

CUTERA INC
Form 10-Q
May 02, 2016
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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 March 31, 2016

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 April 30, 2016 was 13,081,930.

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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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$6,265	\$ 10,868
Marketable investments	38,184	37,539
Accounts receivable, net	11,168	11,669
Inventories	13,475	12,078
Other current assets and prepaid expenses	1,953	1,675
Total current assets	71,045	73,829
Property and equipment, net	1,428	1,473
Deferred tax asset	376	350
Intangibles, net	87	143
Goodwill	1,339	1,339
Other long-term assets	419	384
Total assets	\$74,694	\$ 77,518
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$2,570	\$ 1,959
Accrued liabilities	11,079	13,834
Deferred revenue	8,836	8,638
Total current liabilities	22,485	24,431
Deferred revenue, net of current portion	1,986	2,287
Income tax liability	127	182
Other long-term liabilities	507	584

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Total liabilities	25,105	27,484
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: 13,076,642 and 12,980,807 shares at March 31, 2016 and December 31, 2015, respectively	13	13
Additional paid-in capital	81,319	79,782
Accumulated deficit	(31,723)	(29,672)
Accumulated other comprehensive loss	(20)	(89)
Total stockholders' equity	49,589	50,034
Total liabilities and stockholders' equity	\$74,694	\$ 77,518

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 March 31, 2016 2015	
Net revenue:		
Products	\$17,956	\$14,703
Service	4,467	4,368
Total net revenue	22,423	19,071
Cost of revenue:		
Products	7,648	7,309
Service	2,301	1,743
Total cost of revenue	9,949	9,052
Gross profit	12,474	10,019
Operating expenses:		
Sales and marketing	8,716	8,187
Research and development	2,709	2,445
General and administrative	3,220	2,989
Total operating expenses	14,645	13,621
Loss from operations	(2,171)	(3,602)
Interest and other income, net	144	8
Loss before income taxes	(2,027)	(3,594)
Provision for income taxes	24	50
Net loss	\$(2,051)	\$(3,644)
Net loss per share:		
Basic and Diluted	\$(0.16)	\$(0.25)
Weighted-average number of shares used in per share calculations:		
Basic and Diluted	13,010	14,611

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 March 31,	
	2016	2015
Net loss	\$(2,051)	\$(3,644)
Other comprehensive loss:		
Available-for-sale investments		
Net change in unrealized gain (loss) on available-for-sale investments	69	33
Less: Reclassification adjustment for gains on investments recognized during the period	—	—
Net change in unrealized gain (loss) on available-for-sale investments	69	33
Tax benefit	—	12
Other comprehensive gain, net of tax	69	21
Comprehensive loss	\$(1,982)	\$(3,623)

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)**

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(2,051)	\$(3,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,332	961
Depreciation and amortization	240	327
Other	12	106
Changes in assets and liabilities:		
Accounts receivable	472	737
Inventories	(1,397)	(867)
Other current assets and prepaid expenses	(230)	(15)
Other long-term assets	(35)	(1)
Accounts payable	611	(228)
Accrued liabilities	(2,758)	(2,781)
Other long-term liabilities	(82)	(72)
Deferred revenue	(103)	(559)
Income tax liability	(55)	22
Net cash used in operating activities	(4,044)	(6,014)
Cash flows from investing activities:		
Acquisition of property, equipment and software	(97)	(407)
Proceeds from sales of marketable investments	1,800	5,376
Proceeds from maturities of marketable investments	3,975	12,180
Purchase of marketable investments	(6,399)	(8,867)
Net cash provided by (used in) investing activities	(721)	8,282
Cash flows from financing activities:		
Repurchase of common stock	(279)	(4,550)
Proceeds from exercise of stock options and employee stock purchase plan	511	6,002
Payments on capital lease obligations	(70)	(61)
Net cash provided by financing activities	162	1,391

Net increase (decrease) in cash and cash equivalents	(4,603)	3,659
Cash and cash equivalents at beginning of period	10,868	9,803
Cash and cash equivalents at end of period	\$6,265	\$13,462

Supplemental disclosure of non-cash items:

Repurchase of common stock acquired but not settled	\$27	\$656
Assets acquired under capital lease	\$51	\$—

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 system platforms: *enlighten*TM, *excel HR*TM, *truSculpt*TM, *excel V*TM, and *xeo*[®]. The Company’s systems offer multiple hand pieces and applications, which allow customers to upgrade their systems. The sales of systems, system upgrades, hand pieces, hand piece refills (applicable to *Titan*[®] and *truSculpt*) and the distribution of third party manufactured skincare products are classified as “Products” revenue. In addition to Products 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, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. These subsidiaries market, sell and service the Company’s 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, 2015 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, 2015 filed with the Securities and Exchange Commission (the "SEC") on March 15, 2016.

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, legal matters and claims, 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 March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* as part of its simplification initiative, which involves several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The changes required by this Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is evaluating the impact the adoption of this standard will have on its Consolidated Financial Statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. This guidance requires that lease arrangements longer than twelve months result in a lessee recognizing a lease asset and liability. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The Company is currently evaluating the impact of the updated guidance on its Consolidated Financial Statements.

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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, are held for use in current operations and are classified in current assets as “marketable investments.”

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
March 31, 2016				
Cash and cash equivalents:				
Cash	\$ 4,734	\$ —	\$ —	\$4,734
Money market funds	1,531	—	—	1,531
Commercial paper	—	—	—	—
Total cash and cash equivalents	6,265	—	—	6,265
Marketable investments:				
U.S. government notes	10,400	18	—	10,418
U.S. government agencies	10,626	3	(5)	10,624
Municipal securities	3,764	6	—	3,770
Commercial paper	2,693	2	—	2,695
Corporate debt securities	10,671	9	(3)	10,677
Total marketable investments	38,154	38	(8)	38,184
Total cash, cash equivalents and marketable investments	\$ 44,419	\$ 38	\$ (8)	\$44,449
December 31, 2015				
Cash and cash equivalents:				
Cash	\$ 9,830	\$ —	\$ —	\$9,830

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Money market funds	1,000	—	—	1,000
Commercial paper	38	—	—	38
Total cash and cash equivalents	10,868	—	—	10,868
Marketable investments:				
U.S. government notes	7,780	1	(2)	7,779
U.S. government agencies	12,630	3	(25)	12,608
Municipal securities	4,344	2	—	4,346
Commercial paper	4,041	1	(2)	4,040
Corporate debt securities	8,783	—	(17)	8,766
Total marketable investments	37,578	7	(46)	37,539
Total cash, cash equivalents and marketable investments	\$ 48,446	\$ 7	\$ (46)	\$ 48,407

As of March 31, 2016 and December 31, 2015, total gross unrealized losses were \$8,000 and \$46,000, 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.

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The following table summarizes the contractual maturities of the Company's available-for-sale securities, classified as marketable investments as of March 31, 2016 (in thousands):

	Amount
Due in less than one year	\$29,795
Due in 1 to 3 years	8,389
Total marketable investments	\$38,184

Note 3. Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (*observable inputs*) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (*unobservable inputs*). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (*Level 1*) and the lowest priority to unobservable inputs (*Level 3*). The three levels of the fair value hierarchy are described below:

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

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

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

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

As of March 31, 2016, 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):

March 31, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$1,531	\$—	\$ —	\$1,531
Commercial paper	—	—	—	—
Marketable investments:				
Available-for-sale securities	—	38,184	—	38,184
Total assets at fair value	\$1,531	\$38,184	\$ —	\$39,715

As of December 31, 2015, 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, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$1,000	\$—	\$ —	\$1,000
Commercial paper	—	38	—	38
Marketable investments:				
Available-for-sale securities	—	37,539	—	37,539
Total assets at fair value	\$1,000	\$37,577	\$ —	\$38,577

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 March 31, 2016 is less than 36 months and all of these investments are rated by S&P and Moody's at A or better.

Table Of Contents**Note 4. Inventories**

As of March 31, 2016 and December 31, 2015, inventories consist of the following (in thousands):

	March 31, 2016	December 31, 2015
Raw materials	\$8,635	\$ 7,982
Finished goods	4,840	4,096
Total	\$13,475	\$ 12,078

Note 5. Warranty

The Company provides a standard one-year warranty on all systems. For direct sales to end customers, warranty coverage provided is for labor and parts necessary to repair the systems during the warranty period. For sales to distributors, we provide a 14-month warranty for parts only. The distributor provides the labor to their end customer.

The Company has a direct field service organization in the U.S. Internationally, the Company provides direct service support through its wholly-owned subsidiaries in Australia, Belgium, Canada, France Hong Kong, Spain, Japan, Switzerland and the United Kingdom. In several other countries where it does not have a direct presence, the Company provides service through a network of distributors and third-party service providers.

After the original warranty period, maintenance and support are offered on a service contract basis or on a time and materials basis. The Company currently provides for the estimated cost to repair or replace products under warranty at the time of sale. The following table provides the changes in the product warranty accrual for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31, 2016 2015	
Beginning Balance	\$1,819	\$1,167
Add: Accruals for warranties issued during the period	1,254	816

Less: Settlements made during the period	(1,254)	(780)
Ending Balance	\$1,819	\$1,203

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 months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31, 2016 2015	
Beginning Balance	\$10,469	\$12,949
Add: Payments received	3,263	2,802
Less: Revenue recognized	(3,220)	(3,223)
Ending Balance	\$10,512	\$12,528

Costs for extended service contracts were \$1.6 million and \$1.7 million for the three months ended March 31, 2016 and 2015, respectively.

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

Share Repurchase Program

On February 8, 2016, the Company announced that its Board of Directors approved the expansion of its Stock Repurchase Program by \$10 million, under which the Company is authorized to repurchase shares of its common stock.

In the three months ended March 31, 2016, the Company repurchased 28,013 shares of its common stock for approximately \$305,000. As of March 31, 2016, there remained an additional \$9.7 million available in the Stock Repurchase Program to repurchase shares of common stock. All shares repurchased were retired and returned to authorized but unissued status.

Table Of Contents*Stock-based Compensation Expense*

Stock-based compensation expense by department recognized during the three months ended March 31, 2016 and 2015 were as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Cost of revenue	\$ 141	\$ 103
Sales and marketing	376	185
Research and development	180	182
General and administrative	635	491
Total stock-based compensation expense	\$ 1,332	\$ 961

Activity under the Company's 2004 Equity Incentive Plan, as amended, is summarized as follows:

	Shares	Options Outstanding Number of	Weighted- Average Exercise Price
	Available for Grant	Stock Options Outstanding	
Balance, December 31, 2015	1,263,425	2,148,797	\$ 9.31
Options granted	(28,000)	28,000	11.24
Stock awards granted ⁽¹⁾⁽²⁾	(836,128)	—	—
Options exercised	—	(88,170)	8.44
Options canceled	26,213	(26,213)	10.21
Stock awards canceled ⁽¹⁾	70,278	—	—
Balance, March 31, 2016	495,788	2,062,414	\$ 9.36

The Company has a "fungible share" provision in its 2004 Equity Incentive Plan whereby for each full-value (1)award (RSU/PSU) issued or canceled under the Plan, results in a requirement to subtract / add back 2.12 shares from / to the Shares Available for Grant.

(2)Included in 'Stock awards granted' of 836,128, was 416,474 fungible shares relating to 196,450 of PSUs granted. These PSUs will result in a higher or lower number of shares of common stock that may be paid out on March 15,

2017, based on the achievement of three performance goals at targets that were pre-determined by the Board and disclosed in a Form 8-K on February 8, 2016.

Under the 2004 Equity Incentive Plan, as amended, the Company issued 144,312 shares of common stock during the three months ended March 31, 2016, in conjunction with stock options exercised and the vesting of RSUs and PSUs.

As of March 31, 2016, there was approximately \$6.6 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 2.05 years. The actual expense recorded in the future may be higher or lower based on a number of factors, including, actual forfeitures experienced and the degree of achievement of the performance goals related to the PSUs granted.

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.

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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 March 31,	
	2016	2015
Options to purchase common stock	3,191	3,164
Restricted stock units	405	318
Performance stock units	158	62
Employee stock purchase plan shares	42	33
Total	3,796	3,577

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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. The Company's income tax provision for the three months ended March 31, 2016 and 2015 relates primarily to income taxes of the Company's non-U.S. operations. The Company's U.S. operation continue to be in a loss position and the Company maintains a 100% valuation allowance against its U.S. deferred tax assets. For the three months ended March 31, 2016, the Company's income tax provision declined to \$24,000, compared to \$50,000 in the same period in 2015, due primarily to certain tax benefits recorded discretely in the quarter.

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 enacted 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 March 31, 2016, 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 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

On February 11, 2016, Kendall Jenner and Kendall Jenner Inc. ("Plaintiffs"), filed a lawsuit against the Company in the U.S. District Court, Central District of California, alleging trademark infringement, false endorsement and violation of Jenner's right of publicity. The claims arise out of alleged advertising referring to news articles describing Jenner's blog posting regarding her use of Cutera's Laser Genesis treatment for her acne. In their complaint, the Plaintiffs state that they are seeking "at least \$10 million" in compensatory damages and reasonable costs and attorney's fees. The Company is presently investigating the basis for the claims made, believes it has meritorious defenses to them and intends to defend the matter vigorously. While the Company retains general liability insurance, the insurer is currently denying coverage for this claim. The potential outcome of this litigation cannot be predicted, and the amount of potential damages in the event of an adverse result is not reasonably estimable at this time.

The Company is named from time to time as a party to product liability, contractual lawsuits and other general corporate matters 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 March 31, 2016 and December 31, 2015, the Company had an immaterial accrual for legal matters and claims and did not expect to incur any material costs beyond the amounts accrued.

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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, 2015 as contained in our annual report on Form 10-K filed with the SEC on March 15, 2016. 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 22 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. The sales of systems, system upgrades, hand pieces, hand piece refills (applicable to *Titan* and *truSculpt*) and the distribution of third party manufactured skincare products are classified as “Products” revenue. In addition to Products revenue, we generate 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.

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research and development, regulatory, sales and marketing, service, and administrative activities. We have wholly-owned subsidiaries in Australia, Belgium, Canada, France, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. We market, sell and service our products outside of the United States through our direct employees, third party service providers, as well as a global distributor network in over 40 countries.

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Products

Our revenue is derived from the sale of Products and Services. Products revenue is derived from the sale of Systems, Hand piece refills (applicable to *Titan* and *truSculpt*) and the distribution of third party manufactured Skincare products. Systems revenue includes the 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 primary system platforms include:

enlighten
excel HR
truSculpt
excel V
xeo

Other than the above mentioned five primary systems, we continue to generate revenue from our legacy products such as *GenesisPlus*[™], *CoolGlide*[®], *solera*[®], and a third-party sourced system called *myQ*[™] for the Japanese market. 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”) skincare products.

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.

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 surgery specialties, as well as outside those specialties. Generating ongoing revenue from our growing installed base of customers through the sale of systems, system upgrades, hand piece refills, skincare products, and services.

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, 2015 filed with the SEC on March 15, 2016. 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 March 31, 2016 2015	
Net revenue	100 %	100 %
Cost of revenue	44 %	47 %
Gross margin	56 %	53 %
Operating expenses:		
Sales and marketing	39 %	43 %
Research and development	12 %	13 %
General and administrative	14 %	16 %
Total operating expenses	65 %	72 %
Loss from operations	(9)%	(19)%
Interest and other income, net	— %	— %
Loss before income taxes	(9)%	(19)%
Provision for income taxes	— %	— %
Net loss	(9)%	(19)%

Total Net Revenue

(Dollars in thousands)	Three Months Ended March 31,			
	2016	% Change	2015	
Revenue mix by geography:				
United States	\$11,054	42	%	\$7,792
International	11,369	1	%	11,279
Consolidated total revenue	\$22,423	18	%	\$19,071
<i>United States as a percentage of total revenue</i>	49	%		41 %
<i>International as a percentage of total revenue</i>	51	%		59 %
Revenue mix by product category:				
Systems – North America	\$9,024	59	%	\$5,677
Systems – Rest of World	7,489	(1))%	7,561
Total Systems	16,513	25	%	13,238
Hand Piece Refills	564	(26))%	764
Skincare	879	25	%	701
Service	4,467	2	%	4,368
Consolidated total revenue	\$22,423	18	%	\$19,071

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Discussion of Revenue by Geography:

Our U.S. revenue increased by \$3.3 million, or 42%, in the three months ended March 31, 2016, compared to the same period in 2015. This increase was due primarily to the increase in sales of our *excel V*, *excel HR*, *xeo* and *truSculpt* systems, partially offset by a decline in sales of some of our other legacy systems.

Our international revenue increased by \$90,000, or 1%, in the three months ended March 31, 2016, compared to the same period in 2015. This increase was due primarily to increases in systems revenue from our direct business in Japan and from our distributors in Asia, along with growth in our skincare business in Japan, partially offset by reductions in system revenue from our distributor and direct business in Europe.

Discussion of Revenue by Product Type:

Systems Revenue

Systems revenue in North America increased by \$3.3 million, or 59% in the three months ended March 31, 2016, compared to the same period in 2015. This increase was attributable primarily to:

Increase in revenue from *excel V*, *excel HR*, *xeo*, *truSculpt* and *enlighten*; which was offset partly by
Reduction in revenue from some of our legacy products.

Systems revenue outside of North America (“Rest of the World”) decreased by \$72,000, or 1%, in the three months ended March 31, 2016, compared to the same period in 2015. This decrease was attributable primarily to:

Reduction in revenue from *xeo* and *excel HR*; which was offset partly by
Increase in revenue from *excel V*, *truSculpt* and *enlighten*.

Hand Piece Refills Revenue

Our hand piece refills revenue decreased by \$200,000, or 26%, in the three months ended March 31, 2016, compared to the same period in 2015. This decrease was caused primarily by reduced utilization of the *Titan* hand pieces.

Skincare Revenue

Our skincare revenue increased by \$178,000, or 25%, in the three months ended March 31, 2016, compared to the same period in 2015. This increase was due primarily to expanded product offerings of this distributed product.

Service Revenue

Our worldwide Service revenue increased by \$99,000, or 2%, in the three months ended March 31, 2016, compared to the same period in 2015.

Gross Profit

	Three Months Ended March 31,			
(Dollars in thousands)	2016	% Change		2015
Gross profit	\$12,474	25	%	\$10,019
As a percentage of total net revenue	56	%		53 %

Our cost of revenue consists primarily of material, personnel expenses, royalty expense, product warranty costs, amortization of intangibles and manufacturing overhead expenses. The patents that we licensed for applicable hair-removal products, expired in February 2016. As a result, all our revenue from February 2016 onwards will not be subject to royalties.

Gross margin increased to 56% in the three months ended March 31, 2016, compared to 53% in the same period in 2015. Gross margin increased due primarily to:

- Increased leverage resulting from higher revenue;
- Higher volume of direct sales, which have a higher margin than our distributor sales; and
- A shift in product mix towards higher margin systems.

Table Of Contents***Sales and Marketing***

(Dollars in thousands)	Three Months Ended March 31,			
	2016	% Change		2015
Sales and marketing	\$8,716	6	%	\$8,187
As a percentage of total net revenue	39	%		43 %

Sales and marketing expenses consist primarily of personnel expenses, expenses associated with customer-attended workshops and trade shows, post-marketing studies, and advertising. Sales and marketing expenses increased by \$529,000, and represented 39% of total net revenue in the three months ended March 31, 2016, compared to 43% in the same period in 2015. The \$529,000 increase was due primarily to:

\$488,000 net increase in North American personnel related expenses, which were driven primarily by higher headcount and commissions due to higher revenue;
 \$251,000 of higher travel related expenses in North America, resulting from higher activity; partially offset by
 \$259,000 of decreased international expenses, due primarily to decreased personnel and travel related expenses.

Research and Development (“R&D”)

(Dollars in thousands)	Three Months Ended March 31,			
	2016	% Change		2015
Research and development	\$2,709	11	%	\$2,445
As a percentage of total net revenue	12	%		13 %

R&D expenses consist primarily of personnel expenses, clinical research, regulatory and material costs. R&D expenses increased by \$264,000, and represented 12% of total net revenue in the three months ended March 31, 2016, compared to 13% for the same period in 2015. This increase in expense was due primarily to:

\$103,000 of increased personnel, travel and consulting related expenses;
 \$89,000 of increased material spending, related to project timing; and
 \$67,000 of increased equipment related expense.

General and Administrative (“G&A”)

(Dollars in thousands)	Three Months Ended March 31,			
	2016	% Change		2015
General and administrative	\$3,220	8	%	\$2,989
As a percentage of total net revenue	14	%		16 %

G&A expenses consist primarily of personnel expenses, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses. G&A expenses increased by \$231,000 and represented 14% of total net revenue in the three months ended March 31, 2016, compared to 16% in the same period in 2015. This increase in expense was due primarily to:

\$306,000 of increased personnel related expenses; partially offset by \$86,000 of decreased excise tax, due to the two-year moratorium on U.S. medical excise tax effective January 1, 2016.

Interest and Other Income, Net

Interest and other income, net, consists of the following:

(Dollars in thousands)	Three Months Ended March 31,			
	2016	% Change		2015
Interest income	\$77	(25)%	\$102
Other income (expense), net	67	171	%	(94)
Total interest and other income, net	\$144	1,700	%	\$8

Interest and other income, net, increased \$136,000 for the three months ended March 31, 2016, compared to the same period in 2015. This increase was due primarily to a reduction in net foreign exchange losses, partially offset by lower interest income as a result of a decrease in our marketable investments balance.

Table Of Contents*Provision for Income Taxes*

(Dollars in thousands)	Three Months Ended March 31,		
	2016	% Change	2015
Loss before income taxes	\$(2,027)	(44)%	\$(3,594)
Provision for income taxes	24	(52)%	50

Our income tax provision for the three months ended March 31, 2016 and 2015 relates primarily to income taxes of our non-U.S. operations. Our U.S. operation continues to be in a loss position and we maintain a 100% valuation allowance against our U.S. deferred tax assets. For the three months ended March 31, 2016, our income tax provision declined to \$24,000, compared to \$50,000 in the same period in 2015, due primarily to certain tax benefits recorded discretely in the quarter.

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)	March 31,	December 31,	Change
	2016	2015	
Cash and cash equivalents	\$6,265	\$ 10,868	\$(4,603)
Marketable investments	38,184	37,539	645

Total \$44,449 \$ 48,407 \$(3,958)

Cash Flows

(Dollars in thousands)	Three Months Ended March 31,	
	2016	2015
Net cash flow provided by (used in):		
Operating activities	\$(4,044)	\$(6,014)
Investing activities	(721)	8,282
Financing activities	162	1,391
Net increase (decrease) in cash and cash equivalents	\$(4,603)	\$3,659

Cash Flows from Operating Activities

Net cash used in operating activities in the three months ended March 31, 2016 was \$4.0 million, which was due primarily to:

\$467,000 used due to the net loss of \$2.1 million reduced by non-cash related items of \$1.6 million consisting primarily of stock-based compensation expense of \$1.3 million and depreciation and amortization expenses of \$240,000;

\$2.8 million used to pay down the high year-end accrued liabilities balance;

\$1.4 million used to increase inventories; partially offset by

\$578,000 generated from a decrease in other working capital changes.

Net cash used in operating activities in the three months ended March 31, 2015 was \$6.0 million, which was due primarily to:

\$2.3 million used due to the net loss of \$3.6 million reduced by non-cash related items of \$1.4 million consisting primarily of stock-based compensation expense of \$1.0 million and depreciation and amortization expenses of \$327,000;

\$2.8 million used to pay down the high year-end accrued liabilities balance;

\$867,000 used to increase inventory as a result of our expanded product line;

\$559,000 used by a decrease in deferred revenue; partially offset by

\$737,000 generated from the collection of cash from the seasonally high accounts receivable balance as of December 31, 2014.

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Cash Flows from Investing Activities

We used net cash of \$721,000 in our investing activities in the three months ended March 31, 2016, which was attributable primarily to:

\$624,000, used to purchase, net of proceeds from sales and maturities, marketable investments; and

\$97,000 used in the acquisition of furniture and equipment.

We generated net cash of \$8.3 million in our investing activities in the three months ended March 31, 2015, which was attributable primarily to:

\$8.7 million in net proceeds from the sales and maturities of marketable investments; partially offset by

\$407,000 of cash used to purchase property, equipment and software.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$162,000 in the three months ended March 31, 2016, which was primarily due to:

\$511,000 of proceeds from the issuance of common stock due to employees exercising their stock options; partially offset by
the repurchase of common stock for \$279,000.

Net cash provided by financing activities was \$1.4 million in the three months ended March 31, 2015, which was primarily due to:

\$6.0 million of proceeds from the issuance of common stock due to employees exercising their stock options; partially offset by

the repurchase of common stock for \$4.6 million.

Adequacy of Cash Resources to Meet Future Needs

We had cash, cash equivalents, and marketable investments of \$44.4 million as of March 31, 2016. For the first three months of 2016, 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. We believe the existing capital resources, including cash, cash equivalents and marketable investments of \$44.4 million, are sufficient to meet our operating and capital requirements for the next several years, and enable us to repurchase stock pursuant to our \$10 million Share Repurchase Program.

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, 2015, filed with the SEC on March 15, 2016, except for the lawsuit filed against us in February 2016 — see the Legal Proceedings section below.

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 10-K for the year ended December 31, 2015, filed with the SEC on March 15, 2016.

Interest Rate Fluctuations:

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 debt securities 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 March 31, 2016, 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 \$215,000.

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Foreign Exchange Fluctuations:

While we transact business primarily in U.S. Dollars, and a significant proportion of our revenue and costs are denominated in U.S. Dollars, we are exposed to foreign currency fluctuations in countries where we have a direct operation. We do not actively hedge our exposure to currency rate fluctuations. The three major currencies that we have exposure to and have assets and liabilities denominated in local currencies in, are Japanese Yen, Euro and Australian Dollar. In the three months ended March 31, 2016, versus the same period in 2015, the changes in the exchange rate did not have a material impact to our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Definition of Disclosure Controls

Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Report, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure Controls are also designed to reasonably assure that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Our Disclosure Controls include components of internal control over financial reporting, which consists of control processes designed to provide

reasonable assurance regarding the reliability of its financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the U.S. To the extent that components of our internal control over financial reporting are included within Disclosure Controls, they are included in the scope of our annual controls evaluation.

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.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On February 11, 2016, Kendall Jenner and Kendall Jenner Inc. (“Plaintiffs”), filed a lawsuit against us in the U.S. District Court, Central District of California, alleging trademark infringement, false endorsement and violation of Jenner’s right of publicity. The claims arise out of alleged advertising referring to news articles describing Jenner’s blog posting regarding her use of our Laser Genesis treatment for her acne. In their complaint, the Plaintiffs state that they are seeking “at least \$10 million” in compensatory damages and reasonable costs and attorney’s fees. We are presently investigating the basis for the claims made, believe we have meritorious defenses to them and intend to defend the matter vigorously. While we retain general liability insurance, the insurer is currently denying coverage for this claim. The potential outcome of this litigation cannot be predicted, and the amount of potential damages in the event of an adverse result is not reasonably estimable at this time.

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 March 31, 2016, we had an immaterial accrual for legal matters and claims and do not expect to incur any material costs beyond the amounts accrued.

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. Our business, financial condition and results of operations may be impacted by a number of factors. In addition to the factors discussed elsewhere in this report, the following risks and uncertainties could materially harm our business, financial condition or results of operations, including causing our actual results to differ materially from those projected in any forward-looking statements. The following list of significant risk factors is not all-inclusive or necessarily in order of importance. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, also may materially adversely affect us in future periods. 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 months ended March 31, 2016, our U.S. revenue increased by 42% compared to the same period in 2015. 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 49% of our total revenue in the three months ended March 31, 2016, compared to 41% in the same period of 2015. U.S. revenue increased by 42% in the three months ended March 31, 2016, compared to the same period in 2015, due to several factors, including:

In the last two years, we continued to expand our North American direct sales force, restructured their compensation arrangements, and hired new sales management experienced in the medical equipment industry. Demand for our portfolio of products in the U.S. remains strong, due in part to the continued strength of the U.S. economy.

There can be no assurance that we will 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 continue to 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 and we could experience a material adverse effect on total revenue, profitability, employee retention and stock price.

In over seven years we have only had three 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, 2012 and 2015, we have otherwise 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 our recently released products in 2014 — *enlighten- Q4'14* and *excel HR- Q2'14* — have resulted in the growth of our revenue over the last seven quarters ended December 31, 2015, sales of our *truSculpt* product introduced in 2012 have not penetrated the market to the degree we had expected.

In an effort to improve our revenue, we have invested in the restructuring and expansion of our global sales force, re-evaluated and changed the structure of their compensation arrangements, hired new senior sales management with prior experience in the aesthetic medical device industry, and increased our marketing and promotional activities. We have also invested heavily in training our new sales employees to sell our products and in marketing efforts to generate additional revenue.

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For the full-year 2015, compared to 2014, our revenue increased by \$16.6 million but our combined cost of revenue and operating expenses increased by \$10.5 million. Our ability to return to sustained profitability depends on the extent to which we can increase revenue and control our costs to be able to leverage our expenses. In addition, we need to be able to 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, unforeseen litigation expenses, etc., we are unable to predict the extent of our future profitability or losses.

If our revenue does not continue to improve, or we do not achieve adequate growth in the future, or if we are not able to control our costs to leverage our expenses, like we had in 2015, then we may not be able to sustain quarterly profitability or be able to generate 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 the core market, consisting of 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. 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. In addition, due to the competition for sales professionals in our industry, we have recruited sales professionals from outside the industry. Sales professionals from outside the industry take longer to train and to become familiar with our products and the procedures in which they are used. As a result of a lack of industry knowledge, these sales professionals may take longer to become productive members of our sales force.

Over the past approximately eighteen months, we restructured and have been expanding our North American direct sales force and sales management. We have increased our efforts to hire industry 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 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.

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 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.

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) improved to 56% in the three months ended March 31, 2016, compared to 53% in the same period in 2015. 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.

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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 while the increase in revenue exceeded the increase in sales and marketing expenses in 2015, the productivity of our new sales professionals may not continue to improve and be 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, our profitability may not improve in the future.

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.

In February 2016, a lawsuit was filed against us by Kendall Jenner and Kendall Jenner Inc. (“Plaintiffs”), alleging trademark infringement, false endorsement and violation of Jenner’s right of publicity. There can be no assurance regarding the potential outcome of this litigation, or its impact upon us, at this time. The expense of defending and resolving this lawsuit may adversely impact our future earnings, cash flows and stock price.

On February 11, 2016, Kendall Jenner and Kendall Jenner Inc. (“Plaintiffs”), filed a lawsuit against the Company in the U.S. District Court, Central District of California, alleging trademark infringement, false endorsement and violation of Jenner’s right of publicity. The claims arise out of alleged advertising referring to news articles describing Jenner’s blog posting regarding her use of our Laser Genesis treatment for her acne. In their complaint, the Plaintiffs state that they are seeking “at least \$10 million” in compensatory damages and reasonable costs and attorney’s fees. We are presently investigating the matter and intend to defend the matter vigorously.

While we believe we have meritorious defenses to the claims made, there can be no assurance regarding the potential outcome of this litigation, or its impact upon us, at this time. The expense of defending and resolving this lawsuit may adversely impact our future earnings, cash flows 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, tattoo removal, and skin rejuvenation, including the treatment of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and benign pigmented lesions, etc. In the fourth quarter of 2014, we launched *enlighten*, a dual wavelength, dual pulse duration tattoo removal and benign pigmented lesions treatment system featuring picosecond technology. Additionally, in the second quarter of 2014 we launched *excel HR*, a premium hair removal platform for all skin types. 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.

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.

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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; and
Currency exchange rate fluctuations.

Macroeconomic developments, like the global recession and the financial crisis in the U.S. and certain countries in the European Union during 2007 to 2009, 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.

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.

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

International revenue is a material component of our business strategy, and represented 51% of our total revenue in the three months ended March 31, 2016 and 48% of our total revenue in 2015. While our international revenue in 2015 increased by 8%, compared to 2014, it was negatively impacted by the appreciation of the U.S. Dollar versus the major currencies in which we transact. 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 declined in 2015, negatively impacting our revenue from international operations.

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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, Spain, Switzerland and the United Kingdom, 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:

- Fluctuating foreign currency exchange rates;
- Difficulties in staffing and managing our foreign operations;
- Political and economic instability;
- Foreign certification and regulatory requirements;
- Lengthy payment cycles and difficulty in collecting accounts receivable;
- Export restrictions, trade regulations and foreign tax laws;
- Customs clearance and shipping delays;
- 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 2015, compared to 2014. 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 depends 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;
- Identification and development of clinical support for new indications of our existing products;
- Product performance;
- Product pricing;
- Quality of customer support;
- Development of successful distribution channels, both domestically and internationally; and
- Intellectual property protection.

To compete effectively, we have to demonstrate that our new and existing products are attractive alternatives to other devices and treatments, by differentiating our products on the basis of such factors as innovation, performance, brand name, service, and price. This is difficult to do, especially in a crowded aesthetic market. Some of our competitors have newer or different products and more established customer relationships than we do, which could inhibit our market penetration efforts. For example, we have encountered, and expect to continue to encounter, situations where, due to pre-existing relationships, potential customers decided to purchase additional products from our competitors. Potential customers also may need to recoup the cost of products that they have already purchased from our competitors and may decide not to purchase our products, or to delay such purchases. If we are unable to increase our market penetration or compete effectively, our revenue and profitability will be adversely impacted.

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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 (acquired by XIO Group in September 2015), 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, XIO Group acquired Lumenis in September 2015, and Valeant acquired Solta in January 2014 and Cynosure acquired Palomar in June 2013. 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.

Continued expansion of the global market for laser and other-energy-based aesthetic procedures is a material assumption of our business strategy. Most procedures performed using our products are elective procedures not reimbursable through government or private health insurance, with the costs borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including:

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

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

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. 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-market 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 the U.S. market may be adversely affected.

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Medical devices may be marketed in the U.S. only for the indications for which they are approved or cleared by the FDA. 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.

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 over three weeks in March 2014. There were no significant findings and only one observation as a result of this audit. Our response to this observation was accepted by the FDA. Failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

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

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

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

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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.

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

- Damage to our brand reputation;
- Loss of customer orders and delay in order fulfillment;
- Increased costs due to product repair or replacement;
- Inability to attract new customers;
- Diversion of resources from our manufacturing and research and development departments into our service department; and
- Legal action.

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

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.

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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 have a non-exclusive right to distribute a Q-switched laser product manufactured by a third party OEM. We also have an exclusive agreement with ZO to distribute certain of their proprietary skincare 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 distribution rights of these products to physicians in Japan.

Each of these distribution agreements presents its own unique risks and challenges. For example, to sell skincare products we need to invest in creating a sales structure that is experienced in the sale of these products 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 skincare 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 March 31, 2016, our balance in marketable investments was \$38 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 March 31, 2016 would have potentially decreased by approximately \$215,000, 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).

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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 December 31, 2015, approximately 52% 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, 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. 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 competitors;
- Regulatory developments or delays concerning our, or our competitors' products; and
- The initiation of any other 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.

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 March 31, 2016, we had 34 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.

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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. For example, as of December 31, 2015, one distributor partner accounted for 10% of our outstanding accounts receivable balance. 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 adversely affect our financial condition.

Some of our customers and prospective customers have had difficulty 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 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.

Our ability to use net operating losses and tax credit carryforwards to offset future tax liabilities may be limited.

As of December 31, 2015, we had cumulative net operating loss carry-forwards (“NOLs”) for federal and state income tax reporting purposes of approximately \$41.8 million and \$11.2 million, respectively, and research and development tax credits (“R&D tax credits”) for federal and state income tax purposes of approximately \$4.7 million and \$5.7 million, respectively. A lack of future taxable income would adversely affect our ability to utilize these NOLs and R&D tax credit carryforwards. In addition, under Section 382 of the U.S. Internal Revenue Code, or the Code, a corporation that experiences a more-than 50% ownership change over a three-year testing period is subject to limitations on its ability to utilize its pre-change NOLs and R&D tax credit carryforwards to offset future taxable income. We have not conducted a study to-date to assess whether a limitation would apply under Section 382 of the Code. In the event it is determined that we previously experienced an ownership change, or should we experience an ownership change in the future, the amount of NOLs and R&D tax credit carryovers available in any taxable year, could be limited and may expire unutilized, and any such adjustment is not reflected in the NOL and R&D tax credits balances reported.

From time to time we may become subject to income tax audits or similar proceedings, and as a result we may incur additional costs and expenses or owe additional taxes, interest and penalties that may negatively impact our operating results.

We are subject to income taxes in the United States and certain foreign jurisdictions where we operate through a subsidiary including Australia, Belgium, Canada, France, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. Our determination of our tax liability is subject to review by applicable domestic and foreign tax authorities.

In July 2015, our Japan subsidiary underwent an income tax audit for the years 2012 to 2014. Although this audit resulted in a minimal adjustment, the final timing and resolution of any tax examinations are subject to significant uncertainty and could result in our having to pay amounts to the applicable tax authority in order to resolve examination of our tax positions, which could result in an increase or decrease of our current estimate of unrecognized tax benefits and may negatively impact our financial position, results of operations or cash flows.

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Any acquisitions that we make could result in operating difficulties, dilution, and other consequences that may adversely impact our business and results of operations.

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. 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.

We have limited experience as a team with acquiring companies and products. 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. Acquisitions could diminish our available cash balances for other uses, result in the incurrence of debt, contingent liabilities, or amortization expenses, and restructuring charges. Also, the anticipated benefits or value of our acquisitions or investments may not materialize and could result in an impairment of goodwill and/or purchased long-lived assets, similar to the \$650,000 charge we recorded in the fourth quarter of 2014 related to an acquisition completed in 2012.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, incur unanticipated liabilities, and harm our business and our financial condition or results.

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 certain key employees, 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.

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The following table summarizes the activity related to stock repurchases for the three months ended March 31, 2016 (in thousands except share and per share data):

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Program
March 1-31, 2016	28,013	\$ 10.89	28,013	\$ 9,695
As of March 31, 2016	28,013	10.89	28,013	9,695

On February 8, 2016, our Board of Directors approved the expansion of the Stock Repurchase Program by \$10 million, under which the Company is authorized to repurchase shares of its common stock. In the three months ended March 31, 2016, we repurchased 28,013 shares of our common stock for approximately \$305,000. As of March 31, 2016, there remained an additional \$9.7 million to be purchased. All shares repurchased were retired and returned to authorized but unissued status.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

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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 Amended and Restated Equity Incentive Plan.
<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 27, 2015.

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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 2nd day of May, 2016.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)