. Subsequent Events

Management evaluated all activity of the Company and concluded that no subsequent events have occurred that would require recognition in the Condensed Consolidated Financial Statements or disclosure in Notes to Condensed Consolidated Financial Statements as of September 30, 2010.

## TABLE OF CONTENTS

### 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 condensed consolidated financial statements and notes thereto, and with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2009 as contained in our annual report on Form 10-K filed with the SEC on March 15, 2010. This quarterly report, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Throughout this report, and particularly in this Item 2, the forward-looking statements are based upon our current expectations, estimates and projections and reflect our beliefs and assumptions based upon information available to us at the date of this report. In some cases, you can identify these statements by words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “potential” or “continue,” and other similar terms. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and assumptions that are difficult to predict. Our actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements relating to our future financial performance, the ability to grow our business, increase our revenue, manage expenses, generate additional cash, achieve and maintain profitability, develop and commercialize existing and new products and applications, and improve the performance of our worldwide sales and distribution network, and 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 21, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. We caution you to not 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, 2010.

#### Executive Summary

#### Company Description

We are a global medical device company engaged in the design, development, manufacture, marketing and servicing of laser and other energy-based aesthetics systems for practitioners worldwide. We offer aesthetic systems on three platforms—Xeo, CoolGlide, and Solera— for use by physicians and other qualified practitioners to allow our customers to offer safe and effective aesthetic treatments to their customers. The Xeo and Solera platforms offer multiple hand pieces and applications, which allow customers to upgrade their systems (Upgrades revenue). In addition to systems and upgrades revenue, we generate revenue from the sale of extended warranty contracts, labor and materials for products that are out of warranty, Titan hand piece refills, and the distribution of third party dermal filler and cosmeceuticals in Japan.

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

## TABLE OF CONTENTS

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, Titan hand piece refills, and dermal fillers and cosmeceuticals. Product revenue represents the sale of a system platform, which consists of a console that incorporates a universal graphic user interface, a laser and/or other energy-based module, control system software and high voltage electronics, and one or more hand pieces. However, depending on the application, the laser or other energy-based module is sometimes contained in the hand piece, such as with our Pearl and Pearl Fractional applications, 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 to their system as their practice grows. This enables customers to upgrade their systems whenever they want and provides us with a source of recurring revenue, which we classify as Upgrades revenue. Service revenue includes extended warranty contracts and services on out-of-warranty products, which is comprised of labor and material. Service revenues from extended warranty contracts are deferred and amortized over the lives of the associated contracts and services on out-of-warranty products are recognized at the time the services are provided. 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 has been used.

In addition, we have distribution agreements with BioForm, Inc. (BioForm), acquired by Merz Pharma Group in January 2010, to distribute its Radiesse® dermal filler product in Japan, and with Obagi Medical Products, Inc. (Obagi) to distribute its cosmeceuticals, or skin care products, in Japan. In addition, we offer Obagi products as part of an introductory promotion program pursued by us and Obagi in the U.S. and Canadian markets. Revenue from these arrangements is shown under the category of Dermal filler and cosmeceuticals. In December 2009, we entered into a distribution agreement with Sound Surgical Technologies, LLC (SST) to distribute its VASER® Lipo System in certain European countries and Canada. However, in September 2010, we decided to discontinue distributing the VASER product.

### Significant Business Trends

#### Growth

We believe that our ability to grow revenue will be primarily dependent on the following:

- Continuing to expand our product offerings.
- Investments made in our global sales and marketing infrastructure.
- Use of clinical results to support new aesthetic products and applications.
- Enhanced luminary development and reference selling efforts (to develop a location where our products can be displayed and used to assist in selling efforts).
  - Customer demand for our products and consumer demand for the applications they offer.
- Marketing to physicians in the core dermatology and plastic surgeon specialties, as well as outside those specialties.
- Generating Service, Upgrade, Titan hand piece refill, and Dermal filler and cosmeceuticals revenue from our growing installed base of customers.

#### U.S. Revenue

Our U.S. revenue decreased by 13% in the three months and 14% in the nine months ended September 30, 2010, compared to the same periods in 2009. We believe these decreases are, in part, due to:

- many of our current and prospective customers that do not have established medical offices continue to be reluctant to purchase capital equipment. In times of general economic uncertainty and tight credit, individuals often reduce or delay their capital equipment purchase decisions;
  - there continues to be a lack of availability of consumer credit for some of our customers that do not have established medical offices, e.g. Med - Spas, which is contributing to reduced volume; and
- lower average selling price (ASP), which is resulting from our customers purchasing fewer applications on our platforms and competitive pricing pressures in the marketplace.

#### Voluntary Titan XL Recall

In 2010, we initiated a voluntary recall of our Titan XL hand pieces. As part of the voluntary recall program, we provided our customers with a fully “refilled” Titan XL hand piece. As a result of this voluntary recall, our Titan hand piece refill revenue



## TABLE OF CONTENTS

decreased 50% in the three months and 28% in the nine months ended September 30, 2010, compared to the same periods in 2009. Further, in our results of operations, we recorded an expense \$487,000 in 2010, for the estimated cost of this voluntary recall. These factors adversely affected our gross margin in each of the quarters in 2010, compared to the same periods in 2009.

### Discontinuation of Distribution Agreement

In September 2010, we decided to discontinue distributing the VASER product in European countries and Canada. As such, we recorded an expense of \$171,000 in the third quarter of 2010 to write down our VASER inventory.

### 2009 Reduction in Force

In 2009, in response to the economic environment and our reduced revenue in 2008 and 2009, we reduced our company-wide workforce by approximately 18% and implemented other cost-reduction measures in the first-half of 2009. The headcount reductions impacted all departments and functions and resulted in restructuring charges of approximately \$880,000 in the first-half of 2009. As a result of these cost-reduction measures, our operating expenses declined in the nine months ended September 30, 2010, compared to the same period in 2009.

### 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 future performance depends on our ability to compete successfully. Additionally, our future performance is dependent upon our ability to continue to expand our product offerings, develop 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 execute on the aforementioned initiatives, our business would be adversely affected. A detailed discussion of these and other factors that could impact our future performance are provided in Part II, Item 1A “Risk Factors” section below.

### Critical Accounting Policies and Estimates.

The preparation of our Condensed Consolidated Financial Statements and related disclosures in conformity with generally accepted accounting principles in the United States, or GAAP, requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates, judgments and assumptions are based on historical experience and on various other factors that we believe are reasonable under the circumstances. We periodically review our estimates and make adjustments when facts and circumstances dictate. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected.

Critical accounting estimates, as defined by the Securities and Exchange Commission (SEC), are those that are most important to the portrayal of our financial condition and results of operations and require our management’s most difficult and subjective judgments and estimates of matters that are inherently uncertain. The accounting policies and estimates that we consider to be critical, subjective, and requiring judgment 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, 2009 filed with SEC on March 15, 2010. There have been no significant changes to the accounting policies and estimates disclosed in our Form 10-K, except for our Titan XL voluntary recall program.

### Titan XL Voluntary Recall

In the first-half 2010, we initiated a voluntary recall of our global installed base of Titan XL hand pieces to replace certain components. We estimated the cost of the Titan XL voluntary recall to be \$487,000 based on the direct costs of

Edgar Filing: CUTERA INC - Form 10-Q

replacing certain components of the estimated number of hand pieces to be replaced. At September 30, 2010, our remaining accrual balance was \$11,000.

Recent Accounting Pronouncements

For a full description of recent accounting updates, including the respective expected dates of adoption and effects on results of operations and financial condition see Note 1 “Summary of Significant Accounting Policies – Recent Accounting Updates” in the Notes to 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 total revenue, net.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
<b>Operating Ratio:</b>								
Net revenue	100	%	100	%	100	%	100	%
Cost of revenue	47	%	40	%	44	%	42	%
Gross profit	53	%	60	%	56	%	58	%
<b>Operating expenses:</b>								
Sales and marketing	48	%	42	%	49	%	47	%
Research and development	16	%	14	%	13	%	13	%
General and administrative	19	%	17	%	19	%	22	%
Litigation settlement	—	%	—	%	—	%	2	%
Total operating expenses	83	%	73	%	81	%	84	%
Loss from operations	(30	)%	(13	)%	(25	)%	(26	)%
Interest and other income, net	1	%	2	%	1	%	4	%
Loss before income taxes	(29	)%	(11	)%	(24	)%	(22	)%
Provision for income taxes	—	%	100	%	—	%	24	%
Net loss	(29	)%	(111	)%	(24	)%	(46	)%

Percentages in this table and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments.

Total Net Revenue

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,				
	2010	% Change	2009	2010	% Change	2009		
<b>Revenue mix by geography:</b>								
United States	\$4,214	(13	)%	\$4,825	\$13,545	(14	)%	\$15,721
International	7,878	7	%	7,346	24,513	9	%	22,545
Consolidated total revenue	\$12,092	(1	)%	\$12,171	\$38,058	(1	)%	\$38,266
<b>United States as a percentage</b>								
of total revenue	35	%	40	%	36	%	41	%
<b>International as a percentage</b>								
of total revenue	65	%	60	%	64	%	59	%

## Revenue mix by product category:

Products (1)	\$5,767	(3	)%	\$5,964	\$18,888	1	%	\$18,758
Upgrades	1,414	5	%	1,352	3,955	(8	)%	4,307
Service	3,166	(1	)%	3,210	9,917	1	%	9,860
Titan hand piece refills	647	(50	)%	1,287	2,929	(28	)%	4,075
Dermal fillers and cosmeceuticals (1)	1,098	207	%	358	2,369	87	%	1,266
Consolidated total revenue	\$12,092	(1	)%	\$12,171	\$38,058	(1	)%	\$38,266

(1) Beginning in 2010, we classified revenue from sales of BioForm's Radiesse® dermal filler product in Japan and sales of Obagi's cosmeceuticals product in the revenue category 'Dermal filler and cosmeceuticals.' Previously, we classified these sales in the revenue category 'Products.' As such, we reclassified the 2009 revenue from BioForm's Radiesse® dermal filler product sales in Japan and Obagi cosmeceuticals product sales from 'Products' to 'Dermal filler and cosmeceuticals.'

## Discussion of Revenue by Product Type:

## Products Revenue

As explained in more detail in the Products section of the Executive Summary above, our Products consist of configurable system platform that includes a console and one or more hand pieces. Each Product is configured to give our customers the ability to select the combination of platform and hand pieces that provides the applications that best fit their practice.

Products revenue decreased 3% in the three months and increased 1% in the nine months ended September 30, 2010, compared to the same periods in 2009. The decrease in the three-month period was due primarily to a decline in the weighted average selling price (ASP) both in the U.S. and internationally; a decline in unit sales internationally, offset by an increase in unit sales in the U.S. The slight increase in the nine-month period was due primarily to higher units sold in the U.S. and internationally but at lower weighted ASPs. The decline in weighted ASPs resulted primarily from a combination of the following factors that are not stated in an order of magnitude as we are not able to separately quantify the impacts of each of these factors due to the custom system configuration of the units sold:

- customers purchasing fewer applications on our platforms; and
- competitive pricing pressures in the marketplace.

## Upgrades Revenue

As explained in more detail in the Products section of the Executive Summary above, our configurable system platforms allow customers to add applications to their existing systems to meet the changing needs of their practices. In some cases, when certain

## TABLE OF CONTENTS

applications are desired that are only available on a platform other than the one owned by the customer, the upgrades revenue will include a platform exchange and additional hand pieces.

Upgrades revenue increased 5% in the three months, compared to the same period in 2009. This increase was due primarily to: (i) an increase in hand piece upgrade unit sales (except Pearl Fractional), offset by a decline in our ASPs.

Upgrades revenue decreased 8% in the nine months ended September 30, 2010, compared to the same period in 2009. This decrease was due primarily to a decrease in hand piece weighted ASPs, coupled with an unfavorable mix of applications due to fewer Pearl Fractional upgrade unit sales a premium priced hand piece and a decrease in platform upgrade revenue. These decreases were partially offset by an increase in hand piece upgrade unit sales (excluding the Pearl Fractional).

### Service Revenue

Our service revenue slightly decreased by 1% in the three months and increased by 1% in the nine months ended September 30, 2010, compared to the same periods in 2009. This revenue has remained relatively flat over the past several quarters due primarily to higher services on out-of-warranty products, offset by lower extended warranty contract amortization, as a result of lower ASP's on our extended warranty contracts.

### Titan Hand Piece Refill Revenue

Our Titan hand piece refill revenue decreased 50% in the three months and 28% in the nine months ended September 2010, compared to the same periods in 2009. These decreases were due primarily to the voluntary recall of our Titan XL hand piece in the first-half of 2010, in which we provided our eligible customers with a fully "refilled" Titan XL hand piece.

### Dermal Filler and Cosmeceuticals Revenue

Our dermal fillers and cosmeceuticals revenue increased 207% in three months and 87% in the nine months ended September 30, 2010, compared to the same periods in 2009. These increases were due primarily to the commencement of the sale of Obagi products in Japan in February 2010.

### Discussion of Revenue by Geography:

#### U.S. Revenue

U.S revenue decreased 13% in the three months and 14% in the nine months ended September 30, 2010, compared to the same period in 2009. This decrease was due primarily to:

- a decrease in Products and Upgrades revenue of 6% in the three months and 16% in the nine months ended September 30, 2010 due primarily to a decline in the weighted average selling price (ASP) offset by an increase in unit sales; and
- a decline in Titan hand piece refill revenue by 68% in the three months and 38% in the nine months ended September 30, 2010, which was a result of our Titan XL recall.

#### International Revenue

International revenue increased 7% in the three months and 9% in the nine months ended September 30, 2010, compared to the same periods in 2009. This increase was due primarily to:

- an increase in our Japan revenue by 48% in the three months and 40% in the nine months ended September 30, 2010, compared to the same periods in 2009 due to higher Product, Upgrade and Cosmeceutical revenue.; partially offset by

- a decline in our Europe revenue by 38% in the three months and 32% in the nine months ended September 30, 2010, compared to the same periods in 2009, due in part to the economic uncertainty that resulted from the 2010 European debt crisis and a decline in Titan hand piece refill revenue.

Gross Profit

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,				
	2010	% Change	2009	2010	% Change	2009		
Gross profit	\$6,431	(11 )%	\$7,261	\$21,233	(5 )%	\$22,290		
As a percentage of net revenue	53	%	60	%	56	%	58	%

Our cost of revenue consists primarily of material, personnel expenses, royalty expense, warranty and manufacturing overhead expenses.

Gross margin was 53% in the three months ended September 30, 2010, compared to 60% for the same period in 2009. This decrease in gross margin was due primarily to:

TABLE OF CONTENTS

- a decline in the ASP's for Products and Upgrades, resulting primarily from customers purchasing fewer applications on our platforms and lower pricing see discussion above in the Revenue section;
- a 50% decrease in our higher margin Titan hand piece refill revenue coupled with the expenses associated with refurbishing our global installed base of Titan XL hand pieces, due to our voluntary Titan XL recall; and
- the write down of our VASER inventory by \$171,000, due to our intent to discontinue the distribution of this product.

Gross margin was 56% in the nine months ended September 30, 2010, compared to 58% for the same period in 2009. This decrease in gross margin was due primarily to:

- a 28% decrease in our higher margin Titan hand piece refill revenue coupled with the expenses associated with refurbishing our global installed base of Titan XL hand pieces, due to our voluntary Titan XL recall, due to our voluntary Titan XL recall;
- the write down of our VASER inventory by \$171,000, due to our intent to discontinue the distribution of this product; and
- a decline in the ASP's for Products and Upgrades, resulting primarily from customers purchasing fewer applications on our platforms and lower pricing see discussion above in the Revenue section.

## Sales and Marketing

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,			
	2010	% Change	2009	2010	% Change	2009	
Sales and marketing	\$5,799	13	% \$5,112	\$18,612	2	% \$18,186	
As a percentage of total revenue	48	%	42	% 49	%	47	%

Sales and marketing expenses consist primarily of personnel expenses, expenses associated with customer-attended workshops, and trade shows, post-marketing studies, and advertising.

Sales and marketing expenses increased \$687,000 in the three months ended September 30, 2010, compared to the same period in 2009. This increase was due primarily to:

- expenses of \$236,000 related to the creation of three new departments in the first quarter of 2010: post marketing studies (clinical development), business development and telesales;
- higher personnel expenses of \$235,000, due mainly to higher international sales commission expenses resulting from higher international revenue and increased headcount in Japan resulting from our Obagi cosmeceuticals business; and
- higher consulting service fees of \$152,000, due mainly to the expansion of our Japan operations for the cosmeceuticals business.

Sales and marketing expenses increased \$426,000 in the nine months ended September 30, 2010, compared to the same period in 2009. This increase was mainly due to:

-

Edgar Filing: CUTERA INC - Form 10-Q

expenses of \$777,000 related to the creation of three new departments in the first quarter of 2010: post marketing studies (clinical development), business development and telesales; partially offset by

- lower personnel expenses of \$321,000, due primarily to lower sales headcount in the U.S., resulting from our 2009 restructuring efforts, and lower sales commission expenses resulting from lower revenue in the U.S. sales.

Sales and marketing expenses, as a percentage of net revenue, increased to 48% for the three months ended September 30, 2010, compared to 42% for the same period in 2009. This increase was due primarily to higher expense coupled with slightly lower revenue in the three months ended September 30, 2010, compared to the same period in 2009. Sales and marketing expenses, as a percentage of net revenue, increased to 49% for the nine months ended September 30, 2010, compared to 47% for the same period in 2009. This increase was due primarily to higher expenses coupled with slightly lower revenue in the nine months ended September 30, 2010, compared to the same period in 2009.

Research and Development (R&D)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,				
	2010	% Change	2009	2010	% Change	2009		
Research and development	\$1,871	11	% \$1,684	\$4,831	(2	)% \$4,922		
As a percentage of total revenue	16	%	14	%	13	%	13	%

R&D expenses consist primarily of personnel expenses, clinical research, regulatory and material costs.

R&D expenses increased by \$187,000 in the three months ended September 30, 2010, compared to the same period in 2009. This increase was due primarily to a net increase in personnel expenses and consulting services of \$243,000, resulting mainly from an increase in headcount in the second quarter of 2010.

R&D expenses slightly decreased by \$91,000 for the nine months ended September 30, 2010, compared to the same period in 2009. This decrease was due primarily to lower material spending of \$112,000 and lower prototype equipment expense in clinical research of \$101,000 reflecting R&D efforts for our TruSculpt product during the first-nine months of 2009; that was not replicated in the first-nine months of 2010. These decreases were partially offset by an increase in personnel expenses consulting services of \$212,000, resulting mainly from an increase in headcount beginning in the second quarter of 2010.

R&D expenses, as a percentage of net revenue, increased to 16% for the three months ended September 30, 2010, compared to 14% for the same period in 2009. This increase was due primarily to higher expense coupled with slightly lower revenue in the three months ended September 30, 2010, compared to the same period in 2009. R&D expenses, as a percentage of net revenue, remained flat at 13% for the nine months ended September 30, 2010, compared to the same period in 2009.

General and Administrative (G&A)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,				
	2010	% Change	2009	2010	% Change	2009		
General and Administrative	\$2,352	11	% \$2,121	\$7,338	(11	)% \$8,257		
As a percentage of total revenue	19	%	17	%	19	%	22	%

General and administrative expenses consist primarily of personnel expenses, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses.

G&A expenses increased \$231,000 in the three months ended September 30, 2010, compared to the same period in 2009. This increase was primarily due to:

- higher personnel and travel expenses of \$102,000;
- higher legal settlement expenses of \$59,000; and
- higher professional services fee expenses of \$46,000, resulting from an increase in accounting and tax services.

G&A expenses decreased \$919,000 in the nine months ended September 30, 2010, compared to the same period in 2009. This decrease was primarily due to:

- lower bad debt expense of \$620,000, resulting primarily from one leasing company that defaulted on its payment in 2009; and
- lower professional services fee expenses of \$345,000, resulting from reduced accounting, tax and legal services in the first-half of 2010 compared to the same period in 2009.

G&A expenses, as a percentage of net revenue, increased to 19% for the three months ended September 30, 2010, compared to 17% for the same period in 2009. This increase was due primarily to higher expenses coupled with slightly lower revenue in the three months ended September 30, 2010, compared to the same period in 2009. G&A expenses, as a percentage of net revenue decreased to 19% for the nine months ended September 30, 2010, compared to 22% for the same period in 2009. This decrease was due primarily to lower expenses coupled with slightly lower revenue in the nine months ended September 30, 2010, compared to the same period in 2009.

#### Litigation Settlement

We were a defendant in a Telephone Consumer Protection Act class action lawsuit (see Note 8, "Commitments and Contingencies Litigation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q). We included \$850,000 in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2009 for the estimated cost of the settlement, net of administrative expenses and amounts that were recovered from our insurance



TABLE OF CONTENTS

carrier.

## Interest and Other Income, Net

Interest and other income, net consist of the following:

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	% Change	2009	2010	% Change	2009
Interest income	\$104	(64 )%	\$288	\$407	(65 )%	\$1,148
Other income, net	28	N/A	—	32	(87 )%	250
Total Interest and other income, net	\$132	(54 )%	\$288	\$439	(69 )%	\$1,398

Interest and other income, net, decreased by \$156,000 for the three months and \$959,000 for the nine months ended September 30, 2010, compared to the same periods in 2009. These decreases were the result of:

- A decrease in interest income of \$184,000 in the three months and \$741,000 in the nine months ended September 30, 2010, compared to the same periods in 2009, due primarily to reduced interest yields as a result of the Federal Reserve cutting interest rates; and
- A decrease in other income of \$218,000 in the nine months ended September 30, 2010, compared to the same period in 2009. This decrease was due primarily to net foreign exchange losses resulting primarily from translation losses that arose from the appreciation of the U.S. dollar relative to the currencies of the majority of our foreign subsidiaries in 2010, compared to foreign exchange gains resulting primarily from translation gains that arose from the devaluation of the U.S. dollar relative to the currencies against certain of our foreign subsidiaries in 2009.

## Provision for Income Taxes

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	% Change	2009	2010	% Change	2009
Loss before income taxes	\$(3,459 )	153 %	\$(1,368 )	\$(9,109 )	7 %	\$(8,527 )
Provision for income taxes	\$—	(100 )%	\$12,126	\$129	(99 )%	\$9,159
Effective tax rate	— %		(886 )%	(1 )%		(107 )%

We recorded an income tax provision of less than \$1,000 for the three months and \$129,000 for the nine months ended September 30, 2010, compared to \$12.1 million for the three months and \$9.2 million for the nine months ended September 30, 2009. Our income tax provision for the three and nine months ended September 30, 2010 is primarily related to income taxes of our non-U.S. operations. Our income tax provision for the three and nine months ended September 30, 2009 reflects applicable United States federal and state income tax, the tax impact of non-U.S. operations, reduced primarily by tax exempt interest income and research and development (R&D) tax credit.

In the quarter ended September 30, 2009, we recorded a valuation allowance against our U.S. deferred tax assets as we determined that it was more likely than not that some of the deferred tax assets will not be realized. We anticipate we will continue to record a valuation allowance against the losses of certain jurisdictions, primarily federal and state, until such time as we are able to determine it is more likely than not the deferred tax asset will be realized. Such position is dependent on whether there will be sufficient future taxable income to realize such deferred tax assets. We expect our future tax provisions, during the time such valuation allowances are recorded, will consist primarily of the tax expense of our non-U.S. jurisdictions that are profitable.

## Net Loss per Diluted Share

Three Months Ended September 30,                      Nine Months Ended September 30,

Edgar Filing: CUTERA INC - Form 10-Q

(Dollars in thousands)	2010	% Change	2009	2010	% Change	2009
Net loss	\$(3,459 )	(74 )%	\$(13,494 )	\$(9,238 )	(48 )%	\$(17,686 )
Net loss per diluted share	\$(0.25 )	(75 )%	\$(1.01 )	\$(0.68 )	(49 )%	\$(1.33 )

Net loss per diluted share decreased \$0.76, or 75%, in the three months and \$0.65, or 49%, in the nine months ended September 30, 2010, compared to the same periods in 2009. These decreases, net, were due primarily to:

- lower tax provision of \$12.1 million in the three months and \$9.0 million in the nine months ended September 30, 2010;
- just affecting the nine month comparison lower operating expenses of \$584,000 in the nine months ended September 30, 2010, due primarily to our 2009 restructuring efforts, and
- just affecting the nine month comparison lower litigation settlement expense of \$855,000 in the nine months ended September 30, 2010, compared to the same period in 2009; partially offset by

TABLE OF CONTENTS

- lower interest and other income of \$156,000 in the three months and \$959,000 in the nine months ended September 30, 2010; and
- just affecting the three month comparison higher operating expenses of \$1.1 million in the three months ended September 30, 2010, compared to the same period in 2009.

## 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 and stock option exercises. We actively manage our cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet our daily needs. The majority of our cash and investments are held in U.S. banks and our foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short-term operating expenses.

## Liquidity Ratios

(Dollars in thousands)	September 30, 2010	December 31, 2009
Working Capital(2)	\$90,805	\$96,015
Current Ratio(3)	7.8:1	6.9:1

(2) Working capital measures how much in liquid assets a company has available to operate its business. Working capital is defined as the difference between current assets and current liabilities.

(3) The current ratio is a financial ratio that measures a company's resources to pay its current liabilities over the next 12 months. The current ratio is defined as current assets divided by current liabilities.

## 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:

(Dollars in thousands)	September 30, 2010	December 31, 2009	Change
Cash and cash equivalents	\$21,703	\$22,829	\$(1,126 )
Marketable investments	69,154	76,780	(7,626 )
Long-term investments	6,683	7,275	(592 )
Total	\$97,540	\$106,884	\$(9,344 )

## Cash Flows

(Dollars in thousands)	Nine Months Ended September 30,	
	2010	2009
Net cash flow provided by (used in):		
Operating activities	\$(7,631 )	\$(3,135 )
Investing activities	6,125	461
Financing activities	380	436
Net decrease in cash and cash equivalents	\$(1,126 )	\$(2,238 )

## Cash Flows from Operating Activities

Net cash used in operating activities in the nine months ended September 30, 2010 was \$7.6 million, which was attributable primarily to:

- \$4.8 million used by the net loss of \$9.2 million after adjusting for non-cash related items of \$4.4 million; consisting primarily of stock-based compensation expense of \$3.7 million and other items of \$731,000;
- \$3.1 million used to pay down the higher 2009 year-end accrued liabilities relating primarily to: (i) a reduction of professional and legal fees of \$1.4 million resulting primarily from a settlement payment of \$950,000 relating to our TCPA litigation matter (see Note 8, "Commitments and Contingencies - Litigation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q) and \$369,000 related primarily to payment of other legal settlements, (ii) reduction of customer deposits by \$588,000 resulting from converting customer prepayments to revenue, (iii) reduction of accrued warranty expenses of \$389,000 due primarily to fewer units remaining under warranty, (iv) reduction of accrued personnel expenses by \$279,000 resulting primarily from the pay-down of year-end commissions and bonuses, and (v) net reduction of \$208,000 for accrued sales and marketing expenses;
- \$1.1 million used as a result of a decrease in deferred revenue due primarily to a decrease in unit sales volume of Products and Upgrades that included purchases of extended service contracts, a reduction in our service contract pricing,

TABLE OF CONTENTS

a shift by customers towards purchasing shorter term contracts, and fewer customers purchasing extended service contracts; and

- \$953,000 used to purchase inventory, which primarily resulted from our distribution agreements with Obagi and BioForm; partially offset by
- \$1.8 million amortization of discounts and purchased interest relating to our marketable and long-term investments.

Net cash used in operating activities was \$3.1 million in the nine months ended September 30, 2009, which was due primarily to:

- \$2.2 million used by the net loss of \$17.7 million after adjusting for non-cash related items of \$15.5 million- consisting primarily of valuation allowance on our deferred tax asset of \$12.3 million as of December 31, 2008, stock-based compensation expense of \$3.4 million, net increase in the allowance for doubtful accounts of \$550,000 due primarily to one leasing company that has defaulted on its payment and an increase in the provision for excess and obsolete inventories of \$247,000 resulting from the reduced future demand for our products;
- \$3.0 million used as a result of a decrease in deferred revenue due primarily to a decrease in unit sales volume of Products and Upgrades that included purchases of extended service contracts, a reduction in our service contract pricing beginning in 2009, a shift by customers towards purchasing shorter term contracts, and fewer customers purchasing extended service contracts in response to improved product reliability and to a tougher economy; and
- \$1.7 million used to pay down the higher 2008 year-end accrued liabilities relating primarily to: (i) lower accrued personnel expenses of \$679,000 due primarily to reduced accruals for commissions and employee benefit expenses; (ii) reduction of accrued warranty expenses of \$827,000 due primarily to fewer units remaining under warranty; (iii) reduction of the income taxes payable balance by \$285,000; and (iv) net reduction of \$245,000 of accrued royalties due to the reduced revenue in the third quarter of 2009. This was partially offset by higher accrued legal settlement expense of \$850,000 relating to our TCPA litigation matter (see Note 8, "Commitments and Contingencies - Litigation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q); partially offset by
- \$2.6 million of cash generated by the decrease in gross accounts receivable balance from December 31, 2008 to September 30, 2009 that resulted from the collection of the higher 2008 year-end accounts receivable balances; and
- \$1.8 million generated by the decrease in gross inventory balance from December 31, 2009 to September 30, 2009, that resulted from the management of our inventories to better match the reduced sales of our products.

Cash Flows from Investing Activities

We generated net cash of \$6.1 million from investing activities in the nine months ended September 30, 2010, which was attributable primarily to:

- \$72.9 million in net proceeds from the sales and maturities of marketable investments; partially offset by
  - \$66.6 million of cash used to purchase marketable investments.

We generated net cash of \$461,000 from investing activities in the nine months ended September 30, 2009, which was attributable primarily to:

- \$31.4 million in net proceeds from the sales and maturities of marketable investments; partially offset by
  - \$30.8 million of cash used to purchase marketable investments.

#### Cash Flows from Financing Activities

Net cash provided by financing activities was \$380,000 in the nine months ended September 30, 2010 and \$436,000 in the nine months ended September 30, 2009, which resulted from cash generated by the issuance of stock through our stock option and employee stock purchase plan.

#### Adequacy of cash resources to meet future needs

We had cash, cash equivalents, marketable investments, and long-term investments of \$97.5 million as of September 30, 2010. Of this amount, we had \$6.7 million invested in student loan auction rate securities (ARS), which are classified as long-term assets. For the first nine months of 2010, we financed our operations through the sales and maturities of marketable investments, and cash from interest income. We believe the existing capital resources, including cash and cash equivalents and marketable investments

## TABLE OF CONTENTS

of \$90.9 million, are sufficient to meet our operating and capital requirements for the foreseeable future. Except for the recent trend of cash used to fund our operating activities, we are unaware of any other known trends or any known demands, commitments, events or uncertainties, including collectability of our accounts receivable, that will result in, or that are reasonably likely to result in, liquidity increasing or decreasing in any material way.

### 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.

We have certain contractual arrangements that create potential risk for us and are not recognized in our Condensed Consolidated Balance Sheets. Discussed below are off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources.

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

### Commitments and Contingencies

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments were not material at September 30, 2010.

We are party to various legal proceedings. See Note 8, "Commitments and Contingencies - Litigation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

We initiated a voluntary recall of our global installed base of Titan XL hand pieces starting May 2010. Though we continue to actively attempt to reach all customers through various communications notifying them of the voluntary recall, we may not be able to replace all our hand pieces before a patient of our customer is injured. If we are not able to completely replace all Titan XL hand pieces and there is a defective hand piece that results in an injury, or if there are patients injured due to the malfunctioning of one of our voluntarily recalled Titan XL hand pieces, we could incur significant legal fees and expenses in defending and, or settling such claims. Although we maintain product liability insurance, there is no assurance that all losses will be covered. Each potential claim will be evaluated on a case by case basis. At September 30, 2010, we have not recognized any expense in our Condensed Consolidated Financial Statements with respect to any potential contingent liability associated with any potential lawsuits that may arise.

### Contractual Obligations

Other than our renegotiated lease in August 2010, which extended our lease for another four years and expires December 31, 2017, we believe that there were no other significant changes during the nine months ended September 30, 2010 in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

The following are our contractual obligations as of September 30, 2010 (in thousands):

Contractual Obligations	Total	Less Than			More Than
		1 Year	1-3 Years	3-5 Years	5 Years
Operating leases	\$10,051	\$1,713	\$2,895	\$2,473	\$2,970
Purchase Obligations (1)	120	120	—	—	—
Total	\$10,171	\$1,833	\$2,895	\$2,473	\$2,970

(1) In December 2009, we entered into an agreement with Obagi Medical Products, Inc., to distribute certain of their proprietary skin care products in Japan (Obagi Agreement). Our Obagi Agreement requires us to purchase at least \$1.25 million of Obagi Medical Products, Inc. product in 2010. The minimum purchase requirement for 2011 and beyond has yet to be determined.

#### Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, we entered into indemnification agreements with each of our directors and executive officers. Our exposure under the various indemnification obligations, including those under the indemnification agreements with



## TABLE OF CONTENTS

our directors and executive officers, is unknown since indemnification obligations involve future claims that may be made against us. We have not accrued or paid any amounts for any such indemnification obligations to date.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Interest Rate Sensitivity

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 and municipal bonds, and, by policy, restrict our exposure to any single type of investment or 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) 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 would have potentially declined by approximately \$524,000 as of September 30, 2010.

We hold interest bearing ARS that represent investments in pools of student loans issued by the Federal Family Education Loan Program. At the time of acquisition, these ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. Uncertainties in the credit markets affected our holdings in ARS investments and auctions for some of our investments in these securities continue to fail. As of September 30, 2010, \$5.1 million of our original \$13.4 million par value portfolio had been redeemed in full and we had \$8.3 million par value (fair value of \$6.7 million) whose auctions continue to fail. These investments are not currently liquid and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument. Maturity dates for these ARS investments range from 2028 to 2043. We currently classify all of these investments as long-term investments in our Condensed Consolidated Balance Sheet because of our continuing inability to determine when these investments will settle. We have also modified our current investment strategy and increased our investments in more liquid money market investments, United States Treasury securities, municipal bonds, and eliminated investments in corporate debt. The valuation of our ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact its valuation include, duration of time that the ARS remain illiquid, changes to credit ratings of the securities, rates of default of the underlying assets, changes in the underlying collateral value, market discount rates for similar illiquid investments, ongoing strength and quality of credit markets. If there is a further decline in the valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; and (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk. If the decline in fair value is considered other-than-temporary then we would have to record an impairment charge in our Condensed Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings and harm our business.

#### Foreign Currency Exchange Risk

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. Although the majority of our revenue and purchases are denominated in U.S. dollars, we have revenue to certain international customers and expenses denominated in the Japanese Yen, Euro, Pounds Sterling, Australian Dollars,

Swiss Francs and Canadian Dollars. The net foreign exchange losses were approximately \$68,000 in the nine months ended September 30, 2010, which is included in our Condensed Consolidated Statements of Operations. Movements in currency exchange rates could cause variability in our revenues, expenses or interest and other income (expense). Though 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. 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.

#### Derivative Financial Instruments

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments.

#### ITEM 4. CONTROLS AND PROCEDURES

##### Evaluation of Disclosure Controls and Procedures

Attached as exhibits to this Quarterly Report are certifications of our 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,

## TABLE OF CONTENTS

and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

We 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 our management, including the CEO and CFO. Based on this evaluation, the CEO and CFO have concluded that as of the end of the period covered by this report the 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 our 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 our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Our Disclosure Controls include components of internal control over financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the U.S. To the extent that components of our internal control over financial reporting are included within Disclosure Controls, they are included in the scope of our annual controls evaluation.

### Limitations on the Effectiveness of Controls

Our management, including the CEO and CFO, does not expect that our 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, 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 our internal control over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



TABLE OF CONTENTS

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information under the heading “Litigation” set forth in Note 8 of the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report on Form 10-Q is incorporated herein by reference.

ITEM 1A. RISK FACTORS

For the quarter ended September 30, 2010, our quarterly U.S. revenue decreased by approximately 13%, compared to the same period in 2009. Our U.S. revenue is significantly below the pre-2009 level and many of our prospective customers remain reluctant to purchase capital equipment and our average selling prices (or ASPs) are lower than they were pre-2009. If our U.S. revenue does not improve, it could have a material adverse effect on our total revenue, profitability, employee retention and stock price.

For the quarter ended September 30, 2010, our quarterly U.S. revenue decreased by approximately 13%, compared to the same period in 2009. Our U.S. revenue is significantly below the pre-2009 level due to several factors, some of which are:

- We believe many of our current and prospective customers that do not have established medical offices continue to be reluctant to purchase capital equipment. In times of general economic uncertainty and tight credit, individuals often reduce or delay their capital equipment purchase decisions and we believe the credit market is negatively affecting sales.
- Our ASPs are lower than their pre-2009 levels as a result of customers purchasing fewer applications and lower prices being charged by our sales representatives due to competitive reasons.
- We believe there continues to be a lack of availability of consumer credit for some of our customers that do not have established medical offices, e.g. medi-spas, which is contributing to reduced volume.

If our U.S. revenue does not improve, it could have a material adverse effect on our total revenue, profitability, employee retention and stock price.

If we are not able to reduce expenses, our loss from operations may and cash used will increase, which could reduce our cash asset and have a material adverse effect on our stock price.

In response to reduced revenue, we cut various sales, customer relations, manufacturing, and service expenses in the first half of 2009. We implemented three reduction-in-force (or RIF) programs in 2009, specifically targeting positions that were directly impacted by the business slow down. Even though we implemented the restructurings, we had a significant loss from operations and used significant cash in our operations during the nine months ended September 30, 2010. If our revenues do not improve, or if we are not able to further reduce expenses, we may continue to generate losses from operations and use cash, which could reduce our cash asset and have a material adverse effect on our operations and stock price.

We face various risks and uncertainties as a result of our voluntary Titan XL recall program, including harm to our business, reputation, financial position and results of operations.

We discovered that under specific conditions, such as infrequent use or operators not following the prescribed maintenance program outlined in the owner’s manual, certain component parts of one of our hand pieces – the Titan XL

could become defective. As a result, the defective hand piece could produce energy above that stated on the device setting, which could cause injury to patients, including redness, erythema, blisters and burns. In response to discovering this issue, we initiated a voluntary recall of our global installed base of Titan XL hand pieces starting May 2010. Though we continue to actively attempt to reach all customers through various communications notifying them of the voluntary recall, we may not be able to replace all our hand pieces before a patient of our customer is injured. Following a voluntary recall, there is generally an increase in product liability lawsuits filed against the Company.

If we are not able to completely replace all Titan XL hand pieces and there is a defective hand piece that results in an injury, or if there are patients injured due to the malfunctioning of one of our voluntarily recalled Titan XL hand pieces, we could incur significant legal fees and expenses in defending and/or settling such claims. Although we maintain product liability insurance, there is no assurance that all losses will be covered. Each potential claim will be evaluated on a case by case basis. At September 30, 2010, we have not recognized any expense in our Condensed Consolidated Financial Statements with respect to any potential contingent liability associated with any potential lawsuits that may arise.

Our Titan hand piece refill revenue decreased 50% in the three months and 28% in the nine months ended September 2010, compared to the same periods in 2009. These decreases were due primarily to our voluntary recall of our Titan XL hand piece in the first nine months of 2010, in which we provided our eligible customers with a fully “refilled” Titan XL hand piece. If customers do not return to using their Titan hand pieces due to this voluntary recall, our Titan refill revenue could be negatively

TABLE OF CONTENTS

impacted in the future.

If either of the above mentioned two risks materializes, our revenue and profitability may be adversely affected, could materially harm our business, and our stock price could decline.

We rely heavily on our sales professionals to market and sell our products worldwide. If we are unable to hire, effectively train, manage, improve the profitability of, and retain the sales professionals, our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on our ability to hire, train manage and improve the productivity levels of our sales professionals worldwide. Because of our focus on the non-core market in the past our sales professionals do not have established relationships with core market physicians (dermatologists and plastic surgeons) or where those relationships exists, the are not very strong. We are selectively hiring new sales professionals in key territories to fill vacant positions. We also need to train our existing sales professionals to better understand our product technology and how it can be positioned against our competitors' products. Measures we implement in an effort to retain, train and manage our sales professionals, strengthen their relationships with core market physicians, and improve their productivity may not be successful.

Demand for our products in any of our markets could be weakened by several factors, including:

- Current lack of credit financing for some of our potential customers;
- Poor financial performance of market segments that try introducing aesthetic procedures to their businesses;
- The inability to differentiate our products from those of our competitors;
- Reduced patient demand for elective aesthetic procedures;
- Failure to build and maintain relationships with opinion leaders within the various market segments;
- An increase in malpractice lawsuits that result in higher insurance costs; and
- Our ability to develop and market our products to the core market specialties of dermatologists and plastic surgeons.

If we do not achieve anticipated demand for our products our revenue may be adversely impacted.

The aesthetic equipment market is characterized by rapid innovation. To compete effectively, we must develop and/or acquire new products, market them successfully, and 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 offered laser and other energy-based aesthetic procedures. We have recently started distributing topical skin creams and dermal fillers in the Japanese market. To grow in the future, we must develop and acquire new and innovative aesthetic products and applications, identify new markets, and successfully launch the newly acquired or developed product offerings.

To successfully expand our product offerings, we must, among other things:

- Develop and acquire new products that either add to or significantly improve our current product offerings;

- Convince our existing and prospective customers that our product offerings would be an attractive revenue-generating addition to their practice;
  - Sell our product offerings 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.

With the exception of 2009, we have introduced at least one new product every year since 2000. In the third quarter of 2010, we introduced GenesisPlus, a laser specifically created for the aesthetic treatment of toes and feet. In November 2009, we announced that we postponed indefinitely the release of our TruSculpt body contouring product. Historically, product introductions have been



TABLE OF CONTENTS

a significant component of our financial performance. To be successful in the aesthetics industry, we need to continue to innovate. Our business strategy has therefore been based, in part, on our expectation that we will continue to increase our product offerings. We need to continue to devote substantial research and development resources to make new product introductions, which can be costly and time consuming to our organization.

We also believe that, to increase revenue from sales of new products and related upgrades, we need to continue to develop our clinical support, further expand and nurture relationships with industry thought leaders and increase market awareness of the benefits of our new products. However, even with a significant investment in research and development, we may be unable to continue to develop, acquire or effectively launch and market new products and technologies regularly, or at all. If we fail to successfully commercialize new products, our business may 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 effectively compete and generate additional revenue from new and existing products depend upon our ability to distinguish our company and our products from our competitors and their products, and to develop and effectively market new and existing products. Our success is dependent on many factors, including the following:

- Speed of new and innovative product development;
- Effective strategy and execution of new product launches;
- Identify and develop clinical support for new indications of our existing products;
  - Product performance;
  - Product pricing;
  - Quality of customer support;
- Development of successful distribution channels, both domestically and internationally; and
  - Intellectual property protection.

To compete effectively, we have to demonstrate that our new and existing products are attractive alternatives to other devices and treatments, by differentiating our products on the basis of such factors as innovation, performance, brand name, service, and price. This is difficult to do, especially in a crowded aesthetic market. Some of our competitors have newer or different products and more established 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 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 increase our market penetration or compete effectively, our revenue and profitability will be adversely impacted.

We compete against companies that offer alternative solutions to our products; or have greater resources, a larger installed base of customers and broader product offerings than ours. If we are not able to effectively compete with these companies, it may harm our business.

Our industry is subject to intense competition. Our products compete against similar products offered by public companies, such as Cynosure, Elen (in Italy), Iridex, Palomar, Solta, and Syneron and as well as private companies such as Alma, Lumenis, Sciton and several other companies. Recently, there has been consolidation in the aesthetic industry leading to companies combining their resources. For example, Solta (previously Thermage) acquired Reliant in December 2008 and Aesthera in February 2010; and Syneron acquired Candela in September 2009. We are likely to compete with new companies in the future. Competition with these companies could result in reduced selling prices, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

TABLE OF CONTENTS

The energy-based aesthetic market faces competition from non energy-based medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include 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.

If there is not sufficient consumer 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 business 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:

- Consumer disposable income and access to consumer credit, which as a result of the unstable economy, may have been significantly impacted;
- The cost of procedures performed using our products;
- The cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser or other energy-based technologies and treatments which use pharmaceutical products;
- The success of our sales and marketing efforts; and
- 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.

Any defects in the design, material or workmanship of our products may not be discovered prior to shipment to customers, which could materially increase our expenses, adversely impact profitability and harm our business.

The design of our products is complex. To manufacture them successfully, we must procure quality components and employ individuals with a significant degree of technical expertise. If our designs are defective, or the material components used in our products subject to wear out, or if suppliers fail to deliver components to specification, or if our employees fail to properly assemble, test and package our products, the reliability and performance of our products will be adversely impacted. As an example, in the first-nine months of 2010, we incurred significant expenses for the voluntary recall of our Titan XL hand pieces.

If our products contain defects that cannot be repaired easily, inexpensively, or on a timely basis, we may experience:

- Damage to our brand reputation;
- Loss of customer orders and delay in order fulfillment;

- Increased costs 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 increase expenses, adversely impact profitability and harm our business.

Federal regulatory reforms and changes occurring at the U.S. Food and Drug Administration, or FDA, could adversely affect our ability to sell our products profitably and financial condition.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a device. It is impossible to predict whether legislative

## TABLE OF CONTENTS

changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. Changes in FDA regulations may lengthen the regulatory approval process for medical devices and require additional clinical data to support regulatory clearance for the sale and marketing of our new products. In addition, it may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market. Either of these changes lengthen the duration to market, increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

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.

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 heating for the temporary relief of muscle aches and pains; and to market our Pearl Fractional product in the United States only for skin resurfacing. Therefore we are prevented from promoting or advertising Titan in the United States and Pearl Fractional 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 frequently changing. 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

TABLE OF CONTENTS

products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

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

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

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

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.

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 historically experienced steep increases in our product liability insurance premiums as a percentage of revenue. 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.

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



## TABLE OF CONTENTS

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.

We have recently entered into strategic alliances to distribute third party products internationally. To successfully market and sell these products, we must address many issues that are unique to these businesses and could reduce our available cash reserves and negatively impacting our profitability.

Recently, we have entered into distribution arrangements pursuant to which we utilize our sales force and distributors to sell products manufactured by other companies. We entered into an agreement with Obagi Medical Products, Inc. (Obagi), to distribute certain of their proprietary cosmeceuticals, or skin care products, in Japan. This agreement requires us to purchase a minimum dollar amount of Obagi products of \$1.25 million in 2010, and the purchase commitments for 2011 and beyond have yet to be determined. In addition, in December 2009, we entered into an agreement with Sound Surgical Technologies, Inc. to distribute their VASER® Lipo System in certain European countries and Canada. However, in September 2010, we decided to discontinue distributing the VASER product. Finally, we also have an agreement with BioForm Medical Inc. (acquired by Merz Pharma Group in January 2009), to distribute their Radiesse® dermal filler product in Japan. Each of these distribution agreements presents its own unique risks and challenges. For example, to sell products in partnership with Obagi we need to invest in creating a sales structure that is experienced in the sale of cosmeceuticals and not in capital equipment. We need to commit resources to training this sales force, obtaining regulatory licenses in Japan and developing new marketing materials to promote the sale of Obagi products. For each of these distribution arrangements, until we can develop our own experienced sales force, we may need to pay third party distributors to sell the products which will result in higher fees and lower margins than if we sell direct to customers. In addition, the minimum commitments and other costs of distributing products manufactured by these companies may exceed the incremental revenue that we derive from the sale of their products thereby reducing our available cash reserves and negatively impacting our profitability.

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

Our international revenue was \$7.9 million, or 65% of our total revenue, in the three months ended September 30, 2010 and \$24.5 million, or 64% of our total revenue, in the nine months ended September 30, 2010. International revenue is a material component of our business strategy. We depend on third-party distributors and a direct sales force to sell our products internationally, and if they underperform, we may be unable to increase or maintain our level of international revenue. To grow our business, we will need to improve productivity in current sales territories and expand into new territories. However, direct sales productivity may not improve and distributors may not accept our business or commit the necessary resources to market and sell our products to the level of our expectations. As a result, we may not be able to increase or maintain international revenue growth.

We believe, as we continue to manage our international operations and develop opportunities in additional international territories, our international revenue will be subject to a number of risks, including:

- Difficulties in staffing and managing our foreign operations;
- Export restrictions, trade regulations and foreign tax laws;

Edgar Filing: CUTERA INC - Form 10-Q

- Fluctuating foreign currency exchange rates;
- Foreign certification and regulatory requirements;
- Lengthy payment cycles and difficulty in collecting accounts receivable;
  - Customs clearance and shipping delays;
  - Political and economic instability;
- Lack of awareness of our brand in international markets;
- 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, we may not be able to sell our products in a particular market and, as a result, our revenue

TABLE OF CONTENTS

may decline.

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. Revenue from PSS declined significantly in 2009, compared to 2008. Our revenue from PSS, as a percentage of worldwide revenue, was 5% for the nine months ended September 30, 2010, 7% in 2009 and 14% in 2008. Although we continue to work closely with, and focus our attention on, our PSS relationship, there is no assurance that this 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.

Adverse conditions in the global banking industry and credit markets may adversely impact the value of our marketable investments or impair our liquidity.

We invest our excess cash primarily in money market funds and in highly liquid debt instruments of the U.S. government and its agencies, and U.S. municipalities. As of September 30, 2010, our balance in marketable investment was \$69.2 million. 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, 2010 would have potentially decreased by approximately \$524,000, 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).

We may be required to record impairment charges in future quarters as a result of the decline in value of our long-term investments in auction rate securities (ARS).

Included under the caption of "Long-term investments" in the Condensed Consolidated Balance Sheet as of September 30, 2010, are \$6.7 million of ARS. These ARS are designed to provide liquidity through an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days. Though approximately \$5.1 million (par value) of our original holdings of \$13.4 million (par value) of ARS have been redeemed at full par value since 2008, auctions for the remaining ARS in our portfolio at September 30, 2010 have continued to fail since February 2008 due to the lack of liquidity and 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, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument.

If there is a decline in fair value in our ARS that is considered other-than-temporary then we would have to record an impairment charge in our Condensed Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings, harm our business and may cause our stock price to decline.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire, train 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. Except for Change of Control and Severance Agreements for our executive officers, 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 may face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract, train and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

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, 2010, approximately 54% of our outstanding shares of common stock were held by 10 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

TABLE OF CONTENTS

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, due to the current concentration of stockholders, it 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:

- The general market conditions unrelated to our operating performance;
- 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 by us or our competitor;
  - Regulatory developments or delays concerning our, or our competitors' products; and
    - The initiation of litigation by us or against us.

Actual or perceived instability in our stock price could reduce demand from potential buyers of our stock, thereby causing our stock price to either remain depressed or to decline further.

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.

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. 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.

While we from time to time evaluate potential 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.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply shortages and price

TABLE OF CONTENTS

fluctuations, which could harm our business.

Many of the components and materials that comprise our products are currently manufactured by a limited number of suppliers. A supply interruption or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our products until a new source of supply is identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- Interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
  - A lack of long term supply arrangements for key components with our suppliers;
  - Inability to obtain adequate supply in a timely manner, or on reasonable terms;
- Difficulty locating and qualifying alternative suppliers for our components in a timely manner;
- Production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
  - Delay in supplier deliveries.

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

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 December 31, 2009, we had thirteen 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.

Healthcare reform legislation could adversely affect our future profitability and financial condition.

The President and members of Congress passed legislation relating to healthcare reform. Our products are not reimbursed by insurance companies or federal or state governments and some of this legislation will, therefore, not affect us. This legislation, however, does include several aspects that will apply to us, including a tax on our U.S. revenue which is applicable to us beginning in 2013. While we are presently evaluating the full scope of how this legislation will impact our operations, including how to administer this tax, we believe this will adversely affect our future profitability and financial condition.

We offer credit terms to some qualified customers and also to leasing companies to finance the purchase of our products. In the event that any of these customers default on the amounts payable to us, our earnings may be adversely affected.

While we qualify customers to whom we offer credit terms (generally net 30 to 60 days), we cannot provide any assurance that the financial position of these customers will not change adversely before we receive payment. Our general and administrative expenses and earnings are negatively impacted by customer defaults and cause an increase in the allowance for doubtful accounts. In the event that there is a default by any customers to whom we have provided credit terms in the future, we may recognize a bad debt charge in our general and administrative expenses and this could negatively affect our earnings and results of operations.



TABLE OF CONTENTS

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

As a result of recent fluctuations in currency markets and the strong dollar relative to many other major currencies, our products priced in U.S. dollars may be more expensive relative to products of our foreign competitors, which could result in lower revenue. 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 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).

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.

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

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

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

These provisions, as well as Change of Control and Severance Agreements entered into with each of our executive officers, 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.

TABLE OF CONTENTS

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. [REMOVED AND RESERVED]

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.
10.19	First Amendment to Brisbane Technology Park Lease dated August 11, 2010 by and between the Company and BMR-Bayshore Boulevard LLC, as successor-in-interest to Gal-Brisbane, L.P., the original landlord, for office space located at 3240 Bayshore Boulevard, Brisbane, California.
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)

Edgar Filing: CUTERA INC - Form 10-Q

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 1st day of November, 2010.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

Executive Vice President and Chief

Financial Officer

(Principal Financial and Accounting Officer)

