

CUTERA INC
Form 10-Q
November 07, 2011

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, 2011

OR

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

For the transition period _____ to _____.

Commission file number: 000-50644

Cutera, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

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

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

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

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

Edgar Filing: CUTERA INC - Form 10-Q

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 31, 2011 was 13,908,207

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>	12
Item 3 <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4 <u>Controls and Procedures</u>	23
PART II OTHER INFORMATION	
Item 1 <u>Legal Proceedings</u>	24
Item 1A <u>Risk Factors</u>	24
Item 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 3 <u>Defaults Upon Senior Securities</u>	35
Item 4 <u>[Removed and Reserved]</u>	35
Item 5 <u>Other Information</u>	35
Item 6 <u>Exhibits</u>	36
<u>Signature</u>	37

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CUTERA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	September 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,874	\$ 12,519
Marketable investments	74,502	77,484
Accounts receivable, net	4,085	4,208
Inventories	9,659	6,448
Deferred tax asset	17	63
Other current assets and prepaid expenses	1,841	2,740
Total current assets	103,978	103,462
Property and equipment, net	643	597
Long-term investments	3,014	6,784
Intangibles, net	493	637
Deferred tax asset, net of current portion	345	325
Other long-term assets	493	—
Total assets	\$ 108,966	\$ 111,805
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,151	\$ 1,296
Accrued liabilities	7,339	6,194
Deferred revenue	5,447	5,633
Total current liabilities	14,937	13,123
Deferred rent	1,432	1,501
Deferred revenue, net of current portion	775	1,287
Income tax liability	489	477
Total liabilities	17,633	16,388
Commitments and Contingencies (Note 8)		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value; authorized: 5,000,000 shares; none issued and outstanding	—	—
	14	14

Edgar Filing: CUTERA INC - Form 10-Q

Common stock, \$0.001 par value; authorized: 50,000,000 shares; issued and outstanding: 13,888,554 and 13,629,713 shares at September 30, 2011 and December 31, 2010, respectively

Additional paid-in capital	94,594	90,423
Retained earnings (accumulated deficit)	(2,438)	6,736
Accumulated other comprehensive loss	(837)	(1,756)
Total stockholders' equity	91,333	95,417
Total liabilities and stockholders' equity	\$ 108,966	\$ 111,805

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

TABLE OF CONTENTS

CUTERA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenue	\$ 15,232	\$ 12,092	\$ 41,748	38,058
Cost of revenue	6,772	5,661	18,472	16,825
Gross profit	8,460	6,431	23,276	21,233
Operating expenses:				
Sales and marketing	6,426	5,799	18,720	18,612
Research and development	2,352	1,871	6,828	4,831
General and administrative	2,310	2,352	7,226	7,338
Total operating expenses	11,088	10,022	32,774	30,781
Loss from operations	(2,628)	(3,591)	(9,498)	(9,548)
Interest and other income, net	91	132	474	439
Loss before income taxes	(2,537)	(3,459)	(9,024)	(9,109)
Provision for income taxes	326	—	150	129
Net loss	\$ (2,863)	\$ (3,459)	\$ (9,174)	\$ (9,238)
Net loss per share:				
Basic and Diluted	\$ (0.21)	\$ (0.25)	\$ (0.67)	\$ (0.68)
Weighted-average number of shares used in per share calculations:				
Basic and Diluted	13,862	13,589	13,765	13,512

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

TABLE OF CONTENTS

CUTERA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (9,174)	\$ (9,238)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,105	3,670
Tax benefit from stock-based compensation	21	—
Excess tax benefit related to stock-based compensation	(21)	—
Depreciation and amortization	483	560
Provision for excess and obsolete inventories	(174)	217
Provision for doubtful accounts receivable	17	(91)
Change in deferred tax asset net of valuation allowance	26	(29)
Gain on sale of marketable investments, net	(2)	(74)
Tax on unrealized gains on marketable and long term investments	194	—
Changes in assets and liabilities:		
Accounts receivable	106	394
Inventories	(3,037)	(953)
Other current assets and prepaid expenses	1,951	1,761
Other long-term assets	(493)	—
Accounts payable	855	620
Accrued liabilities	1,086	(3,058)
Deferred rent	(10)	(158)
Deferred revenue	(698)	(1,069)
Income tax liability	12	(183)
Net cash used in operating activities	(5,753)	(7,631)
Cash flows from investing activities:		
Acquisition of property and equipment	(421)	(193)
Disposal of property and equipment	36	—
Proceeds from sales of marketable and long-term investments	17,597	38,800
Proceeds from maturities of marketable investments	35,085	34,135
Purchase of marketable investments	(46,255)	(66,617)
Net cash provided by investing activities	6,042	6,125
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	1,045	380
Excess tax benefit related to stock-based compensation	21	—
Net cash provided by financing activities	1,066	380
Net increase (decrease) in cash and cash equivalents	1,355	(1,126)

Edgar Filing: CUTERA INC - Form 10-Q

Cash and cash equivalents at beginning of period	12,519	22,829
Cash and cash equivalents at end of period	\$ 13,874	\$ 21,703

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

TABLE OF CONTENTS

CUTERA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Description of Operations and Principles of Consolidation.

Cutera, Inc. (Cutera or the Company) is a global provider of laser and light-based aesthetic systems for practitioners worldwide. The Company designs, develops, manufactures, and markets the CoolGlide, Xeo, Solera, GenesisPlus and Excel V product platforms for use by physicians and other qualified practitioners to allow its 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 (Upgrade revenue). In addition to systems and upgrade revenue, the Company generates revenue from the sale of post warranty service contracts, providing services for products that are out of warranty, Titan hand piece refills, and dermal fillers and cosmeceuticals.

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries in Australia, Canada, France, Japan, Spain, Switzerland (however, beginning October 1, 2011 the Company engaged a distributor in Switzerland instead of selling directly) 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 in the Company's Condensed Consolidated Financial Statements 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, 2010 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, 2010 filed with the Securities and Exchange Commission, or SEC, on March 15, 2011.

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, 2010 filed with the SEC on March 15, 2011, and have not changed significantly as of September 30, 2011, except for the accounting standard on revenue recognition explained below.

TABLE OF CONTENTS

Revenue Recognition

The FASB amended the accounting standards for multiple deliverable revenue arrangements to:

- provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated;
- require an entity to allocate revenue in an arrangement using estimated selling price (ESP) of deliverables if a vendor does not first have vendor-specific objective evidence (VSOE) of selling price or secondly does not have third-party evidence (TPE) of selling price; and
- eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

Multiple-element arrangements - A multiple-element arrangement includes the sale of one or more tangible product offerings with one or more associated services offerings, each of which are individually considered separate units of accounting. The determination of the Company's units of accounting did not change with the adoption of the new revenue recognition guidance and as such the Company allocates revenue to each element in a multiple-element arrangement based upon the relative selling price of each deliverable. When applying the relative selling price method, the Company determines the selling price for each deliverable using VSOE of selling price, if it exists, or TPE of selling price. If neither VSOE nor TPE of selling price exist for a deliverable, the Company uses its best estimate of selling price for that deliverable. Revenue allocated to each element is then recognized when the other revenue recognition criteria are met for each element.

The above mentioned update was effective for the Company from January 1, 2011 and the Company elected to apply it prospectively to new or materially modified revenue arrangements after its effective date. This did not have a material impact on the Company's financial position or results of operations for the three and nine-month periods ended September 30, 2011 and does not change the units of accounting for its revenue transactions.

The new accounting standard, if applied to the year ended December 31, 2010, would not have had a material impact on our revenue for that year.

Recent Accounting Pronouncements

On January 1, 2011, the Company adopted changes issued by the FASB to the classification of certain employee share-based payment awards. These changes clarify that there is not an indication of a condition that other than market, performance or service if an employee share-based payment award's exercise price is denominated in the currency of a market in which a substantial portion of the entity's equity securities trade and differs from the functional currency of the employer entity or payroll currency of the employee. An employee share-based payment award is required to be classified as a liability if the award does not contain a market, performance or service condition. Prior to this guidance, the Company did not consider the difference between the currency denomination of an employee share-based payment award's exercise price and the functional currency of the employer entity or payroll currency of the employee in determining the proper classification of the share-based payment award. The adoption of these changes had no impact on the Company's financial statements.

On January 1, 2011, the Company adopted changes issued by the FASB to disclosure requirements for fair value measurements. Specifically, the changes require a reporting entity to disclose, in the reconciliation of fair value measurements using significant unobservable inputs (Level 3), separate information about purchases, sales, issuances and settlements, i.e., on a gross basis rather than as one net number. These changes were applied to the disclosure in the Fair Value of Financial Instruments section of Note 2 to the Condensed Consolidated Financial Statements. The adoption of these changes had no impact on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04 “Fair Value Measurement: Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards”. Some of the amendments clarify the Board’s intent about the application of existing fair value measurement requirements. Other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011. The Company is still evaluating the potential future effects of this guidance.

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on the Company's financial statements.

TABLE OF CONTENTS

As discussed in detail in the Revenue Recognition section above, the Company adopted prospectively from January 1, 2011 the FASB amended standards for multiple deliverable revenue arrangements.

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 tables summarize cash, cash equivalents, marketable investments and long-term investments (in thousands):

	September 30, 2011	December 31, 2010
Cash and cash equivalents:		
Cash	\$ 1,424	\$ 1,989
Cash equivalents:		
Money market funds	10,700	8,330
Commercial paper	1,750	2,200
Total cash and cash equivalents	13,874	12,519
Marketable investments:		
U.S. government notes	3,672	2,070
U.S. government agencies	28,930	24,087
Municipal securities	6,811	15,011
Commercial paper	10,693	11,465
Corporate debt securities	24,396	24,851
Total marketable investments	74,502	77,484
Long-term investments in Auction Rate Securities (ARS)	3,014	6,784
Total cash, cash equivalents, marketable investments and long-term investments	\$ 91,390	\$ 96,787

The following table summarizes unrealized gains and losses related to our marketable investments and long-term investments, both designated as available-for-sale (in thousands):

September 30, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash and cash equivalents	\$ 13,874	\$ —	\$ —	13,874
Marketable investments				
U.S. government notes	3,660	12	—	3,672
U.S. government agencies	28,894	41	(5)	28,930
Municipal securities	6,759	53	(1)	6,811
Commercial paper	10,690	3	—	10,693
Corporate debt securities	24,415	19	(38)	24,396

Edgar Filing: CUTERA INC - Form 10-Q

Total marketable investments	74,418	128	(44)	74,502
Long-term investment in ARS	3,900	—	(886)	3,014
Total cash, cash equivalents, marketable investments and long-term investments	\$ 92,192	\$ 128	\$ (930)	\$ 91,390

TABLE OF CONTENTS

December 31, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash and cash equivalents	\$ 12,519	\$ —	\$ —	12,519
Marketable investments				
U.S. government notes	2,069	1	—	2,070
U.S. government agencies	24,088	17	(18)	24,087
Municipal securities	15,029	2	(20)	15,011
Commercial Paper	11,459	7	(1)	11,465
Corporate debt securities	24,825	55	(29)	24,851
Total marketable investments	77,470	82	(68)	77,484
Long-term investment in ARS	8,325	—	(1,541)	6,784
Total cash, cash equivalents, marketable investments and long-term investments	\$ 98,314	\$ 82	\$ (1,609)	\$ 96,787

The following table summarizes the estimated fair value of our marketable investments and long-term investments classified by the contractual maturity date of the security as of September 30, 2011 (in thousands):

	Amount
Due in less than one year	\$ 47,336
Due in 1 to 3 years	27,166
Due in 3 to 5 years	—
Due in 5 to 10 years	—
Due in greater than 10 years	3,014
	\$ 77,516

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.

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, 2011, 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	\$ 13,874	\$ —	\$ —	\$ 13,874
Short-term marketable investments:				
Available-for-sale securities	—	74,502	—	74,502
Long-term investments:				
Available-for-sale ARS	—	—	3,014	3,014
Total assets at fair value	\$ 13,874	\$ 74,502	\$ 3,014	\$ 91,390

TABLE OF CONTENTS

The Company's Level 1 financial assets are money market funds, highly liquid debt instruments of U.S. federal and municipal governments and their agencies and commercial paper 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 commercial paper and corporate bonds. 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, 2011, observable market information was not available to determine the fair value of the Company's ARS investments. Therefore, the fair value was 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 associated with Level 3 financial assets, which represents the Company's investment in ARS for the nine months ended September 30, 2011 (in thousands):

	September 30, 2011
Balance at December 31, 2010	\$ 6,784
Total gains or losses (realized or unrealized):	
Included in earnings (or changes in net assets)	—
Included in other comprehensive income (loss)	655
Purchases and issuances	—
Settlements	(4,425)
Transfers in and/or out of Level 3	—
Balance at September 30, 2011	\$ 3,014

Inventories:

Inventories consist of the following (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	\$ 5,867	\$ 4,204
Finished goods	3,792	2,244
Total	\$ 9,659	\$ 6,448

Intangible Assets:

Intangible assets comprise a patent sublicense acquired from Palomar in 2006 and a technology sublicense acquired in 2002. The components of intangible assets were as follows (in thousands):

	September 30, 2011		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount

Edgar Filing: CUTERA INC - Form 10-Q

Patent sublicense	\$	1,218	\$	758	\$	460
Technology sublicense		538		505		33
Total	\$	1,756	\$	1,263	\$	493

TABLE OF CONTENTS

	December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 656	\$ 562
Technology sublicense	538	463	75
Total	\$ 1,756	\$ 1,119	\$ 637

Amortization expense for intangible assets was \$144,000 for each of the nine-month periods ended September 30, 2011 and 2010.

Based on intangible assets recorded at September 30, 2011, 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,	Amount
2011 (remainder)	\$ 48
2012	158
2013	138
2014	138
2015	11
Thereafter	—
Total	\$ 493

Note 3. Warranty and Service Contract

Warranty Obligations

The Company provides a standard one-year 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.

The following table provides the changes in the product warranty accrual for the nine-month period ended September 30, 2011 and 2010 (in thousands):

	September 30,	
	2011	2010
Beginning Balance	\$ 796	\$ 1,049
Add: Accruals for warranties issued during the period	2,918	2,058
Less: Settlements made during the period	(2,710)	(2,447)
Ending Balance	\$ 1,004	\$ 660

Deferred Service Contract revenue

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

Edgar Filing: CUTERA INC - Form 10-Q

The following table provides changes in deferred service contract revenue for the nine-month period ended September 30, 2011 and 2010 (in thousands):

	September 30,	
	2011	2010
Beginning Balance	\$ 6,765	\$ 8,128
Add: Payments received	6,332	6,004
Less: Revenue recognized	(7,024)	(7,210)
Ending Balance	\$ 6,073	\$ 6,922

Costs incurred under service contracts were \$3.1 million for the nine-month period ended September 30, 2011 and \$3.2 million for the nine-month period ended September 30, 2010 and are recognized as incurred.

TABLE OF CONTENTS

Note 4. Stock-based Compensation Expense

Stock-based compensation expense by department recognized during the three and nine-month periods ended September 30, 2011 and 2010 was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Cost of revenue	\$ 179	\$ 191	\$ 505	\$ 566
Sales and marketing	210	214	625	476
Research and development	184	316	524	904
General and administrative	321	360	1,451	1,724
Total stock-based compensation expense	\$ 894	\$ 1,081	\$ 3,105	\$ 3,670

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		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Numerator:				
Net loss	\$ (2,863)	\$ (3,459)	\$ (9,174)	\$ (9,238)
Denominator:				
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per share	13,862	13,589	13,765	13,512

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		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Options to purchase common stock	3,990	3,484	3,619	3,110
Restricted stock units	56	72	62	40
Employee stock purchase plan shares	30	23	51	45
Total	4,076	3,579	3,732	3,195

Note 6. Income Taxes

The Company's income tax provision for the three and nine months ended September 30, 2011 and 2010 was primarily related to income taxes of the Company's non U.S. operations and other discrete items as explained below. The Company recorded a 100% valuation allowance against its U.S. deferred tax assets and as such did not record any income tax benefit related to its U.S. loss for the three and nine-month periods ended September 30, 2011 and 2010.

For the three months ended September 30, 2011, the Company's income tax provision was \$326,000, compared to a provision of less than \$1,000 for the three months ended September 30, 2010. Included in the \$326,000 provision for the three months ended September 30, 2011, was a discrete charge of \$262,000 for the clearing of disproportionate tax effects in accumulated other comprehensive loss related to unrealized gains and losses on marketable and long term investments.

TABLE OF CONTENTS

For the nine months ended September 30, 2011, the Company's income tax provision was \$150,000, compared to a provision of \$129,000 for the nine months ended September 30, 2010. Included in the \$150,000 provision for the nine months ended September 30, 2011 was a discrete net charge of \$194,000 for the clearing of disproportionate tax effects in other comprehensive income related to unrealized gains and losses on marketable investments, offset by a discrete tax benefit of \$246,000 resulting from the carry-back of fiscal year 2010 federal losses to obtain a refund of alternative minimum taxes paid for fiscal year 2008.

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. As of September 30, 2011 and December 31, 2010, the Company had a 100% valuation allowance against its U.S. deferred tax assets. 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 carry-back 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.

As of September 30, 2011, 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 as of December 31, 2010.

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 gain 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		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Net loss	\$ (2,863)	\$ (3,459)	\$ (9,174)	\$ (9,238)
Net change in unrealized gain (loss) on available-for-sale-securities, net of tax	297	(54)	919	(142)
Comprehensive loss	\$ (2,566)	\$ (3,513)	\$ (8,255)	\$ (9,380)

Note 8. Commitments and Contingencies

Facility Leases

The Company leases its Brisbane, California, office and manufacturing facility under a non-cancelable operating lease which expires on 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, 2011, 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,	Amount
2011 (remainder)	\$ 454
2012	1,674

2013	1,737
2014	1,782
2015	1,367
Thereafter	2,654
Future minimum rental payments	\$ 9,668

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.

In the first quarter of 2010, the Company entered into an agreement with Obagi to distribute certain of their proprietary cosmeceuticals, or skin care products, in Japan. In order to maintain an exclusive right to distribute Obagi products in the physician dispensed channel in Japan, the Company needs to purchase a minimum of \$1.75 million of products in 2011 and \$2.0 million in 2012. The Company's other open inventory purchase commitments were not material at September 30, 2011.

TABLE OF CONTENTS

Litigation

The Company is named from time to time as a party to product liability and other claims and lawsuits in the normal course of its business. As of September 30, 2011, the Company was not a party to any material pending litigation.

Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, the Company has entered into indemnification agreements with each of its directors and executive officers. The Company's exposure under its various indemnification obligations is unknown and not reasonably estimable as they involve future claims that may be made against the Company. As such, the Company has not accrued any amounts for such obligations.

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, 2010 as contained in our annual report on Form 10-K filed with the SEC on March 15, 2011. 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 24, 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.

Executive Summary

Company Description

We are a global medical device company specializing in the design, development, manufacture, marketing and servicing of laser and light-based aesthetics systems for practitioners worldwide. We offer easy-to-use products based on five platforms — CoolGlide®, Xeo®, Solera®, GenesisPlus™ and Excel VTM — each of which enables physicians and other qualified practitioners to perform safe and effective aesthetic procedures for their customers. Commencing in the fourth quarter of 2011, we plan to launch a new Q-switched laser product called myQ™ in Japan, that Cutera shall be sourcing from a third party original equipment manufacturer (OEM). In addition to systems and upgrade revenue, we generate revenue from the sale of post warranty service contracts, providing services for products that are out of warranty, Titan hand piece refills, and dermal fillers and cosmeceuticals.

TABLE OF CONTENTS

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 through direct sales and service employees, and a distribution relationship with PSS World Medical Shared Services, Inc. (“PSS”), a wholly owned subsidiary of PSS World Medical which has over 700 sales representatives serving physician offices throughout the United States. We also sell certain items such as our Titan hand piece refills and marketing brochures online.

International sales are generally made through direct sales employees and a worldwide distributor network in over 35 countries. Outside of the United States, we have a direct sales presence in Australia, Canada, France, Japan, Spain, Switzerland (however, beginning October 1, 2011 we engaged a distributor in Switzerland instead of selling directly) and the United Kingdom.

Products

Our revenue is derived from the sale of Products, Upgrades, Service, Titan hand piece refills, and Dermal fillers and cosmeceutical products. Product revenue represents the sale of a system. A system consists of a console that incorporates a universal graphic user interface, a laser and/or light-based module, control system software and high voltage electronics; as well as one or more hand pieces. However, depending on the application, the laser or light-based module is sometimes contained in the hand piece such as with our Pearl and Pearl Fractional applications instead of within the console. Commencing in the fourth quarter of 2011, we plan to launch a new Q-switched laser system called myQ.

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 provides customers the flexibility to upgrade their systems whenever they want and provides us with a source of recurring revenue which we classify as Upgrade revenue. Service revenue relates to amortization of prepaid service contract revenue and receipts for time and materials services on out-of-warranty products. Titan hand piece refill revenue is associated with our Titan hand piece which requires replacement of the optical source after a set number of pulses have been used. In Japan, we distribute Merz Pharma GmbH’s (Merz) Radiesse® dermal filler product and Xeomin®; and Obagi Medical Products, Inc.’s (Obagi) cosmeceutical products.

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 both through internal development and sourcing from other vendors.
 - Ongoing investment 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.
 - Consumer demand for the application of our products.
- Marketing to physicians in the core dermatology and plastic surgeon specialties, as well as outside those specialties.
- Generating ongoing revenue from our growing installed base of customers through the sale of Service, Upgrade, Titan hand piece refills, and Dermal fillers and cosmeceutical products.

U.S. Revenue

Edgar Filing: CUTERA INC - Form 10-Q

Our U.S. revenue increased by \$1.8 million, or 43%, in the three-month period ended September 30, 2011 and by \$2.4 million, or 18%, in the nine-month period ended September 30, 2011, compared to the same periods in 2010, respectively. This increase was primarily attributable to an increase in product revenue due to the:

- FDA clearance of our GenesisPlus system for onychomycosis, or toenail fungus, in April 2011;
- Commencement of Excel V shipments in the second quarter of 2011; and
- Result of effective U.S. sales management changes implemented in early 2011.

TABLE OF CONTENTS

International Revenue

International revenue increased by \$1.3 million or 17%, in the three-month period ended September 30, 2011 and by \$1.3 million or 5% in the nine-month period ended September 30, 2011, compared to the same periods in 2010, respectively. This increase was primarily attributable to:

- Higher product revenue from Canada, Australia and several of our distributor countries as a result of new products and a general improved economic environment in the three and nine-month period ended September 30, 2011, compared to the same period in 2010;
- An increase in our Dermal filler and cosmeceuticals revenue in Japan, due primarily to a higher number of customers purchasing Obagi products, which we began distributing in the first quarter of 2010, and due to the expansion of product lines being distributed; which was partly offset by
- A decline in our direct and distributor revenue from European countries due primarily to a restructuring of our sales team.

Product Revenue

Products revenue increased by \$3.2 million or 56%, in the three-month period ended September 30, 2011 and by \$3.6 million, or 19%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. These increases in revenue were due primarily to the U.S. FDA clearance of our GenesisPlus system for toenail fungus in April 2011 and the commencement of Excel V shipments in the second quarter of 2011. This was offset by a decline in revenue for the nine-month period ended September 30, 2011, compared to the same period in 2010, due to the catastrophic earthquake in Japan in March 2011 and a decline in our European revenue due to the European debt crisis and sales employee turnover.

Upgrade Revenue

Upgrades revenue decreased by \$727,000, or 51%, in the three-month period ended September 30, 2011 and by \$1.6 million, or 40%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. In the past, we introduced new products that allowed existing customers to upgrade their previously purchased systems to obtain benefits from the additional capabilities, which drove our Upgrade revenue. However, since 2008 we have not introduced any new products that our customers could purchase as an upgrade to their previously purchased system. Instead, we have launched new stand alone products (GenesisPlus and Excel V), which has resulted in a decline of our upgrade revenue since 2009.

Voluntary Titan XL Recall

In the second quarter of 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, our Titan hand piece refills revenue was negatively impacted since the announcement of the recall and as of the third quarter ended September 30, 2011, it has not recovered to the pre-recall revenue level of approximately \$1.3 to \$1.4 million per quarter. Cost of revenue for the nine months ended September 30, 2010, included an expense of \$487,000 for the estimated cost of this voluntary recall.

Factors that May Impact Future Performance.

Our industry is impacted by numerous competitive, regulatory, macroeconomic and other significant factors. The March 2011 earthquake and tsunami in Japan had a negative impact on our Japanese business and operations. 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, 2010 filed with the SEC on March 15, 2011. There have been no significant changes to the accounting policies and estimates disclosed in our Form 10-K, except for revenue recognition as described in Note 1.

TABLE OF CONTENTS

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,	
	2011	2010	2011	2010
Operating Ratio:				
Net revenue	100%	100%	100%	100%
Cost of revenue	44%	47%	44%	44%
Gross margin	56%	53%	56%	56%
Operating expenses:				
Sales and marketing	42%	48%	45%	49%
Research and development	16%	16%	17%	13%
General and administrative	15%	19%	17%	19%
Total operating expenses	73%	83%	79%	81%
Loss from operations	(17)%	(30)%	(23)%	(25)%
Interest and other income, net	0%	1%	1%	1%
Loss before income taxes	(17)%	(29)%	(22)%	(24)%
Provision for income taxes	2%	—%	—%	—%
Net loss	(19)%	(29)%	(22)%	(24)%

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,		
	2011	Change %	2010	2011	Change %	2010
Revenue mix by geography:						
United States	\$6,037	43 %	\$4,214	\$15,941	18 %	\$13,545
International	9,195	17 %	7,878	25,807	5 %	24,513
Consolidated total revenue	\$15,232	26 %	\$12,092	\$41,748	10 %	\$38,058
United States as a percentage of total revenue						
	40 %		35 %	38 %		36 %
International as a percentage of total revenue						
	60 %		65 %	62 %		64 %
Revenue mix by product category:						

Edgar Filing: CUTERA INC - Form 10-Q

Products	\$8,975	56	%	\$5,767	\$22,462	19	%	\$18,888
Upgrades	687	(51	%)	1,414	2,364	(40	%)	3,955
Service	3,227	2	%	3,166	10,149	2	%	9,917
Titan hand piece refills	1,031	59	%	647	3,336	14	%	2,929
Dermal fillers and cosmeceuticals	1,312	19	%	1,098	3,437	45	%	2,369
Consolidated total revenue	\$15,232	26	%	\$12,092	\$41,748	10	%	38,058

TABLE OF CONTENTS

Discussion of Revenue by Product Type:

Products Revenue

As explained in more detail in the Products section of the Executive Summary above, some of our products consist of a 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 increased by \$3.2 million, or 56%, in the three-month period ended September 30, 2011 and by \$3.6 million, or 19%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. These increases in revenue were due primarily to the U.S. FDA clearance of our GenesisPlus system for toenail fungus in April 2011 and the commencement of Excel V shipments in the second quarter of 2011. This was offset by a decline in revenue for the nine-month period ended September 30, 2011, compared to the same period in 2010, due to the catastrophic earthquake in Japan in March 2011 and a decline in our European revenue due to the European debt crisis and sales employee turnover.

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 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 decreased by \$727,000, or 51%, in the three-month period ended September 30, 2011 and by \$1.6 million, or 40%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. In the past, we introduced new products that allowed existing customers to upgrade their previously purchased systems to obtain benefits from the additional capabilities, which drove our Upgrade revenue. However, since 2008 we have not introduced any new products that our customers could purchase as an upgrade to their previously purchased system. Instead we have launched new stand alone products (GenesisPlus and Excel V), which has resulted in a decline of our upgrade revenue since 2009.

Service Revenue

Our worldwide service revenue increased by \$61,000, or 2%, in the three-month period ended September 30, 2011 and by \$232,000 or 2% in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. This increase was the result of higher international service revenue being partially offset by a decline in U.S. service revenue. The increase in international service revenue is due to an increased installed base and a higher number of purchased service contracts. The decline in our U.S. service revenue was primarily attributable to lower contract amortizations as a result of fewer customers purchasing extended service contracts.

Titan Hand Piece Refill Revenue

Our Titan hand piece refill revenue increased by \$384,000 or 59% in the three-month period ended September 30, 2011 and by \$407,000 or 14% in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. This increase was due primarily to the partial recovery of our Titan refill revenue following the voluntary recall of our Titan XL hand piece commencing in the second quarter of 2010, in which we provided our eligible customers with a fully “refilled” Titan XL hand piece, which delayed their purchase of a refill.

Dermal Filler and Cosmeceuticals Revenue

Our Dermal fillers and cosmeceuticals revenue increased by \$214,000, or 19%, in the three-month period ended September 30, 2011 and by \$1.1 million, or 45%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010. This increase was due primarily to the higher number of customers purchasing Obagi

products, which we began distributing in Japan in the first quarter of 2010, and due to the expansion of product lines being distributed.

Discussion of Revenue by Geography:

U.S. Revenue

Our U.S. revenue increased by \$1.8 million, or 43%, in the three-month period ended September 30, 2011 and by \$2.4 million, or 18%, in the nine-month period ended September 30, 2011, compared to the respective periods in 2010.

This increase was primarily attributable to an increase in product revenue due to the:

- FDA clearance of our GenesisPlus system for onychomycosis, or toenail fungus, in April 2011;
- Commencement of Excel V shipments in the second quarter of 2011; and
- Result of effective US sales management changes implemented in early 2011.

TABLE OF CONTENTS

International Revenue

International revenue increased by \$1.3 million, or 17%, in the three-month period ended September 30, 2011 and by \$1.3 million or 5% in the nine-month period ended September 30, 2011, compared to the respective periods in 2010.

This increase was primarily attributable to:

- Higher Product revenue from Canada, Australia and several of our distributor countries as a result of new products and a general improved economic environment in the three and nine-month periods ended September 30, 2011, compared to the same periods in 2010;
- An increase in our Dermal filler and cosmeceuticals revenue in Japan, due primarily to additional Obagi and Merz product lines being added and a higher number of customers purchasing such products from Cutera as we started distributing Obagi products in Japan in the first quarter of 2010; which was partly offset by
- A decline in our direct and distributor revenue from European countries due primarily to a restructuring of our sales team.

Gross Profit

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
Gross profit	\$ 8,460	32%	\$ 6,431	\$ 23,276	10%	\$ 21,233
As a percentage of total net revenue	56%		53%	56%		56%

Our cost of revenue consists primarily of material, personnel expenses, royalty expense, warranty and manufacturing overhead expenses. Gross margin (which is gross profit divided by net revenue) was 56% in the three-month period ended September 30, 2011, compared to 53% for the same period in 2010. Gross margin was 56% in the nine-month period ended September 30, 2011, and 56% for the same period in 2010. Our gross margins were impacted primarily by the following factors:

- Our gross margin was favorably impacted in the three and nine-month periods ended September 30, 2011, due to the leverage of our relatively fixed manufacturing costs as a result of higher Product volume;
- Our Titan refill gross margin was favorably impacted given we did not incur any expenses related to the voluntary Titan XL recall in the nine months ended September 30, 2011, compared to \$487,000 of expenses recorded in the nine months ended September 30, 2010;.
- Higher direct revenue as a percentage of total revenue, in the three and nine months ended September 30, 2011, compared to the same periods in 2010, resulted in an improvement of our margins because direct business has a better gross margin than our distributor business; and
- Our gross margins in the three and nine months ended September 30, 2011, compared to the same periods in 2010, were adversely impacted by an unfavorable product mix towards lower margin products.

Sales and Marketing

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
Sales and marketing	\$ 6,426	11%	\$ 5,799	\$ 18,720	1%	\$ 18,612
As a percentage of total net revenue	42%		48%	45%		49%

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 \$627,000, and represented 42% of total net revenue, in the three-month period ended September 30, 2011, compared to 48% in the same period in 2010. This increase was due primarily to: (i) increased personnel expenses of \$351,000

attributable primarily to higher commission expenses relating primarily to the higher revenue; and (ii) increased travel, entertainment and sales meeting expenses by \$332,000 due to the increased sales activity.

Sales and marketing expenses increased \$108,000, and represented 45% of total net revenue, in the nine-month period ended September 30, 2011, compared to 49% in the same period in 2010. This increase was due primarily to: (i) increased personnel expenses of \$609,000 attributable primarily to higher commission expenses relating to the higher revenue; (ii) increased travel, entertainment and sales meeting expenses of \$474,000 due primarily to increased sales activity; offset by (iii) reduced promotional and marketing related spending of approximately \$789,000 attributable to fewer workshops, and lower spending on public relation and other marketing activities.

Research and Development (R&D)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
Research and development	\$ 2,352	26%	\$ 1,871	\$ 6,828	41%	\$ 4,831
As a percentage of total net revenue	16%		16%	17%		13%

TABLE OF CONTENTS

R&D expenses consist primarily of personnel expenses, clinical research, regulatory and material costs. R&D expenses increased by \$481,000, and represented 16% of total net revenue, in the three-month period ended September 30, 2011, compared to 16% for the same period in 2010. The increase in expenses was due primarily to: (i) higher personnel expenses of \$414,000 due to higher headcount to ramp up the research, development and clinical support of our new products (iii) higher consulting services related to our product development efforts of \$98,000; offset by (iv) a decrease in material expenses of \$106,000 primarily due to significant spending in the three months ended September 30, 2010 related to new product development expenses.

R&D expenses increased by \$2.0 million in the nine-month period ended September 30, 2011, compared to the same period in 2010. R&D expenses, as a percentage of total net revenue, increased to 17% for the nine-month period ended September 30, 2011, compared to 13% for the same period in 2010. The increase in expenses was due primarily to: (i) higher personnel expenses of \$1.4 million due to higher headcount and higher consulting fees of \$176,000, both, to ramp up the research, development and clinical support of our new products; and (ii) higher material expenses of \$252,000 related to spending on prototype product development related primarily to our Excel V product launch.

General and Administrative (G&A)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
General and Administrative	\$ 2,310	(2%)	\$ 2,352	\$ 7,226	(2%)	\$ 7,338
As a percentage of total net revenue	15%		19%	17%		19%

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 decreased \$42,000 in the three-month period ended September 30, 2011, compared to the same period in 2010. This decrease was due primarily to: (i) lower personnel expenses of \$86,000 attributable to reduced headcount; (ii) lower accounting and tax services fees of \$74,000; offset by (iii) an increase of \$92,000 related to higher facility costs due to the planned relocation of our offices in Tokyo, Japan.

G&A expenses decreased by \$112,000 in the nine-month period ended September 30, 2011, compared to the same period in 2010. G&A expenses, as a percentage of net revenue, decreased to 17% for the nine-month periods ended September 30, 2011, compared to 19% for the same period in 2010. This decrease was due primarily to: (i) lower personnel expenses of \$244,000 attributable to reduced headcount; (ii) lower accounting and tax services fee of \$96,000; offset by (iii) a \$108,000 increase attributable to a reduced benefit associated with doubtful debt recoveries in the nine months ended September 30, 2010, that did not recur in the nine months ended September 30, 2011; and (iv) \$92,000 of expenses related to higher facility costs due to the planned relocation of our offices in Tokyo, Japan.

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,		
	2011	% Change	2010	2011	% Change	2010
Interest income	\$ 139	34 %	\$ 104	\$ 457	12%	\$ 407
Other income (expense), net	(48)	(271%)	28	17	(47%)	32
Total interest and other income, net	\$ 91	(31%)	\$ 132	\$ 474	8 %	\$ 439

Edgar Filing: CUTERA INC - Form 10-Q

Interest and other income, net, decreased \$41,000 for the three-month period ended September 30, 2011, compared to the same period in 2010, and increased \$35,000 for the nine-month period ended September 30, 2011, compared to the same period in 2010. The increases in interest income in the three and nine months ended September 30, 2011, compared to the same periods in 2010, were primarily attributable to improved yields on our investments as a result of shifting some investments to higher yielding corporate debt instruments, versus municipal bonds. The reduction in other income (expense), net, in the three months ended September 30, 2011, compared to the same period in 2010, was due primarily to an increase in foreign exchange losses of \$68,000.

Provision for Income Taxes

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
Loss before income taxes	\$ (2,537)	27%	\$ (3,459)	\$ (9,024)	1%	\$ (9,109)
Provision for income taxes	326	NA	—	150	16%	129
Effective tax rate	(13%)		—%	(2%)		(1%)

Our income tax provision for the three and nine months ended September 30, 2011 and 2010 was primarily related to income taxes of our non U.S. operations and other discrete items as explained below. We have recorded a 100% valuation allowance against our U.S. deferred tax assets and as such we did not record any income tax benefits related to our U.S. loss.

TABLE OF CONTENTS

For the three months ended September 30, 2011, our income tax provision was \$326,000, compared to a provision of less than \$1,000 for the three months ended September 30, 2010. Included in the \$326,000 provision for the three months ended September 30, 2011, was a discrete charge of \$262,000 for the clearing of disproportionate tax effects in accumulated other comprehensive loss related to unrealized gains and losses on marketable and long-term investments.

For the nine months ended September 30, 2011, our income tax provision was \$150,000, compared to a provision of \$129,000 for the nine months ended September 30, 2010. Included in the \$150,000 provision for the nine months ended September 30, 2011 was a discrete net charge of \$194,000 for the clearing of disproportionate tax effects in accumulated other comprehensive loss related to unrealized gains and losses on marketable and long term investments, offset by a discrete tax benefit of \$246,000 relating to the carry-back of fiscal year 2010 federal losses to obtain a refund of alternative minimum taxes paid for fiscal year 2008.

Net Loss per Diluted Share

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	% Change	2010	2011	% Change	2010
Net loss	\$ (2,863)	17%	\$ (3,459)	\$ (9,174)	1%	\$ (9,238)
Net loss per diluted share	\$ (0.21)	16%	\$ (0.25)	\$ (0.67)	1%	\$ (0.68)

Net loss per diluted share decreased \$0.04, or 16%, in the three-month period ended September 30, 2011, compared to the same period in 2010, due primarily to:

- Higher net revenue of \$3.1 million;
- Improved gross margin from 53% to 56%;
- Reduction in general and administrative expenses by \$42,000; which was partially offset by
 - Increased sales and marketing expenses of \$627,000;
 - Increased R&D expenses of \$481,000;
- Reduction in interest and other income, net, by \$41,000; and
- An increase in the income tax provision by \$326,000.

Net loss per diluted share decreased \$0.01, or 1%, in the nine-month period ended September 30, 2011, compared to the same period in 2010, due primarily to:

- Higher net revenue of \$3.7 million;
- Reduction in general and administrative expenses by \$112,000;
- Increase in interest and other income, net, by \$35,000; which was partly offset by
 - Increased R&D expenses of \$2.0 million;
 - Increased sales and marketing expenses of \$108,000; and
 - An increase in the income tax provision by \$21,000.

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, 2011	December 31, 2010
Working Capital(1)	\$ 89,041	\$ 90,339
Current Ratio(2)	7.0:1	7.9:1

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

(2) The current ratio is a financial ratio that measures a Company's resources to pay its current liabilities and is defined as current assets divided by current liabilities.

TABLE OF CONTENTS

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, 2011	December 31, 2010	Change
Cash and cash equivalents	\$ 13,874	\$ 12,519	\$ 1,355
Marketable investments	74,502	77,484	(2,982)
Long-term investments	3,014	6,784	(3,770)
Total	\$ 91,390	\$ 96,787	\$ (5,397)

Cash Flows

(Dollars in thousands)	Nine Months Ended September 30,	
	2011	2010
Net cash flow provided by (used in):		
Operating activities	\$ (5,753)	\$ (7,631)
Investing activities	6,042	6,125
Financing activities	1,066	380
Net increase (decrease) in cash and cash equivalents	\$ 1,355	\$ (1,126)

Cash Flows from Operating Activities

Net cash used in operating activities in the nine-month period ended September 30, 2011 was \$5.8 million, which was due primarily to:

- \$5.6 million used by the net loss of \$9.2 million after adjusting for non-cash related items of \$3.6 million consisting primarily of stock-based compensation expense of \$3.1 million, depreciation and amortization of \$483,000 and the tax on unrealized gains of marketable and long term investments of \$194,000, partially offset by the provision for excess and obsolete inventories of \$174,000;
- \$3.0 million used to increase inventory relating primarily to raw materials and finished goods associated with the ramp up of our recently introduced products — GenesisPlus and Excel V;
- \$698,000 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, a shift by customers towards purchasing shorter term contracts, and fewer customers purchasing extended service contracts;
- \$493,000 used in other long-term assets, which was primarily related to a \$443,000 lease deposit for our Japan facility; which was offset by
- \$2.0 million generated from the reduction of other current assets primarily from the receipt of a U.S. income tax refund of \$1.2 million and \$1.1 million amortization of discounts and purchased interest relating to our marketable investments, offset by an increase in prepaid expenses of \$212,000;
- \$1.1 million generated by an increase in accrued liabilities relating primarily to an increase in customer deposits of \$453,000, an increase in accrued royalties by \$178,000, and accrued but unpaid personnel costs of \$464,000; and
 - \$855,000 generated by an increase in accounts payable due primarily to higher inventory purchases.

Net cash used in operating activities in the nine-month period ended September 30, 2010 was \$7.6 million, which was due primarily to:

- \$5.0 million used by the net loss of \$9.2 million after adjusting for non-cash related items of \$4.2 million; consisting primarily of stock-based compensation expense of \$3.7 million and other items of \$583,000;
- \$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 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 sales, (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 a (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, 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 Merz; partially offset by
- \$1.8 million amortization of discounts and purchased interest relating to our marketable and long-term investments.

TABLE OF CONTENTS

Cash Flows from Investing Activities

We generated net cash of \$6.0 million from investing activities in the nine-month period ended September 30, 2011, which was attributable primarily to:

- \$52.7 million in net proceeds from the sales and maturities of marketable investments; and
- \$46.3 million of cash used to purchase marketable investments.

We generated net cash of \$6.1 million from investing activities in the nine-month period ended September 30, 2010, which was attributable 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.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$1.1 million in the nine-month period ended September 30, 2011 and \$380,000 in the nine-month period ended September 30, 2010, which primarily resulted from cash generated by the issuance of stock as a result of employees exercising their stock options and shares issued pursuant to our employee stock purchase plan.

Adequacy of cash resources to meet future needs

We had cash, cash equivalents, marketable investments, and long-term investments of \$91.4 million as of September 30, 2011. Of this amount, we had \$3.0 million of long-term ARS investments. For the first nine months of 2011, we financed our operations through the sales and maturities of marketable investments and cash from the sale of stock through employee stock option exercises and our employee stock purchase plan. We believe the existing capital resources, including cash and cash equivalents and marketable investments of \$88.4 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. In order to maintain an exclusive right to distribute Obagi products in the physician dispensed channel in Japan, we need to purchase a minimum of \$1.75 million of products in 2011 and \$2.0 million in 2012. Our other open inventory purchase commitments were not material at September 30, 2011.

TABLE OF CONTENTS

We are named from time to time as a party to product liability and contractual lawsuits in the normal course of our business. As of September 30, 2011, we were not a party to any material pending litigation. 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.

Contractual Obligations

The following are our obligations for future minimum lease commitments related to facility leases as of September 30, 2011 (in thousands):

Contractual Obligations	Total	Payments Due by Period			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases	\$ 9,668	\$ 1,695	\$ 3,507	\$ 2,793	\$ 1,673

Purchase Commitments

We maintain certain open inventory purchase commitments with our suppliers to ensure a smooth and continuous supply for key components. Our 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. Our open inventory purchase commitments were not material at September 30, 2011. As a result, this amount is not included in the contractual obligations table above.

Income Tax Liability

We have included in our Consolidated Balance Sheet \$489,000 in long-term income tax liability with respect to unrecognized tax benefits and accrued interest as of September 30, 2011. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years beyond 12 months due to uncertainties in the timing of tax audit outcomes. As a result, this amount is not included in the contractual obligations table above.

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 is unknown and not reasonably estimable as they involve future claims that may be made against us. As such, we have not accrued any amounts for such obligations.

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 \$538,000 as of September 30, 2011.

TABLE OF CONTENTS

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, 2011, of our original \$13.4 million par value of ARS portfolio, \$9.5 million has been redeemed in full and we had \$3.9 million par value (fair value of \$3.0 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 2032 to 2041. As a result of the ARS failing, we modified our investment strategy and increased our investments in more liquid money market investments, United States Treasury securities, municipal bonds, commercial paper and high-grade 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 from 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 \$25,000 in the nine-month period ended September 30, 2011, 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, 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 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.

TABLE OF CONTENTS

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.

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

We operate in a rapidly changing economic and technological environment that presents numerous risks, many of which are driven by factors that we cannot control or predict. The following discussion, as well as our discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations (Item 2), highlights some of these risks. The risks described below are not exhaustive and you should carefully consider these risks and uncertainties before investing in our securities.

In the three and nine-month periods ended September 30, 2011, our U.S. revenue increased by approximately 43% and 18%, respectively, compared to the same periods in 2010. However, in fiscal year 2010 our U.S. revenue decreased by approximately 8% compared to the same period in 2009. Even though our U.S. revenue has increased in 2011, it continues to be significantly below the pre-2009 levels. If our U.S. revenue does not continue to improve, it could have a material adverse effect on our total revenue, profitability, employee retention and stock price.

In the three and nine-month periods ended September 30, 2011 our U.S. revenue increased by approximately 43% and 18% respectively, compared to the same periods in 2010. However it remains significantly below the pre-2009 level due to several factors, some of which are:

Our Product and Upgrade ASPs were lower than the pre-2009 levels as a result of customers purchasing fewer applications for systems, lower pricing resulting from competitive discounting pressures and the impact of a shift in our product mix towards lower priced systems.

- Historically, we have introduced a new product every year since 2000, which typically resulted in increased revenue. However, in 2009 and until August 2010, we did not have a new product. In August 2010, we launched GenesisPlus and in February 2011, we launched Excel V. Even though we have introduced these new products and experienced sales increases as a result, there can be no assurance that they will translate into increased revenue in the long term in the U.S.
- Although our U.S. Titan hand piece refill revenue increased by 75% in the three-month period ended September 30, 2011, compared to the same period in 2010, our U.S. Titan hand piece refill revenue for the three-month period ended September 30, 2011 was still lower than the levels prior to the second quarter of 2010. That was due to a voluntary recall of certain Titan XL hand pieces in the second quarter of 2010, whereby all customers that had a Titan XL hand piece subject to the recall were provided with a fully refilled Titan XL hand piece. This delayed their purchase of a refill and resulted in a decline of our Titan refill revenue.

If our U.S. revenue does not continue to improve to our pre-2009 levels, it could have a material adverse effect on our total revenue, profitability, employee retention and stock price.

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 productivity of, and retain the sales professionals, our business will be harmed, which would impair our future revenue and profitability.

TABLE OF CONTENTS

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, several of our sales professionals do not have established relationships with core market physicians (Dermatologists and Plastic Surgeons) or where those relationships exist, they are not very strong. In addition, we have lost some of our sales professionals in response to the decline in their earnings resulting from the decreases in their commissions.

We have selectively hired new sales professionals and managers in key territories to fill vacant positions. For example, in December 2010, Michael Poole joined us as Vice President of North American Sales, which allowed our previous Vice President of North American Sales to return to Japan in an expanded role to lead our Pacific Rim operations. Although Mr. Poole has over 17 years of a broad range of sales experience and was employed by us from 2004 to 2008, Mr. Poole has limited prior experience in managing a large sales force. We have been training our existing, and recently recruited, sales professionals to better understand our product technology and how it can be positioned against our competitors' products. These initiatives are intended to improve the productivity of our sales professionals, our revenue and profitability.

In the third quarter of 2011, our European sourced direct and distributor revenue declined significantly, compared to the same period in 2010. We have restructured our European sales team as well as our direct hub operation in Switzerland. For Switzerland, we recently engaged a distributor that was set up by some of our former sales employees. In addition, we continue to hire additional sales personnel to manage our European business. These initiatives are intended to improve our European sourced revenue.

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 and may instead contribute to instability in our operations, additional departures from our sales organization, or further reduce our revenue and harm our business.

If our revenue does not continue to improve from the 2010 level, or if our cost of revenue and/ or operating expenses increase, our gross margins and operating margins may be adversely impacted, our loss from operations will increase, and our cash used in operating activities will increase, which could reduce our assets and have a material adverse effect on our stock price.

Our gross margin remained flat at 56% in the nine-month period ended September 30, 2011 compared to 56% in the same period of 2010. Our gross margin for the full-year was 57% in 2010, compared with 59% in 2009 and 61% in 2008. Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. Our future revenue may be adversely affected by a number of factors including, the competitive market environment in which we operate, which may result in a decrease in the number of units sold, a decrease in the number of applications per system purchased by customers, a decrease in the average selling prices achieved for our product sales, or a shift in our product mix towards products with lower average selling prices. Our cost of revenue may also be adversely impacted by various factors such as obsolescence of our inventory, increased expenses associated with repairing defective products covered by our warranty program, utilization of our relatively fixed manufacturing costs, and a shift in our product mix towards products that have a higher cost of manufacturing. We have also been investing significant resources in our research and development activities and using cash in the process. We plan to continue making such investments in order to bring new products to market.

If our revenue does not continue to improve from the 2010 level, or if our cost of revenue increases, or if we are not able to reduce expenses in the event of a decline in revenue, we may continue to generate losses from operations and use cash, which could reduce our assets and have a material adverse effect on our operations and stock price.

Economic, political and market conditions, including the recent recession and global economic crisis, and catastrophic events may adversely affect our business, results of operations, financial condition and stock price.

Our business is influenced by a range of factors that are beyond our control, including:

- General economic and business conditions;
- The overall demand for our products by the core market specialties of dermatologists and plastic surgeons;
 - Governmental budgetary constraints or shifts in government spending priorities;
 - General political developments;
 - Natural disasters, such as the March 2011 earthquake and tsunami in Japan; and
 - Currency exchange rate fluctuations.

TABLE OF CONTENTS

Macroeconomic developments like the recent recessions in the U.S. and Europe and the debt crisis in the U.S. and certain countries in the European Union could negatively affect our business, operating results or financial condition which, in turn, could adversely affect our stock price. A general weakening of, and related declining corporate confidence in, the global economy or the curtailment in government or corporate spending could cause current or potential customers to reduce their budgets or be unable to fund product or upgrade application purchases, which could cause customers to delay, decrease or cancel purchases of our products and services or cause customers not to pay us or to delay paying us for previously purchased products and services.

In addition, political unrest in regions like the Middle East, terrorist attacks around the globe and the potential for other hostilities in various parts of the world, potential public health crises and natural disasters continue to contribute to a climate of economic and political uncertainty that could adversely affect our results of operations and financial condition, including our revenue growth and profitability. For example, the March 2011 earthquake and tsunami, and other collateral events in Japan adversely affected the demand for our products and services in the Japanese market. These factors may have a strong effect on our sales of product or upgrade application purchases and, to a lesser extent, also may affect our renewal rates for contract service agreements, which may cause a decline in revenues and negatively affect our operating results.

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

- Our ability to develop and market our products to the core market specialties of dermatologists and plastic surgeons;
 - 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
 - The lack of credit financing for some of our potential customers.

If we do not achieve anticipated demand for our products, it could have a material adverse effect on our total revenue, profitability, employee retention and stock price.

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. Commencing in the fourth quarter of 2011, we plan to begin distribution of a Q-switched laser in Japan, that Cutera shall be sourcing from a third party OEM for superficial and deep pigmented lesions (i.e. melasma), skin rejuvenation, laser skin toning and tattoo removal. Currently, these applications represent the majority of offered laser and light-based aesthetic procedures. Since the first quarter of 2010, we have been distributing topical skin creams and dermal fillers in the Japanese market. To grow in the future, we must continue to 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.

Except for 2009, we have introduced a new product every year since 2000. In the first quarter 2011, we announced the release of our Excel V laser system (we commenced recognizing revenue in the second quarter 2011), a unique vascular work station designed specifically for the core-market of dermatologists and plastic surgeons. In 2010, we launched GenesisPlus, a laser specifically created for the aesthetic treatment of toes and feet. Historically, product introductions have been 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.

In January 2011, we announced the appointment of Len DeBenedictis as Chief Technology Officer to lead our research and product development efforts. Our current Vice President of Research and Development reports to Mr. DeBenedictis. Although Mr. DeBenedictis has over 20 years of laser and light-based industry experience and an outstanding background to lead our research and product development efforts, there is no guarantee that we will be able to continue our trend of regular new product introductions or that such management change will result in an improved research and development organization. Also, we may need additional research and development resources to make new product introductions, which may be more costly and time consuming to our organization.

TABLE OF CONTENTS

We also believe that, to increase revenue from sales of new products, 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.

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.

TABLE OF CONTENTS

Continued expansion of the global market for laser and light-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 light-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 are subject to wearing 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 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.

As a result of our voluntary Titan XL recall in 2010, our Titan refills revenue declined significantly lower than the revenue levels prior to the recall. If customers do not return to using their Titan hand pieces at our pre second quarter 2010 revenue levels due to this voluntary recall, our Titan refill revenue and profitability could be negatively impacted in the future.

Although our worldwide Titan hand piece refill revenue for the three and nine-month periods ended September 30, 2011 increased 59% and 14%, respectively, compared to the same periods in 2010, our Titan hand piece refill revenue in the U.S. remains below the revenue level for the second quarter of 2010. For the full-year of 2010, it decreased by

31%, compared to 2009. These decreases were due primarily to our voluntary recall of our Titan XL hand piece in 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 at our pre-2010 revenue levels due to this voluntary recall, our Titan refill revenue and profitability could be negatively impacted in the future.

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

International revenue represented 62% of our total revenue for the nine-month period ended September 30, 2011 and 64% for the full-year 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. In the fourth quarter of 2011, some of our direct sales personnel in Switzerland set up an independent distributor company. We plan to sell in this geography through this distributor company. 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.

TABLE OF CONTENTS

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;
- 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 may decline.

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 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, up until April 2011 our recently introduced GenesisPlus product had a number of general indications for use in the U.S. that allowed us to market the product in the U.S., however we could only market it internationally for the treatment of toenail fungus as it has a CE Mark approval. In April 2011, we received FDA clearance to market GenesisPlus in the U.S. for the treatment of toenail fungus. Another example is our Pearl Fractional product which is

cleared only for skin resurfacing in the U.S. and our Titan product only for deep heating for the temporary relief of muscle aches and pains in the U.S. Therefore, we are prevented from promoting or advertising Titan 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.

TABLE OF CONTENTS

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

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, recall or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- Withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- Criminal prosecution.

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

If we fail to comply with the FDA's Quality System Regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.

We are currently required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. We had a full quality system audit in 2008 and an FDA audit of compliance with laser performance standards in 2010 and a full quality system audit plus laser performance standard audit in August 2011. There were no significant findings as a result of these audits and our responses have been accepted by the FDA. 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 for obtaining clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may be unable to obtain or maintain regulatory qualifications, clearances or approvals in other countries. We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications. If we experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if we fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in international markets effectively, or at all, which could have a material adverse effect on our business and growth strategy.

TABLE OF CONTENTS

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 customers are not trained and / or our products are used by non-physicians, it could result in product misuse and adverse treatment outcomes, which could harm our reputation, result in product liability litigation, distract management, result in additional costs, all of which could harm our business.

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

In 2010 and 2011 we 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 impact our profitability.

In 2010 and 2011, we entered into distribution arrangements pursuant to which we utilize our sales force and distributors to sell products manufactured by other companies. Commencing in the fourth quarter of 2011, we plan to distribute in Japan a Q-switched Laser Product manufactured by a third party OEM. In the first quarter of 2010, we entered into an agreement with Obagi to distribute certain of their proprietary cosmeceuticals, or skin care products, in Japan. This agreement requires us to purchase an annual minimum dollar amount of their product. The minimum purchase requirement for 2011 and 2012 is \$1.75 million and \$2.0 million respectively. If we do not make these minimum purchases, we could lose exclusivity for distributing Obagi products to physicians in Japan. Finally, we also have an agreement with Merz Aesthetics 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.

TABLE OF CONTENTS

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 has significantly declined since 2008. Our revenue from PSS, as a percentage of worldwide revenue, was 2% during the nine months ended September 30, 2011, 5% in 2010 and 7% in 2009. 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 revenue from PSS does not improve, or if they terminate our relationship, it may have an adverse effect on our revenue, 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, in commercial paper and high grade corporate debt. As of September 30, 2011, our balance in marketable investments was \$74.5 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, 2011 would have potentially decreased by approximately \$538,000, 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 Consolidated Balance Sheet as of September 30, 2011 are \$3.9 million (par value) of ARS. These ARS were designed to provide liquidity through an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days. Though approximately \$9.5 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, 2011 continue to fail and they remain as illiquid. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the prospectus of the individual security, which rate is generally higher than the prevailing 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 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 due to several factors, some of which are discussed below. Further, 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, 2011, approximately 44% 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 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.

TABLE OF CONTENTS

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:

- Litigation surrounding executive compensation has increased with the passage of the Dodd-Frank Wall Street Reform and Consumer Protection Act. If we are involved in a lawsuit related to compensation matters or any other matters not covered by our D&O insurance, there could be material expenses involved, fines, or remedial actions which could negatively affect our stock price;
 - 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.

From time to time we 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 light-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.

TABLE OF CONTENTS

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

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

- Interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
 - A lack of long term supply arrangements for key components with our suppliers;
 - Inability to obtain adequate supply in a timely manner, or on reasonable terms;
- Inability to redesign one or more components in our systems in the event that a supplier discontinues manufacturing such components and we are unable to source it from other suppliers 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 September 30, 2011, we had 19 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.

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 results from operations.

TABLE OF CONTENTS

The expense and potential unavailability of insurance coverage for our customers could adversely affect our ability to sell our products, and therefore our financial condition.

Some of our customers and prospective customers have had difficulty in procuring or maintaining liability insurance to cover their operation and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing laser and light 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;
- 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.

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.

TABLE OF CONTENTS

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.
<u>31.1</u>	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
<u>31.2</u>	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
<u>32.1</u>	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.
101.ins	Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Extension Calculation Linkbase Document
101.lab	XBRL Taxonomy Extension Label Linkbase Document
101.pre	XBRL Taxonomy Extension Presentation Linkbase Document
(1)	Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.
(2)	Incorporated by reference from our Annual Report on Form 10-K filed with the SEC on March 25, 2005.
(3)	Incorporated by reference from our Definitive Proxy Statement on Form 14A filed with the SEC on April 28, 2008.

TABLE OF CONTENTS

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of The Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Brisbane, State of California, on the 7th day of November, 2011.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

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