

CUTERA INC
Form 10-Q
November 03, 2014
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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, 2014

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 **77-0492262**
(State or other jurisdiction of incorporation or organization) **(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

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, 2014 was 14,395,948.

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CUTERA, INC.

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Table Of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CUTERA, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share data)

(unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,377	\$ 16,242
Marketable investments	69,321	66,831
Accounts receivable, net	8,736	9,679
Inventories	11,106	9,006
Deferred tax asset	29	31
Other current assets and prepaid expenses	1,947	1,507
Total current assets	102,516	103,296
Property and equipment, net	1,301	1,362
Deferred tax asset, net of current portion	316	329
Intangibles, net	1,438	2,019
Goodwill	1,339	1,339
Other long-term assets	13	324
Total assets	\$ 106,923	\$ 108,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,718	\$ 1,820

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Accrued liabilities	8,975	9,328
Deferred revenue	8,745	7,494
Total current liabilities	20,438	18,642
Deferred revenue, net of current portion	4,596	4,340
Income tax liability	151	108
Other long-term liabilities	1,029	1,314
Total liabilities	26,214	24,404
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value; authorized: 5,000,000 shares; none issued and outstanding	—	—
Common stock, \$0.001 par value; authorized: 50,000,000 shares; issued and outstanding: 14,393,801 and 13,931,833 shares at September 30, 2014 and December 31, 2013, respectively	14	14
Additional paid-in capital	104,284	98,820
Accumulated deficit	(23,607)	(14,620)
Accumulated other comprehensive income	18	51
Total stockholders' equity	80,709	84,265
Total liabilities and stockholders' equity	\$ 106,923	\$ 108,669

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, 2014		Nine Months Ended September 30, 2014	
	2013	2014	2013	2013
Net revenue:				
Products	\$12,480	\$14,409	\$39,056	\$39,332
Service	4,348	4,317	13,299	13,307
Total net revenue	16,828	18,726	52,355	52,639
Cost of revenue:				
Products	5,490	5,877	17,063	16,871
Service	2,161	2,058	6,447	6,215
Total cost of revenue	7,651	7,935	23,510	23,086
Gross profit	9,177	10,791	28,845	29,553
Operating expenses:				
Sales and marketing	6,554	7,805	20,180	22,890
Research and development	2,440	2,628	6,778	7,894
General and administrative	2,160	2,897	6,803	7,796
Total operating expenses	11,154	13,330	33,761	38,580
Loss from operations	(1,977)	(2,539)	(4,916)	(9,027)
Interest and other income, net	140	—	350	218
Loss before income taxes	(1,837)	(2,539)	(4,566)	(8,809)
Provision (benefit) for income taxes	(169)	97	(97)	178
Net loss	\$(1,668)	\$(2,636)	\$(4,469)	\$(8,987)
Net loss per share:				
Basic and Diluted	\$(0.11)	\$(0.18)	\$(0.31)	\$(0.63)
Weighted-average number of shares used in per share calculations:				
Basic and Diluted	14,541	14,334	14,558	14,197

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

Table Of Contents**CUTERA, INC.****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(in thousands)****(unaudited)**

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2013	
Net loss	\$(2,636)	\$(1,668)	\$(8,987)	\$(4,469)
Other comprehensive income (loss):				
Available-for-sale investments				
Net change in unrealized gain (loss) on available-for-sale investments	(57)	94	(29)	(27)
Less: Reclassification adjustment for gains on investments recognized during the respective periods	(3)	(9)	(4)	(9)
Net change in unrealized gain (loss) on available-for-sale investments	(60)	85	(33)	(36)
Tax benefit	10	—	—	—
Other comprehensive income (loss), net of tax	(50)	85	(33)	(36)
Comprehensive loss	\$(2,686)	\$(1,583)	\$(9,020)	\$(4,505)

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, 2014 2013	
Cash flows from operating activities:		
Net loss	\$(8,987)	\$(4,469)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	2,298	2,370
Depreciation and amortization	989	973
Other	222	43
Changes in assets and liabilities:		
Accounts receivable	845	1,347
Inventories	(2,100)	693
Other current assets and prepaid expenses	(181)	212
Other long-term assets	311	49
Accounts payable	898	(7)
Accrued liabilities	(385)	(1,877)
Other long-term liabilities	(214)	(163)
Deferred revenue	1,507	1,870
Income tax liability	43	(343)
Net cash provided by (used in) operating activities	(4,754)	698
Cash flows from investing activities:		
Acquisition of property, equipment and software	(390)	(493)
Proceeds from sales of marketable investments	11,501	12,108
Proceeds from maturities of marketable investments	22,260	26,315
Purchase of marketable investments	(36,539)	(43,901)
Net cash used in investing activities	(3,168)	(5,971)
Cash flows from financing activities:		
Repurchase of common stock	—	(7,623)
Proceeds from exercise of stock options and employee stock purchase plan	3,166	4,600
Payments on capital lease obligations	(109)	(90)

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Net cash provided by (used in) financing activities	3,057	(3,113)
Net decrease in cash and cash equivalents	(4,865)	(8,386)
Cash and cash equivalents at beginning of period	16,242	23,546
Cash and cash equivalents at end of period	\$11,377	\$15,160

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

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CUTERA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Description of Operations and Principles of Consolidation

Cutera[®], Inc. (“*Cutera*” or the “*Company*”) is a global provider of laser and other energy-based aesthetic systems for practitioners worldwide. The Company designs, develops, manufactures, and markets laser and other energy-based product platforms for use by physicians and other qualified practitioners which enable them to offer safe and effective aesthetic treatments to their customers. The Company currently markets the following key product platforms: CoolGlide[®], Xeo[®], Solera[®], GenesisPlus[™], Excel V[™], truSculpt[™], Excel HR[™] and enLIGHTen[™]. The Company’s products offer multiple hand pieces and applications, which allow customers to upgrade their systems. The sales of systems, upgrades, hand pieces, hand piece refills (Titan[®] and truSculpt) and the distribution of third party manufactured dermal fillers and cosmeceuticals are classified as “Product” revenue. In the second quarter of 2014, the Company terminated its agreement with Merz Pharma GmbH (“*Merz*”) for the distribution of its Radiesse[®] dermal filler product. In addition to Product revenue, the Company generates revenue from the sale of post-warranty service contracts, parts, detachable hand piece replacements (except for Titan and truSculpt) and service labor for the repair and maintenance of products that are out of warranty, all of which is classified as “Service revenue.”

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries that are currently operational in Australia, Belgium, Canada, France, Japan, Switzerland and Hong Kong, that market, sell and service its products outside of the United States. The Condensed Consolidated Financial Statements include the accounts of the Company and its subsidiaries. All inter-company transactions and balances have been eliminated.

Unaudited Interim Financial Information

The interim 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, 2013 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 previously filed audited financial statements and the notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (the "SEC") on March 18, 2014.

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 revenue elements, warranty obligations, sales commissions, accounts receivable and sales allowances, provision for excess and obsolete inventories, fair values of marketable investments, fair values of acquired intangible assets, useful lives of intangible assets and property and equipment, fair values of performance stock units and options to purchase the Company's stock, 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and shall take effective on January 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method and the early application of the standard is not permitted. The Company is presently evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures and has not yet selected a transition method.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*. This standard update provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new guidance is effective for all annual and interim periods ending after December 15, 2016. The new guidance will not have an impact on the Company's consolidated financial statements.

Note 2. Cash, Cash Equivalents and Marketable Investments

The Company invests its cash primarily in money market funds, commercial paper, corporate notes and bonds, municipal bonds, and debt securities issued by the U.S. government and its agencies. 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 with maturities of greater than three months at the time of purchase are accounted for as “available-for-sale,” are carried at fair value with unrealized gains and losses reported as a component of stockholders’ equity, held for use in current operations and classified in current assets as “marketable investments.”

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The following tables summarize the components, and the unrealized gains and losses position, related to the Company's cash and cash equivalents and marketable investments (in thousands):

September 30, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash and cash equivalents:				
Cash	\$ 4,224	\$ —	\$ —	\$4,224
Money market funds	4,653	—	—	4,653
Commercial paper	2,500	—	—	2,500
Total cash and cash equivalents	11,377	—	—	11,377
Marketable investments:				
U.S. government notes	18,340	19	—	18,359
U.S. government agencies	19,845	31	(9)	19,867
Municipal securities	3,833	3	(3)	3,833
Commercial paper	8,440	4	—	8,444
Corporate debt securities	18,795	32	(9)	18,818
Total marketable investments	69,253	89	(21)	69,321
Total cash, cash equivalents and marketable investments	\$ 80,630	\$ 89	\$ (21)	\$ 80,698
December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash and cash equivalents:				
Cash	\$ 3,816	\$ —	\$ —	\$3,816
Money market funds	9,926	—	—	9,926
Commercial paper	2,500	—	—	2,500
Total cash and cash equivalents	16,242	—	—	16,242
Marketable investments:				
U.S. government notes	10,516	11	(5)	10,522
U.S. government agencies	25,823	38	(3)	25,858
Municipal securities	2,043	1	(5)	2,039
Commercial paper	10,239	3	—	10,242
Corporate debt securities	18,109	61	—	18,170
Total marketable investments	66,730	114	(13)	66,831
Total cash, cash equivalents and marketable investments	\$ 82,972	\$ 114	\$ (13)	\$ 83,073

As of September 30, 2014 and December 31, 2013, total gross unrealized losses were \$21,000 and \$13,000, respectively, and were related to interest rate changes on available-for-sale marketable investments. The Company has

concluded that it is more-likely-than-not that the securities will be held until maturity or the recovery of their cost basis. No securities were in an unrealized loss position for more than 12 months.

The following table summarizes the contractual maturities of the Company's available-for-sale securities, classified as marketable investments as of September 30, 2014 (in thousands):

	Amount
Due in less than one year	\$29,091
Due in 1 to 3 years	40,230
	\$69,321

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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, 2014, 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 were as follows (in thousands):

September 30, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$4,653	\$—	\$ —	\$4,653
Commercial paper	—	2,500	—	2,500
Marketable investments:				
Available-for-sale securities	—	69,321	—	69,321
Total assets at fair value	\$4,653	\$71,821	\$ —	\$76,474

As of December 31, 2013, 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):

December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$9,926	\$—	\$ —	\$9,926
Commercial paper	—	2,500	—	2,500
Marketable investments:				
Available-for-sale securities	—	66,831	—	66,831
Total assets at fair value	\$9,926	\$69,331	\$ —	\$79,257

The Company's Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The average remaining maturity of the Company's Level 2 investments as of September 30, 2014 is less than 36 months and all of these investments are rated by S&P and Moody's at A- or better.

Note 4. Inventories

As of September 30, 2014 and December 31, 2013, inventories consist of the following (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	\$ 7,458	\$ 5,989
Finished goods	3,648	3,017
Total	\$ 11,106	\$ 9,006

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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 historical service costs to calculate the expected 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 three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Beginning Balance	\$1,080	\$1,049	\$1,202	\$1,212
Add: Accruals for warranties issued during the period	568	691	1,615	2,403
Less: Settlements made during the period	(671)	(682)	(1,840)	(2,557)
Ending Balance	\$977	\$1,058	\$977	\$1,058

Note 6. Deferred Service Contract Revenue

The Company generates Service revenue from the sale of extended service contracts and from time and material services provided to customers who are not under a warranty or extended service contract. Service contract revenue is recognized on a straight-line basis over the period of the applicable contract. Service revenue, from customers whose systems are not under a service contract, is recognized as the services are provided.

The following table provides changes in the deferred service contract revenue balance for the three and nine months ended September 30, 2014 and 2013 (in thousands):

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

	2014	2013	2014	2013
Beginning Balance	\$13,001	\$9,715	\$11,637	\$8,539
Add: Payments received	3,418	3,729	10,985	10,869
Less: Revenue recognized	(3,233)	(2,973)	(9,436)	(8,937)
Ending Balance	\$13,186	\$10,471	\$13,186	\$10,471

Costs for extended service contracts were \$1.8 million and \$1.7 million for the three months ended September 30, 2014 and 2013, respectively, and \$5.3 million and \$5.2 million for the nine months ended September 30, 2014 and 2013, respectively.

Note 7. Stockholders' Equity and Stock-based Compensation Expense

Stock-based Compensation Expense

Stock-based compensation expense by department recognized during the three and nine months ended September 30, 2014 and 2013 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of revenue	\$145	\$159	\$416	\$484
Sales and marketing	195	182	414	579
Research and development	167	103	406	293
General and administrative	473	304	1,062	1,014
Total stock-based compensation expense	\$980	\$748	\$2,298	\$2,370

Under the 2004 Equity Incentive Plan, as amended, the Company issued 373,722 shares of common stock during the nine months ended September 30, 2014, in conjunction with stock options exercised.

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During the nine months ended September 30, 2014, the following number of equity awards of the Company's common stock was granted (in thousands):

	Shares
Stock options	431
Restricted stock units	211
Performance stock units	105 *

* In the third quarter of 2014, the Company granted its executive officers and certain senior management employees 105,000 Performance Stock Units ("*PSU*") that will vest on June 30, 2015, subject to the recipient's continued service through that date. At the vest date, the Company will issue fully-paid up common stock, based on the achievement of three performance goals related to the degree of achievement towards pre-established targets for the Company's revenue and operating loss improvements, compared to the same period in the prior year.

As of September 30, 2014, there was \$4.1 million of unrecognized compensation expense, net of projected forfeitures, related to non-vested equity awards. The expense is expected to be recognized over the remaining weighted-average period of 2.7 years.

Note 8. 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.

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

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

	2014	2013	2014	2013
Options to purchase common stock	3,391	4,134	3,498	3,799
Restricted stock units	209	206	177	168
Performance stock units	—	34	3	34
Employee stock purchase plan shares	31	27	54	60
Total	3,631	4,401	3,732	4,061

Note 9. Income Taxes

The Company's quarterly income taxes reflect an estimate of the corresponding year's annual effective tax rate and include, when applicable, adjustments from discrete tax items. For the three and nine months ended September 30, 2014, the Company's tax provision was \$97,000 and \$178,000, respectively, compared to a tax benefit of \$169,000 and \$97,000 for the three and nine months ended September 30, 2013, respectively. The Company's income tax provision for the three and nine months ended September 30, 2014 was primarily related to income taxes for the Company's non-U.S. operations as the Company's U.S. operations were in a loss position and the Company maintains a 100% valuation allowance for its U.S. deferred tax assets. The Company's income tax benefit for the three and nine months ended September 30, 2013 was primarily attributable to a release of uncertain tax position reserves, partially offset by income taxes of the Company's non-U.S. operations.

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, 2014 and December 31, 2013, 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 subjectivity involved in 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.

Note 10. Commitments and Contingencies

Litigation and Litigation Settlements

The Company is named from time to time as a party to product liability and contractual lawsuits in the normal course of business. The Company routinely assesses the likelihood of any adverse judgments or outcomes related to legal matters and claims, as well as ranges of probable losses. A determination of the amount of the reserves required, if any, for these contingencies is made after analysis of each known issue, historical experience, whether it is more likely

than not that the Company shall incur a loss, and whether the loss is estimable. As of September 30, 2014 and December 31, 2013, the Company was not subject to any material litigation.

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**ITEM MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS
2. 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, 2013 as contained in our annual report on Form 10-K filed with the SEC on March 18, 2014. 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,” “predicts,” “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 20 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.
- 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 leading medical device company specializing in the research, development, manufacture, marketing and servicing of laser and other energy-based aesthetics systems for practitioners worldwide. We offer easy-to-use products which enable physicians and other qualified practitioners to perform safe and effective aesthetic procedures, including treatment of vascular conditions and removal of benign pigmented lesions, hair-removal, skin rejuvenation, body contouring, skin resurfacing, tattoo removal and toenail fungus. Our platforms are designed to be easily upgraded to add additional applications and hand pieces, which provide flexibility for our customers as they expand their practices. 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, hand piece refills, and third-party manufactured dermal fillers and cosmeceuticals. In the second quarter of 2014, we terminated our agreement with Merz for the distribution of its Radiesse® dermal filler product.

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. We market, sell and service our products through direct sales and service employees in the U.S., Australia, Belgium, Canada, France, Japan, Switzerland and Hong Kong. Sales and Service outside of these direct markets are made through a worldwide distributor network in over 60 countries.

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Products

Our revenue is derived from the sale of Products and upgrades, Service, Titan hand piece refills, and Dermal fillers and cosmeceuticals. Product and upgrade revenue includes sales of new systems and additional applications that customers purchase as their practice grows. A system consists of a console that incorporates a universal graphic user interface, a laser and/or other energy-based module, control system software, high voltage electronics and one or more hand pieces.

Our broad portfolio of Product brands include:

enLIGHTen™
Excel V™
Excel HR™
Xeo®
truSculpt™
GenesisPlus™
CoolGlide®
Solera®
myQ™

Service revenue relates to prepaid service contracts, direct billings for detachable hand piece replacements (except for Titan and truSculpt) and revenue for parts and labor on out-of-warranty products. For our Titan and truSculpt hand pieces, after a set number of treatments have been performed, the customer is required to send the hand piece back to the factory for refurbishment, which we refer to as “refilling” the hand piece. In Japan, we distribute ZO Medical Health Inc. (“ZO”) cosmeceutical products and through the second quarter of 2014, we also distributed Merz’s Radiesse® dermal filler product.

Significant Business Trends

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

- Consumer demand for the applications of our products.
- Customer (physicians) demand for our products.
- 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).
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, Products and upgrades, Titan hand piece refills, and Cosmeceutical products.

For a detailed discussion of the significant business trends impacting our business, please see the section titled “Results of Operations” below.

Factors that May Impact Future Performance.

Our industry is impacted by numerous competitive, regulatory, macroeconomic and other significant factors. Our industry is highly competitive and our future performance depends on our ability to compete successfully. Additionally, our future performance is dependent upon our ability to continue to expand our product offerings, develop innovative technologies, obtain regulatory clearances for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. If we fail to execute on the aforementioned initiatives, our business would be adversely affected. A detailed discussion of these and other factors that could impact our future performance are provided in Part II, Item 1A “Risk Factors” section below.

Critical Accounting Policies and Estimates.

The preparation of our Condensed Consolidated Financial Statements and related disclosures in conformity with 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.

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Critical accounting estimates, as defined by the 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, 2013 filed with the SEC on March 18, 2014. There have been no significant changes to the accounting policies and estimates disclosed in our Form 10-K.

Results of Operations

The following table sets forth selected consolidated financial data for the periods indicated, expressed as a percentage of total revenue, net. Percentages in this table and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments.

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2013	
	2014	2013	2014	2013
Net revenue	100%	100 %	100%	100 %
Cost of revenue	42 %	45 %	44 %	45 %
Gross margin	58 %	55 %	56 %	55 %
Operating expenses:				
Sales and marketing	42 %	39 %	43 %	39 %
Research and development	14 %	15 %	15 %	13 %
General and administrative	15 %	13 %	15 %	13 %
Total operating expenses	71 %	67 %	73 %	65 %
Loss from operations	(13)%	(12)%	(17)%	(10)%
Interest and other income, net	— %	1 %	— %	1 %
Loss before income taxes	(13)%	(11)%	(17)%	(9)%
Provision (benefit) for income taxes	1 %	(1)%	— %	— %
Net loss	(14)%	(10)%	(17)%	(9)%

Total Net Revenue

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	% Change	2013	2014	% Change	2013
Revenue mix by geography:						
United States	\$7,607	9 %	\$7,001	\$21,733	3 %	\$21,149
International	11,119	13 %	9,827	30,906	(1)%	31,206
Consolidated total revenue	\$18,726	11 %	\$16,828	\$52,639	1 %	\$52,355
<i>United States as a percentage of total revenue</i>	<i>41 %</i>		<i>42 %</i>	<i>41 %</i>		<i>40 %</i>
<i>International as a percentage of total revenue</i>	<i>59 %</i>		<i>58 %</i>	<i>59 %</i>		<i>60 %</i>
Revenue mix by product category:						
Products and upgrades	\$12,922	24 %	\$10,440	\$33,772	3 %	\$32,671
Titan and truSculpt hand piece refills	824	(11)%	927	2,870	(11)%	3,223
Dermal fillers and cosmeceuticals	663	(40)%	1,113	2,690	(15)%	3,162
Total Products revenue	14,409	15 %	12,480	39,332	1 %	39,056
Service	4,317	(1)%	4,348	13,307	— %	13,299
Consolidated total revenue	\$18,726	(11)%	\$16,828	\$52,639	1 %	\$52,355

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Discussion of Revenue by Geography:

Our U.S. revenue increased by \$606,000, or 9%, and by \$584,000, or 3% in the three and nine months ended September 30, 2014, respectively, compared to the same periods in 2013. These increases were due primarily to an increase in sales of our Excel V and our recently launched Excel HR products, which was partially offset by declines in sales of our Xeo, truSculpt and GenesisPlus products.

Our international revenue increased by \$1.3 million, or 13%, in the three months ended September 30, 2014, compared to the same period in 2013. This increase was due primarily to increases in revenue from our direct business in Australia, Canada and Japan as well as our European distributor countries which were partially offset by a decrease in our revenue from distributors in Asia Pacific countries. Our international revenue decreased by \$300,000, or 1%, in the nine months ended September 30, 2014, compared to the same period in 2013. This decrease was due primarily to a decline in the dermal filler and cosmeceuticals revenue from Japan.

Discussion of Revenue by Product Type:

Product and Upgrade 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.

Product and upgrade revenue increased by \$2.5 million, or 24%, in the three months ended September 30, 2014, compared to the same period in 2013 and by \$1.1 million, or 3%, in the nine months ended September 30, 2014, compared to the same period in 2013. These increases were attributable primarily to:

The continued improvement in revenue from our Excel V product
Revenue from our newly introduced Excel HR product; which were offset partly by
Reduction in revenue from our Xeo, truSculpt and GenesisPlus products

Titan and truSculpt Hand Piece Refill Revenue

Our Titan and truSculpt hand piece refill revenue decreased by \$103,000, or 11%, in the three months ended September 30, 2014, and by \$353,000, or 11%, in the nine months ended September 30, 2014, compared to the same periods in 2013. These decreases were due primarily to declines in Titan hand piece refill revenue, caused partially by reduced utilization and partly due to the decline in the Japanese Yen relative to the U.S. Dollar. In addition, there was a decrease in revenue from truSculpt refills due to a repositioning of the product in the third quarter of 2013 to include hand piece refills as part of the warranty of the product.

Dermal Filler and Cosmeceuticals Revenue

Our dermal filler and cosmeceuticals revenue decreased by \$450,000, or 40%, in the three months ended September 30, 2014, and by \$472,000, or 15%, in the nine months ended September 30, 2014, compared to the same periods in 2013. These declines were due primarily to the termination of our agreement with Merz for the distribution of their Radiesse® dermal filler product in the second quarter of 2014.

Service Revenue

Our worldwide Service revenue decreased by 1% in the three months ended September 30, 2014, and was flat in the nine months ended September 30, 2014, compared to the same periods in 2013.

Gross Profit

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	% Change	2013	2014	% Change	2013
Gross profit	\$10,791	(18)%	\$9,177	\$29,553	2%	\$28,845
As a percentage of total net revenue	58%		55%	56%		55%

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

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Gross margin was 58% and 56% in the three and nine months ended September 30, 2014, respectively, compared to 55% for both of the same periods in 2013. These gross margin improvements in the three and nine months ended September 30, 2014 were due primarily to:

- Higher revenue that resulted in increased leverage;
- Improved gross margin from our Service business, due primarily to reduced material expenses resulting from improved reliability of our products; and
- Reduced amortization of intangibles related to the acquisition of Iridex's aesthetic business; and
- A shift in the product mix towards higher margin products.

Sales and Marketing

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	% Change	2013	2014	% Change	2013
Sales and marketing	\$7,805	19	\$6,554	\$22,890	13	\$20,180
As a percentage of total net revenue	42	%	39	43	%	39

Sales and marketing expenses consist primarily of personnel expenses, expenses associated with customer-attended workshops and trade shows, post-marketing studies, and advertising. In an effort to improve our revenue, in the nine months ended September 30, 2014, we expanded our North American sales force and restructured their compensation arrangements, hired new senior sales management with prior experience in the aesthetic medical device industry, and have increased our marketing and promotional activities in North America. Given the time it takes to train new sales employees to sell our products and for the marketing efforts to yield in improved revenue, our total sales and marketing expenses increased to 43% of total net revenue in the nine months ended September 30, 2014, compared to 39% in the same period in 2013.

Sales and marketing expenses increased by \$1.3 million, and represented 42% of total net revenue in the three months ended September 30, 2014, compared to 39% in the same period in 2013. The \$1.3 million increase was due primarily to:

- \$1.1 million net increase in personnel related expenses, which were driven primarily by the expansion of our North American sales force, offset by reduced personnel expenses in Japan and in the marketing department; and
- \$172,000 of increased travel and entertainment expenses due to increased headcount and sales activity.

Sales and marketing expenses increased by \$2.7 million in the nine months ended September 30, 2014, compared to the same period in 2013. The \$2.7 million increase was due primarily to:

\$2.4 million net increase in personnel related expenses, which were driven primarily by the expansion of our North American sales force, offset by reduced personnel expenses in Japan and in the marketing department; and \$370,000 of increased marketing and promotional expenses.

Research and Development (“R&D”)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,			
	2014	% Change	2013	2014	% Change	2013	
Research and development	\$2,628	8	% \$2,440	\$7,894	16	% \$6,778	
As a percentage of total net revenue	14	%	15	% 15	%	13	%

R&D expenses consist primarily of personnel expenses, clinical research and regulatory and material costs. R&D expenses increased by \$188,000, and represented 14% of total net revenue in the three months ended September 30, 2014, compared to 15% for the same period in 2013. This increase in expense was due primarily to:

\$306,000 of increased personnel related expenses; partially offset by 144,000 of decreased material spending, which is project timing related.

R&D expenses increased by \$1.1 million, and represented 15% of total net revenue in the nine months ended September 30, 2014, compared to 13% for the same period in 2013. The increase was due primarily to:

\$604,000 of increased material spending, which is project timing dependent, related to new product development; \$594,000 of increased personnel related expenses due to increased headcount; partially offset by \$104,000 of decreased tools and equipment expenses.

General and Administrative (“G&A”)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,			
	2014	% Change	2013	2014	% Change	2013	
General and administrative	\$2,897	34	% \$2,160	\$7,796	15	% \$6,803	
As a percentage of total net revenue	15	%	13	% 15	%	13	%

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G&A expenses consist primarily of personnel expenses, legal fees, accounting, audit and tax consulting fees, U.S. medical device excise tax and other general and administrative expenses. G&A expenses increased by \$737,000 and represented 15% of total net revenue in the three months ended September 30, 2014, compared to 13% for the same period in 2013. This increase was due primarily to a \$588,000 increase in personnel related expenses.

G&A expenses increased \$1.0 million, and represented 15% of total net revenue in the nine months ended September 30, 2014, compared to 13% for the same period in 2013. This increase was due primarily to:

\$618,000 of increased personnel related expenses; and
\$200,000 of non-recurring management consulting fees incurred in the first quarter of 2014.

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,		
	2014	% Change	2013	2014	% Change	2013
Interest income	\$106	1 %	\$105	\$299	(8)%	\$324
Other income (expense), net	(106)	(403)%	35	(81)	(412)%	26
Total interest and other income, net	\$—	(100)%	\$140	\$218	(38)%	\$350

Interest and other income, net, decreased \$140,000 for the three months ended September 30, 2014, and decreased by \$132,000 for the nine months ended September 30, 2014, compared to the same periods in 2013. These decreases were primarily attributable to net foreign exchange losses.

Provision (Benefit) for Income Taxes

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	% Change	2013	2014	% Change	2013

Loss before income taxes	\$ (2,539)	38	%	\$ (1,837)	\$ (8,809)	93	%	\$ (4,566)	
Provision (benefit) for income taxes	97	(157))%	(169))	178	(284))%	(97)

We recorded an income tax provision for the three and nine months ended September 30, 2014 of \$97,000 and \$178,000, respectively, compared to an income tax benefit of \$169,000 and \$97,000 for the three and nine months ended September 30, 2013, respectively. Our income tax provision for the three and nine months ended September 30, 2014 was primarily related to income taxes of our non-U.S. operations as our U.S. operations were in a loss position and we maintain a 100% valuation allowance for our U.S. deferred tax assets. Our income tax benefit for the three and nine months ended September 30, 2013 was primarily attributable to a release of uncertain tax positions reserves, partially offset by income taxes of our non-U.S. operations.

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, stock option exercises and the liquidation of marketable investments. 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.

Cash, Cash Equivalents and Marketable Investments

The following table summarizes our cash, cash equivalents and marketable investments:

(Dollars in thousands)	September	December	Change
	30,	31,	
	2014	2013	
Cash and cash equivalents	\$ 11,377	\$ 16,242	\$(4,865)
Marketable investments	69,321	66,831	2,490
Total	\$ 80,698	\$ 83,073	\$(2,375)

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(Dollars in thousands)	Nine Months Ended	
	September 30, 2014	2013
Net cash flow provided by (used in):		
Operating activities	\$(4,754)	\$698
Investing activities	(3,168)	(5,971)
Financing activities	3,057	(3,113)
Net decrease in cash and cash equivalents	\$(4,865)	\$(8,386)

Cash Flows from Operating Activities

Net cash used in operating activities in the nine months ended September 30, 2014 was \$4.8 million, which was due primarily to:

\$5.5 million used due to the net loss of \$9.0 million reduced by non-cash related items of \$3.5 million consisting primarily of stock-based compensation expense of \$2.3 million and depreciation and amortization expenses of \$1.0 million;

\$2.1 million used to increase inventory for the anticipated new product launch; offset by

\$1.5 million generated by an increase in deferred revenue primarily from the sale of service contracts to an increasing installed base of customers;

\$0.9 million generated from an increase in accounts payables; and

\$0.8 million generated from the collection of cash from the high accounts receivable balance as of December 31, 2013.

Net cash generated by operating activities in the nine months ended September 30, 2013 was \$0.7 million, which was due primarily to:

\$1.1 million used due to the net loss of \$4.5 million reduced by non-cash related items of \$3.4 million consisting primarily of stock-based compensation expense of \$2.4 million and depreciation and amortization expenses of \$1.0 million;

\$1.9 million used to pay down accrued liabilities as of December 31, 2012; partially offset by

\$1.9 million generated by an increase in deferred revenue primarily from the sale of service contracts to an increasing installed base of customers;

\$1.3 million generated from the collection of cash from the high accounts receivable balance as of December 31, 2012; and
\$0.7 million generated by a reduction in inventories.

Cash Flows from Investing Activities

We used net cash of \$3.2 million in our investing activities in the nine months ended September 30, 2014, which was attributable primarily to:

\$36.5 million of cash used to purchase marketable investments;

\$0.4 million used to acquire property and equipment; partially offset by

\$33.8 million in net proceeds from the sales and maturities of marketable investments.

We used net cash of \$6.0 million from investing activities in the nine months ended September 30, 2013, which was attributable primarily to:

\$43.9 million of cash used to purchase marketable investments;

\$0.5 million used to acquire property and equipment; partially offset by

\$38.4 million in net proceeds from the sales and maturities of marketable investments.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$3.1 million in the nine months ended September 30, 2014 and primarily consisted of proceeds from the issuance of common stock due to employees exercising their stock options and purchasing stock through the Employee Stock Purchase Plan (or “ESPP”) program.

Net cash used in financing activities was \$3.1 million in the nine months ended September 30, 2013, which was primarily due to:

the repurchase of common stock for \$7.6 million, partially offset by
proceeds from the issuance of common stock due to employees exercising their stock options and shares issued pursuant to our employee stock purchase plan of \$4.6 million.

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Adequacy of cash resources to meet future needs

We had cash, cash equivalents, and marketable investments of \$80.7 million as of September 30, 2014. For the first nine months of 2014, we financed our operations through the sales and maturities of marketable investments and cash from the sale of stock due to employees exercising their stock options and shares issued pursuant to our ESPP program. We believe the existing capital resources, including cash and cash equivalents and marketable investments of \$80.7 million, are sufficient to meet our operating and capital requirements for the next several years, and enable us to repurchase up to the remaining \$10.0 million of our stock pursuant to the \$20.0 million share buy-back program approved by our Board.

Except for the recent trend of cash used to fund our operating activities, purchase fixed assets and repurchase our common stock, 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.

Commitments and Contingencies

There have been no material changes to our commitments and contingencies from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 18, 2014.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A summary of the key market risks facing the Company is disclosed below. For a detailed discussion, please see our Annual Report on Form 10K for the year ended December 31, 2013, filed with the SEC on March 18, 2014.

Our exposure to interest rate risk relates primarily to our investment portfolio, which includes primarily debt instruments of the U.S. Government and its agencies, municipal bonds, corporate bonds and commercial paper. Fixed rate securities may have their fair market value adversely impacted if there is an increase in interest rates. While it is our intent to hold these securities to maturity, if for some reason we need to sell a security that has declined in market value due to changes in interest rates, then we may suffer losses in principal. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity of generally less than eighteen months. Based on discounted cash flow modeling with respect to our total investment portfolio as of September 30, 2014, assuming a hypothetical increase in interest rates of one percentage point (or 100 basis points), the fair value of our total investment portfolio would have potentially declined by approximately \$413,000.

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 and Canadian Dollar. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our results from operations.

In the nine months ended September 30, 2014, versus the same period in 2013, the average exchange rate of the Japanese Yen versus the U.S. Dollar declined by approximately 7%. While the effect of this foreign exchange rate decline was not significant to our net operating results, it negatively impacted our Japanese Yen denominated revenue, which was offset by a favorable impact on our cost of revenue and operating expenses.

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.

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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.

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

We are named from time to time as a party to product liability and contractual lawsuits in the normal course of business. We routinely assess the likelihood of any adverse judgments or outcomes related to legal matters and claims, as well as ranges of probable losses. A determination of the amount of the reserves required, if any, for these contingencies is made after analysis of each known issue, historical experience, whether it is more likely than not that we shall incur a loss, and whether the loss is estimable. As of September 30, 2014, we had no material pending product liability and contractual lawsuits.

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.

Revenue from the U.S. represents a significant part of our total revenue. In the three and nine months ended September 30, 2014, our U.S. revenue increased by approximately 9% and 3%, compared to the same periods in 2013, respectively. Unless our U.S. revenue continues to improve, we could experience a material adverse effect on our total revenue, profitability, employee retention and stock price.

Revenue from the U.S. represented 41% and 42% of our total revenue in the three months ended September 30, 2014 and 2013, respectively, and represented 41% and 40% of our total revenue in the nine months ended September 30, 2014 and 2013, respectively. U.S. revenue increased by approximately 9% and 3% for the three and nine months ended September 30, 2014, compared to the same periods in 2013, respectively, due to several factors, including:

In the nine months ended September 30, 2014, we have expanded our North American direct sales force, restructured their compensation arrangements, and have hired new sales management.

Historically, following a new product introduction, we experience revenue growth, compared to the same period in the prior year. We experienced revenue growth from our new Excel HR product launched in the second quarter of 2014 as well as continued growth of our Excel V product.

There can be no assurance that we will continue to introduce new products each year, or that the new product introductions will translate into increased revenue in the long term in the U.S., or that the new direct sales employees and management hired to replace the departed sales employees will be effective and result in improved sales

productivity. Further, if the current economic recovery does not continue, or there is another recession in the U.S., our future revenue would be adversely impacted.

Given the U.S. represents a significant source of our revenue, if our U.S. revenue does not improve further, we could experience a material adverse effect on our total revenue, profitability, employee retention and stock price.

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In over five years we have only had two profitable quarters and we are unable to predict whether we will return to sustained quarterly profits in the future.

Although we had a profitable fourth quarter in 2009 and 2012, we have had net quarterly losses in each quarter since the third quarter of 2008. There is no guarantee that we will be profitable in the future and you should not rely on our operating results for any prior quarterly or annual periods as an indication of our future operating performance. Any predictions about the performance of our operations in the future may not be as accurate as they could be if we had a longer history of profitability.

Revenue growth in our business is driven by several factors and one such factor is new product introductions. While we generated revenue from sales of our newly released Excel HR product in the second and third quarters of 2014 and sales of our Excel V platform increased in 2013 and in the first nine months of 2014, compared with the respective prior year periods, sales of our truSculpt product introduced in 2012 have not gained a share of the market segment to the degree we had expected. If our total revenue does not continue to grow in 2014 compared to 2013, we may not be able to become profitable in future quarters.

In an effort to improve our revenue, in the nine months ended September 30, 2014, we expanded our North American sales force and restructured their compensation arrangements, hired new senior sales management with prior experience in the aesthetic medical device industry, and have increased our marketing and promotional activities in North America. Given the time it takes to train new sales employees to sell our products and for the marketing efforts to yield in improved revenue, our total sales and marketing expenses increased to 43% of total net revenue in the nine months ended September 30, 2014, compared to 39% in the same period in 2013. If our North American revenue does not increase by more than our expenses, we may not be able to become profitable in future quarters.

Our ability to sustain profitability depends on the extent to which we can increase revenue and control our costs in order to, among other things, counter any unforeseen difficulties, complications, product delays or other unknown factors that may require additional expenditures. Because of the numerous risks and uncertainties associated with our growth prospects, product development, sales and marketing and other efforts, we are unable to predict the extent of our future profitability or losses. If our revenue does not achieve adequate growth in the future, we may continue to incur a quarterly net loss and may continue to consume cash in our operations in the future.

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.

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.

We have experienced direct sales employee and sales management turnover in North America for several reasons. One such reason was the consolidation of our specialty podiatry sales force into the mainstream aesthetic sales group in the third quarter of 2013. Further, competition for sales professionals who are familiar and trained to sell in the aesthetic equipment market continues to be strong. As a result, we have lost some of our sales people to our competitors. However, we have also hired a record number of new sales people, including several from our competitors. Several of our sales employees and sales management have been recently hired or recently transferred into different roles, and it will take time for them to be fully trained to improve their productivity. These factors have heavily impacted the revenue we derived from our products and upgrades in the first nine months of fiscal 2014.

In 2013, and in the nine months of 2014, we restructured our North American direct sales force and sales management. In the nine months ended September 30, 2014, we have expanded our direct sales force in North America. We have increased our efforts to hire high quality experienced sales professionals but there can be no guarantee that we will be able to retain all of the hired sales professionals or that they will all become productive in a short period of time. Our industry is characterized by a few established companies that compete vigorously for talented sales professionals. Further, as the economy in North America has rebounded from the recent recession, some of those sales professionals have left our Company for jobs that they perceive to be better opportunities, both within and outside of the aesthetic industry. We believe that the sales employee turnover, restructuring and expansion of the sales force had a negative impact on our North American productivity in the first three quarters of 2014.

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We train our existing and recently recruited sales professionals to better understand our existing and new product technologies and how they can be positioned against our competitors' products. These initiatives are intended to improve the productivity of our sales professionals and our revenue and profitability. It takes time for the sales professionals to become productive following their training and there can be no assurance that the recently recruited sales professionals will be adequately trained in a timely manner, or that our direct sales productivity will improve, or that we will not experience significant levels of attrition in the future. If we are not able to improve the productivity and retention of our North American and international sales professionals, then our total revenue, profitability and stock price may be adversely impacted.

Measures we implement in an effort to recruit, 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 improve, or if our cost of revenue and/or operating expenses increase by a greater percentage than our revenue, 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 (revenue less cost of revenue) was 56% and 55% in the nine months ended September 30, 2014 and 2013, respectively. Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. To the extent that our revenue declines, it is difficult to improve our gross margins as our fixed costs must be spread over a lower revenue base. 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, a shift in our product mix towards products with lower average selling prices, or a shift in our product mix towards products with lower margins.

Our cost of revenue may also be adversely impacted by various factors such as obsolescence of our inventory, increased expenses associated with the repair of 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 and sales and marketing activities. We have expanded our global direct sales force, and it may take time for our new sales professionals to become productive and for the revenue that they generate to become accretive to our operating income. We plan to continue making such investments in order to bring new products to market and to distribute them effectively. If these

investments do not yield increased revenue, we may continue to generate losses and consume cash.

If our revenue does not improve, or if our cost of revenue increases by a greater percentage than our revenue, 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.

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 body contouring, hair removal, treatment of veins and skin rejuvenation, including the treatment of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and pigmented lesions, etc. In the second quarter of 2014, we launched Excel HR, a premium hair removal platform for all skin types. In 2012, we launched truSculpt for the body contouring market and acquired VariLite for the treatment of vascular and pigmented lesions. In 2011, we launched our vascular laser product – Excel V – and began distribution of a Q-switched laser in Japan that Cutera is 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 other energy-based aesthetic procedures. In addition, since the first quarter of 2010, we have been distributing cosmeceuticals and dermal fillers in the Japanese market. In the second quarter of 2014, we terminated our agreement with Merz for the distribution of their Radiesse® dermal filler product. To grow in the future, we must continue to develop and/or 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 are 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.

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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.

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. We expect that any competitive advantage we may enjoy from current and future innovations 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.

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, there could be a material adverse effect on our total revenue, profitability, employee retention and stock price.

Macroeconomic political and market conditions, 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.

Macroeconomic developments like the global recession 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.

Macroeconomic declines, negative political developments, adverse market conditions and catastrophic events may cause a decline in our revenue, negatively affect our operating results, adversely affect our cash flow and could result in a decline in our stock price.

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

International revenue represented 59% of our total revenue in the nine months ended September 30, 2014, compared to 60% in the same period in 2013. 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. For example, our direct business in Japan and Canada as well as revenue from Asia Pacific distributors declined in the nine months ended September 30, 2014, negatively impacting our revenue from international operations.

We have experienced significant turnover of our European sales team in the past. While we continue to have a direct sales and service organization in France, Belgium and Switzerland, a significant portion of our European revenue is generated through our network of distributors. Though we continue to evaluate and replace non-performing distributors, and have recently brought greater focus on collaborating with our distributor partners, there can be no assurance given that these initiatives will result in improved European-sourced revenue or profitability in the future.

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. If we are not able to increase or maintain international revenue growth, our total revenue, profitability and stock price may be adversely impacted.

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.

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

Foreign currency fluctuations could result in volatility of our 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 and Canadian Dollar. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our results from operations. For example, as a result of the recent strengthening of the U.S. Dollar, relative to many other major currencies, our products priced in U.S. dollars have become more expensive relative to products of our foreign competitors. In addition, our revenue earned in foreign currencies, such as our locally generated revenue in Japan, has been negatively impacted upon translation into U.S. dollars. Both these factors had a negative impact on our international revenue in the first nine months of 2014, compared to the same period in 2013. Future foreign currency fluctuations could adversely impact and increase the volatility of our revenue, profitability and stock price.

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.

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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), Lumenis, Solta (acquired by Valeant Pharmaceuticals International, Inc. in January 2014), Syneron, as well as private companies such as Alma, Sciton and several other companies. Recently, there has been consolidation in the aesthetic industry leading to companies combining their resources. For example, Valeant acquired Solta in January 2014, Cynosure acquired Palomar in June 2013 and the aesthetic laser business of HOYA ConBio in June 2011; Syneron acquired Ultrashape in March 2012 and Candela in September 2009; we acquired the aesthetic business unit of Iridex in February 2012; and Solta (previously Thermage) acquired Aesthera in February 2010 and Reliant in December 2008. 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.

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

If, as a result of these factors, there is not sufficient demand for the procedures performed with our products, practitioner demand for our products could be reduced, which could have a material adverse effect on our business, financial condition, revenue and result of operations.

The U.S. Food and Drug Administration (the "FDA"), federal and state agencies and international regulatory bodies have broad enforcement powers. If we fail to comply with applicable regulatory requirements, it could result in enforcement action by the FDA, federal and state agencies or international regulatory bodies.

The FDA, state authorities and international regulatory bodies have broad enforcement powers. For example, in July 2012, we received a warning letter from the FDA concerning the promotional labeling for our GenesisPlus laser. The FDA determined that some of the claims, such as the one related to Skin Rejuvenation, constituted new Indications for Use and required additional 510(k) clearances. The FDA subsequently requested that we review the promotional labeling for all of our products to ensure our claims were within regulatory clearances and that we submit updated promotional labeling for our products to the FDA for their review. In October 2014, following the satisfactory review of our amended marketing materials and website, the FDA issued us a formal notice of closure of the warning letter.

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If we fail to comply with any U.S. law or any of the applicable regulatory requirements of the FDA, or federal or state agencies, or one of the international regulatory bodies, it could result in enforcement action by the agencies, which may include any of the following sanctions:

Warning letters, fines, injunctions, consent decrees and civil penalties;
Repair, replacement, refund, 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 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 U.S. 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 U.S., 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 U.S. and revenue derived from there may be adversely affected.

Medical devices may be marketed in the U.S. 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 clearance of nails that are infected with 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 U.S. 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.

Federal regulatory reforms and changes occurring at the 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.

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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 (the "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 have had multiple quality system audits by the FDA, our Notified Body, and other foreign regulatory agencies, with the most recent inspection by the FDA occurring in March 2014. 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. For example, we designed a larger 40cm² hand piece for our truSculpt product and had to get that approved by the FDA before we could market it, which approval was received in January 2012. 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 U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the U.S. 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 U.S., 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.

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.

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The occurrence of any one or more of the foregoing could materially increase expenses, adversely impact profitability and harm our business.

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 and a few key employees, we do not have employment contracts with any of our officers or other key employees. Any of our officers and other key employees may terminate their employment at any time. We do not have a succession plan in place for each of our officers and key employees. In addition, we do not maintain “key person” life insurance policies covering any of our employees. The loss of any of our senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees are critical factors in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. The staff we hire to perform administrative functions may become stretched due to our increased growth and they may not be able to perform their jobs effectively or efficiently as a result.

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.

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 U.S. 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 the past 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 the past we entered into distribution arrangements pursuant to which we utilize our sales force and distributors to sell products manufactured by other companies. In Japan we distribute a Q-switched laser product manufactured by a third party OEM. We also have an agreement with ZO (which commenced in the fourth quarter of 2013) to distribute certain of their proprietary cosmeceuticals, or skin care products, in Japan. Each of these agreements requires us to purchase annual minimum dollar amounts of their product. If we do not make these minimum purchases, we could lose exclusivity for distributing these products to physicians in Japan. Finally, we had an agreement with Merz Aesthetics to distribute its Radiesse® dermal filler product in Japan, but terminated this agreement in the second quarter of 2014.

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Each of these distribution agreements presents its own unique risks and challenges. For example, to sell cosmeceutical products 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 cosmeceutical products. 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 negatively impacting our profitability and reducing our available cash reserves.

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, 2014, our balance in marketable investments was \$69 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, 2014 would have potentially decreased by approximately \$413,000, 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).

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, 2014, approximately 55% 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. 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 and / or volatility 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.

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

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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, 2014, we had 31 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 U.S.

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.

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.

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 90 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.

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.

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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.

Healthcare reform legislation will continue to adversely affect our profitability and financial condition.

In December 2009, the President and members of Congress passed legislation relating to healthcare reform. Procedures performed by our products are not reimbursed by insurance companies or federal or state governments and as a result this legislation had a limited impact on our business. Medical device manufacturers have to pay an excise tax of 2.3% on certain U.S. medical device revenues. Though there are some exceptions, this excise tax applies to all of our product and upgrade revenue from the U.S. and will continue to have an adverse effect on our operating profitability and financial condition.

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 have limited experience as a team with acquiring companies and products. If we decide to expand our product offerings beyond laser and other energy-based products, we may spend time and money on projects that do not increase our revenue. Any cash acquisition we pursue would diminish our available cash balances to us for other uses, and any stock acquisition could be dilutive to our stockholders.

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

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 and one key employee, 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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.2	(1) Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4	(1) Bylaws of the Registrant.
4.1	(2) Specimen Common Stock certificate of the Registrant.
10.14	(3) Cutera, Inc. 2004 Equity Incentive Plan (as amended on April 27, 2012).
<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.def	XBRL Taxonomy Extension Definition 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 29, 2013.*

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SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of The Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Brisbane, State of California, on the 3rd day of November, 2014.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)