

CUTERA INC
Form 10-Q
November 02, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

OR

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

For the transition period _____ to _____.

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

Edgar Filing: CUTERA INC - Form 10-Q

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (check one):

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

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

The number of shares of Registrant’s common stock issued and outstanding as of October 23, 2009 was 13,410,668.

CUTERA, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page	
PART I	FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations	2
	Condensed Consolidated Statements of Cash Flows	3
	Notes to Condensed Consolidated Financial Statements	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	29
PART II	OTHER INFORMATION	
Item 1.	Legal Proceedings	30
Item 1A	Risk Factors	30
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3.	Defaults Upon Senior Securities	43
Item 4.	Submission of Matters to a Vote of Security Holders	44
Item 5.	Other Information	44
Item 6.	Exhibits	44
	Signature	45

PART I. FINANCIAL INFORMATION

ITEM FINANCIAL STATEMENTS

1.

CUTERA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,302	\$ 36,540
Marketable investments	62,572	60,653
Accounts receivable, net	2,635	5,792
Inventories	7,884	9,927
Deferred tax asset	244	4,257
Other current assets and prepaid expenses	2,644	1,771
Total current assets	110,281	118,940
Property and equipment, net	939	1,357
Long-term investments	7,339	9,627
Intangibles, net	877	1,025
Deferred tax asset, net of current portion	—	6,527
Total assets	\$ 119,436	\$ 137,476
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,212	\$ 1,690
Accrued liabilities	7,281	8,848
Deferred revenue	6,295	6,758
Total current liabilities	14,788	17,296
Deferred rent	1,548	1,713
Deferred revenue, net of current portion	2,331	4,907
Income tax liability	882	1,452
Total liabilities	19,549	25,368
Commitments and Contingencies (Note 8)		
Stockholders' equity:		
Common stock	13	13
Additional paid-in capital	84,148	80,318
Retained earnings	17,247	31,410
Accumulated other comprehensive income (loss)	(1,521)	367
Total stockholders' equity	99,887	112,108
Total liabilities and stockholders' equity	\$ 119,436	\$ 137,476

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

1

CUTERA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net revenue	\$ 12,171	\$ 19,110	\$ 38,266	\$ 65,482
Cost of revenue	4,910	7,823	15,976	25,313
Gross profit	7,261	11,287	22,290	40,169
Operating expenses:				
Sales and marketing	5,112	8,076	18,186	28,786
Research and development	1,684	1,828	4,922	5,617
General and administrative	2,121	2,583	8,257	8,547
Litigation settlement	—	—	850	—
Total operating expenses	8,917	12,487	32,215	42,950
Loss from operations	(1,656)	(1,200)	(9,925)	(2,781)
Interest and other income, net	288	733	1,398	2,491
Other-than-temporary impairment of long-term investments	—	(2,372)	—	(2,372)
Loss before income taxes	(1,368)	(2,839)	(8,527)	(2,662)
Provision (benefit) for income taxes	12,126	(86)	9,159	(28)
Net loss	\$ (13,494)	\$ (2,753)	\$ (17,686)	\$ (2,634)
Net loss per share:				
Basic and Diluted	\$ (1.01)	\$ (0.22)	\$ (1.33)	\$ (0.21)
Weighted-average number of shares used in per share calculations:				
Basic and Diluted	13,382	12,780	13,274	12,762

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

CUTERA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (17,686)	\$ (2,634)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	3,396	3,983
Tax benefit (deficit) from stock-based compensation	(2)	49
Depreciation and amortization	664	671
Provision for excess and obsolete inventories	247	(61)
Other-than-temporary impairment of long term investments	—	2,372
Change in allowance for doubtful accounts	550	149
Change in deferred tax asset and deferred tax liability	10,540	140
Changes in assets and liabilities:		
Accounts receivable	2,607	4,057
Inventories	1,796	(1,159)
Other current assets and prepaid expenses	572	221
Accounts payable	(478)	(230)
Accrued liabilities	(1,686)	(3,557)
Deferred rent	(46)	56
Deferred revenue	(3,039)	1,606
Income tax liability	(570)	207
Net cash provided by (used in) operating activities	(3,135)	5,870
Cash flows from investing activities:		
Acquisition of property and equipment	(98)	(538)
Proceeds from sales of marketable investments	20,794	49,969
Proceeds from maturities of marketable investments	10,560	18,150
Purchase of marketable investments	(30,795)	(58,085)
Net cash provided by investing activities	461	9,496
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	436	263
Net cash provided by financing activities	436	263
Net increase (decrease) in cash and cash equivalents	(2,238)	15,629
Cash and cash equivalents at beginning of period	36,540	11,054
Cash and cash equivalents at end of period	\$ 34,302	\$ 26,683

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

CUTERA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Description of Operations and Principles of Consolidation.

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

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

Unaudited Interim Financial Information

The financial information 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, 2008 Condensed Consolidated Balance Sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America (GAAP). The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The Condensed Consolidated Financial Statements should be read in conjunction with the Company's financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission, or SEC, on March 16, 2009.

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 its estimates, including those related to warranty obligation, sales commission, accounts receivable and sales allowances, fair values of long-term investments, fair values of acquired intangible assets, useful lives of intangible assets and property and equipment, fair values of options to purchase the Company's common stock, deferred tax assets valuation allowance, and effective income tax rates, among others. The Company's management bases its 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's annual report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 16, 2009, and have not changed significantly as of September 30, 2009, except for the policies adopted in the nine months ended September 30, 2009 and discussed in the section below on "Recent Accounting Pronouncements."

Recent Accounting Guidance

Updates issued and adopted

On September 30, 2009, the Company adopted updates issued by the Financial Accounting Standards Board (FASB) to the authoritative hierarchy of GAAP. These changes establish the FASB Accounting Standards Codification™

(ASC) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead the FASB will issue Accounting Standards Updates. Accounting Standards Updates will not be authoritative in their own right as they will only serve to update the Codification. These changes and the Codification itself do not change GAAP. Other than the manner in which new accounting guidance is referenced, the adoption of these changes had no impact on the Condensed Consolidated Financial Statements.

On June 30, 2009, the Company adopted updates issued by the FASB to accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued, otherwise known as “subsequent events.” Specifically, these changes set forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of these changes had no impact on the Condensed Consolidated Financial Statements

On June 30, 2009, the Company adopted updates issued by the FASB to fair value accounting. These changes provide additional guidance for estimating fair value when the volume and level of activity for an asset or liability have significantly decreased and includes guidance for identifying circumstances that indicate a transaction is not orderly. This guidance is necessary to maintain the overall objective of fair value measurements, which is that fair value is 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 under current market conditions. The adoption of these changes had no impact on the Condensed Consolidated Financial Statements.

On April 1, 2009, the Company adopted updates issued by the FASB to the recognition and presentation of other-than-temporary impairments. These changes amend existing other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities. The recognition provision applies only to fixed maturity investments that are subject to the other-than-temporary impairments. If an entity intends to sell, or if it is more likely than not that it will be required to sell an impaired security prior to recovery of its cost basis, the security is other-than-temporarily impaired and the full amount of the impairment is recognized as a loss through earnings. Otherwise, losses on securities which are other-than-temporarily impaired are separated into: (i) the portion of loss which represents the credit loss; or (ii) the portion which is due to other factors.

The credit loss portion is recognized as a loss through earnings, while the loss due to other factors is recognized in other comprehensive income (loss), net of taxes and related amortization. A cumulative effect adjustment is required to accumulated earnings and a corresponding adjustment to accumulated other comprehensive income (loss) to reclassify the non-credit portion of previously other-than-temporarily impaired securities which were held at the beginning of the period of adoption and for which the Company does not intend to sell and it is more likely than not that the Company will not be required to sell such securities before recovery of the amortized cost basis. These changes were effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted these changes effective April 1, 2009. As a result of the implementation of this pronouncement, the Company reclassified the cumulative effect of the non-credit portion of previously recognized other-than-temporarily impaired adjustments of \$3.5 million by increasing accumulated earnings and decreasing accumulated other comprehensive income (loss).

On June 30, 2009, the Company adopted updates issued by the FASB to fair value disclosures of financial instruments. These changes require a publicly traded company to include disclosures about the fair value of its financial instruments whenever it issues summarized financial information for interim reporting periods. Such disclosures include the fair value of all financial instruments, for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position; the related carrying amount of these financial instruments; and the method(s) and significant assumptions used to estimate the fair value. Other than the required disclosures, the adoption of these changes had no impact on the Condensed Consolidated Financial Statements.

On January 1, 2009, the Company adopted updates issued by the FASB to fair value accounting and reporting as it relates to nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on at least an annual basis. These changes define fair value, establish a framework for measuring

fair value in GAAP, and expand disclosures about fair value measurements. This guidance applies to other GAAP that require or permit fair value measurements and is to be applied prospectively with limited exceptions. The adoption of these changes, as it relates to nonfinancial assets and nonfinancial liabilities, had no impact on the Condensed Consolidated Financial Statements. These provisions will be applied at such time a fair value measurement of a nonfinancial asset or nonfinancial liability is required, which may result in a fair value that is materially different than would have been calculated prior to the adoption of these changes.

On January 1, 2009, the Company adopted updates issued by the FASB to accounting for intangible assets. These changes amend the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset in order to improve the consistency between the useful life of a recognized intangible asset outside of a business combination and the period of expected cash flows used to measure the fair value of an intangible asset in a business combination. The adoption of these changes had no impact on the Condensed Consolidated Financial Statements.

On January 1, 2009, the Company adopted updates issued by the FASB to the calculation of earnings per share. These changes state that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method for all periods presented. The adoption of these changes had no impact on the Condensed Consolidated Financial Statements.

Updates issued but not yet adopted

In October 2009, the FASB issued updates to revenue recognition guidance. These changes provide application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. The Company has not determined the impact that this update may have on its Consolidated Financial Statements.

In August 2009, the FASB issued updates to fair value accounting for liabilities. These changes clarify existing guidance that in circumstances in which a quoted price in an active market for the identical liability is not available, an entity is required to measure fair value using either a valuation technique that uses a quoted price of either a similar liability or a quoted price of an identical or similar liability when traded as an asset, or another valuation technique that is consistent with the principles of fair value measurements, such as an income approach (e.g., present value technique). This guidance also states that both a quoted price in an active market for the identical liability and a quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. These changes will become effective for the Company's Consolidated Financial Statements for the year ended December 31, 2009. The Company has not determined the impact that this update may have on its Consolidated Financial Statements.

Note 2. Balance Sheet Details

Cash and Cash Equivalents, Marketable Investments and Long-Term Investments:

The Company considers all highly liquid investments, with an original maturity of three months or less at the time of purchase, to be cash equivalents. Investments in debt securities are accounted for as "available-for-sale" securities, carried at fair value with unrealized gains and losses reported in other comprehensive income (loss), held for use in current operations and classified in current assets as "Marketable investments" and in long term assets as "Long-term investments."

The following is a summary of cash and cash equivalents, marketable investments and long-term investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
September 30, 2009				

Edgar Filing: CUTERA INC - Form 10-Q

Cash and cash equivalents	\$	34,302	\$	-\$	-\$	34,302
Marketable investments:						
Municipal securities		62,127		301	(11)	62,417
Auction rate securities		126		29	—	155
Total marketable investments		62,253		330	(11)	62,572
Long-term investments in auction rate securities		8,920		—	(1,581)	7,339
	\$	105,475	\$	330	\$ (1,592)	\$ 104,213

6

Edgar Filing: CUTERA INC - Form 10-Q

December 31, 2008	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash and cash equivalents	\$ 36,540	\$ —	\$ —	36,540
Marketable investments:				
Municipal securities	59,837	566	—	60,403
Auction rate securities	219	31	—	250
Total marketable investments	60,056	597	—	60,653
Long-term investments in auction rate securities	9,627	—	—	9,627
	\$ 106,223	\$ 597	\$ —	106,820

Fair Value of Financial Instruments:

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

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.
- Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

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

As of September 30, 2009, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 31,868	\$ —	\$ —	31,868
Marketable investments:				
Available-for-sale securities	—	62,572	—	62,572
Long-term investments:				
Available-for-sale ARS	—	—	7,339	7,339

Total assets at fair value	\$	31,868	\$	62,572	\$	7,339	\$	101,779
----------------------------	----	--------	----	--------	----	-------	----	---------

7

The Company's Level 1 financial assets are money market funds and highly liquid debt instruments of federal and municipal governments and their agencies with stated maturities of three months or less from the date of purchase, whose fair values are based on quoted market prices. The Company's Level 2 financial assets are highly liquid debt instruments of federal and municipal governments and their agencies with stated maturities of greater than three months, whose fair values are obtained from readily-available pricing sources for the identical underlying security that may, or may not, be actively traded.

At September 30, 2009, observable market information was not available to determine the fair value of the Company's ARS investments. Therefore, the fair value is based on broker-provided valuation models that relied on Level 3 inputs including those that are based on expected cash flow streams and collateral values, assessments of counterparty credit quality, default risk underlying the security, market discount rates and overall capital market liquidity. The valuation of the Company's ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the valuations in the future include changes to credit ratings of the securities, as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. These financial instruments are classified within Level 3 of the fair value hierarchy.

The table presented below summarizes the change in carrying value associated with Level 3 financial assets for the nine months ended September 30, 2009 (in thousands):

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Beginning Balance	\$ 7,640	\$ 9,627
Transfers out of Level 3	(296)	(2,326)
Unrealized gain (loss) included in other comprehensive income	(5)	38
Ending Balance	\$ 7,339	\$ 7,339

Other Current Assets and Prepaid Expenses:

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

	September 30, 2009	December 31, 2008
Tax receivable	\$ 1,437	\$ 235
Deposits	542	824
Prepaid expense	665	712
	\$ 2,644	\$ 1,771

Inventories:

Inventories consist of the following (in thousands):

	September 30, 2009	December 31, 2008
Raw materials	\$ 4,643	\$ 5,071
Finished goods	3,241	4,856
	\$ 7,884	\$ 9,927

Intangible Assets:

Intangible assets were principally comprised of a patent sublicense acquired from Palomar Medical Technologies in 2006, a technology patent sublicense acquired in 2002 and other intangible assets acquired in 2007. The components of intangible assets at September 30, 2009 and December 31, 2008 were as follows (in thousands):

	September 30, 2009		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 483	\$ 735
Technology patent sublicense	538	396	142
Other intangibles	20	20	—
Total	\$ 1,776	\$ 899	\$ 877

	December 31, 2008		
	Gross Carrying Amount	Accumulated Amortization Amount	Net Carrying Amount
Patent sublicense	\$ 1,218	\$ 379	\$ 839
Technology sublicense	538	356	182
Other intangibles	20	16	4
Total	\$ 1,776	\$ 751	\$ 1,025

For the nine months ended September 30, 2009 and 2008, amortization expense for intangible assets was \$148,000 and \$151,000, respectively.

Based on intangible assets recorded at September 30, 2009, and assuming no subsequent additions to, or impairment of the underlying assets, the remaining estimated annual amortization expense is expected to be as follows (in thousands):

Fiscal Year Ending December 31,	
2009 remainder	\$ 47
2010	192
2011	192
2012	158
2013	138
Thereafter	150
Total	\$ 877

Note 3. Stock-based Compensation Expense

Total pre-tax stock-based compensation expense by department recognized during the three and nine months ended September 30, 2009 and 2008 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Cost of sales	\$ 161	\$ 222	\$ 568	\$ 648
Sales and marketing	250	440	817	1,290
Research and development	116	170	364	443
General and administrative	368	494	1,647	1,602
Total stock-based compensation expense	\$ 895	\$ 1,326	\$ 3,396	\$ 3,983

Option Exchange Program

In July 2009, the Company completed its Option Exchange Program for its employees to exchange certain options outstanding for new options to purchase shares of the Company's common stock. As a result, options to purchase 864,373 shares of the Company's common stock were cancelled and new options to purchase up to 447,841 shares of the Company's common stock were issued in exchange. The new options have an exercise price per share of \$8.49, the closing price of the Company's common stock as reported on the Nasdaq Global Market on the date that the offer expired and Option Exchange Program was completed, are unvested as of the grant date, and subject to an additional six (6) months of vesting over and above the vesting schedule of the surrendered options.

Given the Option Exchange Program was designed to be approximately a "value-for-value" exchange, the Company will not incur any significant additional non-cash compensation charges as the fair value of the replacement options was approximately equal to or less than the fair value of the surrendered options. The Company determined the fair value of stock options using the Black Scholes valuation model.

Note 4. 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 income per share is calculated by using the weighted-average number of common shares outstanding during the period increased to include the number of additional shares of common stock that would have been outstanding if the dilutive potential shares of common stock had been issued. The dilutive effect of outstanding options, Employee Stock Purchase Plan, or ESPP, shares and restricted stock units is reflected in diluted net income per share by application of the treasury stock method, which includes consideration of stock-based compensation. Diluted net loss per common share is the same as basic net loss per common share, as the effect of the potential common stock equivalents is anti-dilutive, and as such, is excluded from the calculations of the diluted net loss per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Numerator:				
Net loss available to common stockholders – Basic and Diluted	\$ (13,494)	\$ (2,753)	\$ (17,686)	\$ (2,634)

Edgar Filing: CUTERA INC - Form 10-Q

Denominator:

Weighted-average number of common shares outstanding used in computing basic and diluted net loss per share	13,382	12,780	13,274	12,762
----------------------------------------------------------------------------------------------------------------	--------	--------	--------	--------

10

Anti-dilutive securities

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Options to purchase common stock	2,846	3,160	2,769	2,812
Restricted stock units	—	13	7	21
Employee stock purchase plan shares	29	31	63	63
Total	2,875	3,204	2,839	2,896

Note 5. Service Contract Revenue

Service contract revenue is recognized on a straight-line basis over the period of the applicable service contract. The following table provides the changes in the deferred revenue for the nine months ended September 30, 2009 and 2008 (in thousands):

	September 30,	
	2009	2008
Beginning Balance	\$ 11,665	\$ 10,564
Add: Payments received	4,643	7,987
Less: Revenue recognized	(7,682)	(6,381)
Ending Balance	\$ 8,626	\$ 12,170

Costs incurred under service contracts during the nine months ended September 30, 2009 and 2008, amounted to \$3.5 million and \$3.4 million, respectively, and are recognized as incurred.

Note 6. Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive income (loss) (OCI). OCI includes certain changes in stockholders' equity that are excluded from net loss. Specifically, the Company includes in OCI net unrealized loss on securities available for sale. The activity in comprehensive loss for the periods presented was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss	\$ (13,494)	\$ (2,753)	\$ (17,686)	\$ (2,634)
Net change in unrealized gain (loss) on available-for sale-securities	(105)	1,733	1,635	(256)
Change in income tax effect on unrealized gain (loss) on available-for sale-securities	(66)	-	1	-
Comprehensive loss	\$ (13,665)	\$ (1,020)	\$ (16,050)	\$ (2,890)

Note 7. Income Taxes

The Company recognized an income tax provision of \$12.1 million and \$9.2 million for the three months and nine months ended September 30, 2009, respectively, despite losses before taxes. The year-to-date provision is primarily due to the recording of a valuation allowance of \$10.2 million on the Company's U.S. deferred tax assets as of September 30, 2009. The valuation allowance was recorded at the end of the third quarter of 2009 to reduce certain U.S. federal and state net deferred tax assets to their anticipated realizable value. The valuation allowance was offset by \$969,000 of certain tax benefits resulting from losses generated during fiscal 2009 that can be carried-back to prior periods. Also, included in the third quarter 2009 provision is the reversal of \$3.1 million tax benefit primarily related to net operating losses previously recognized in the first and second quarters of 2009.

ASC 740 requires the consideration of a valuation allowance to reflect the likelihood of realization of deferred tax assets. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. In evaluating the ability to recover deferred tax assets, the Company considered available positive and negative evidence, giving greater weight to its recent cumulative losses and its ability to carry-back losses against prior taxable income and lesser weight to its projected financial results due to the challenges of forecasting future periods. The Company also considered, commensurate with its objective verifiability, the forecast of future taxable income including the reversal of temporary differences. The Company performed this evaluation as of the year ended December 31, 2008 and the quarters ended March 31, 2009 and June 30, 2009. At that time the Company continued to have sufficient positive evidence, including recent cumulative profits, a reduction in operating expenses, the ability to carry-back losses against prior taxable income and an expectation of improving operating results, showing a valuation allowance was not required. At the end of the quarter ended September 30, 2009, changes in previously anticipated expectations and continued operating losses necessitated a valuation allowance against the tax benefits recognized in this quarter and prior quarters since they are no longer "more-likely-than-not" realizable. Under current tax laws, this valuation allowance will not limit the Company's ability to utilize U.S. federal and state deferred tax assets provided it can generate sufficient future taxable income in the U.S.

As of the end of the third quarter of 2009, the Company recorded a net decrease of approximately \$538,000 in gross unrecognized tax benefits due to a change in management's assessment of its uncertain tax positions. As of September 30, 2009, the gross unrecognized tax benefit for uncertain tax positions was \$882,000.

The Company anticipates it will continue to record a valuation allowance against the losses of certain jurisdictions, primarily federal and state, until such time as we are able to determine it is "more-likely-than-not" the deferred tax asset will be realized. Such position is dependent on whether there will be sufficient future taxable income to realize such deferred tax assets. The Company expects its future tax provisions (benefits), during the time such valuation allowances are recorded, will consist primarily of the tax expense of our non-US jurisdictions that are profitable. The Company's effective tax rate may vary from period to period based on changes in estimated taxable income or loss by jurisdiction, changes to the valuation allowance, changes to federal, state or foreign tax laws, future expansion into areas with varying country, state, and local income tax rates, deductibility of certain costs and expenses by jurisdiction.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$2.5 million and \$2.0 million at September 30, 2009 and 2008, respectively, are considered to be indefinitely reinvested and, accordingly, no provision for U.S. federal and state income taxes has been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to various foreign countries.

Note 8. Commitments and Contingencies

Warranty Obligations

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

The following table provides the changes in the product warranty accrual for the nine months ended September 30, 2009 and 2008 (in thousands):

	September 30,	
	2009	2008
Balance at December 31, 2008 and 2007	\$ 1,916	\$ 2,725
Add: Accruals for warranties issued during the period	1,402	3,735
Less: Settlements made during the period	(2,229)	(4,263)
Balance at September 30, 2009 and 2008	\$ 1,089	\$ 2,197

Facility Leases

The Company leases its Brisbane, California, office and manufacturing facility under a non-cancelable operating lease which expires in 2013. In addition, the Company has leased office facilities in certain international countries, including: Japan, Switzerland, France, and Spain. As of September 30, 2009, the Company was committed to minimum lease payments for facilities and other leased assets under long-term non-cancelable operating leases as follows (in thousands):

Fiscal Year Ending December 31,	
2009 (remainder)	\$ 413
2010	1,443
2011	1,326
2012	1,431
2013	1,545
Future minimum rental payments	\$ 6,158

Purchase Commitments

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments were not material at September 30, 2009.

Litigation

Two securities class action lawsuits were filed against the Company and two of the Company's executive officers in April 2007 and May 2007, respectively, in the U.S. District Court for the Northern District of California following declines in the Company's stock price. The plaintiffs claim to represent purchasers of the Company's common stock from January 31, 2007 through May 7, 2007. The complaints generally allege that materially false statements and omissions were made regarding the Company's financial prospects, and seek unspecified monetary damages. On November 1, 2007, the Court ordered the two cases consolidated. On December 17, 2007, the plaintiffs filed a consolidated, amended complaint, and on January 31, 2008, the Company filed a motion to dismiss that complaint. On September 30, 2008, in response to the Company's motion, the Court issued an order dismissing the plaintiffs' amended complaint without prejudice. On October 28, 2008, the plaintiffs filed a Notice Of Intention Not to File A Second Amended Consolidated Complaint. On November 25, 2008, the Court closed the case on its own initiative. On November 26, 2008, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit, on April 16, 2009 the plaintiffs filed their opening brief with that Court, on June 17, 2009 the Company filed its response to Plaintiff's brief, and on July 1, 2009 the plaintiffs filed their response to the Company's brief. No hearing date with regard to the appeal has been scheduled. The Company intends to continue to defend this case vigorously, regardless of the stage of litigation. Although the Company retains director and officer liability insurance, there is no assurance that such insurance will cover the claims that are made or will insure the Company fully for all losses on covered claims. Since the Company does not believe that a significant adverse result in this litigation is probable and since the amount of potential damages in the event of an adverse result is not reasonably estimable, no expense has been

recorded with respect to the contingent liability associated with this matter.

13

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against the Company in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, Ltd., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that the Company violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, the Company removed the case to federal court in the Northern District of Illinois. On August 25, 2009, following negotiations between the parties, the parties entered into a settlement agreement that would resolve the case on a class-wide basis. The Court gave its preliminary approval to the proposed settlement on August 27, 2009, and a final hearing on the settlement is scheduled for April 6, 2010. Under the terms of the settlement, the Company will cause to be paid a total of \$950,000 in exchange for a full release of facsimile-related claims. The Company included in its Condensed Consolidated Statement of Operations for the nine months ended September 30, 2009, \$850,000 for the estimated cost of the settlement, net of administrative expenses and amounts that are expected to be recoverable from its insurance carrier. If the proposed settlement does not receive final approval, the Company intends to defend this case vigorously.

An employment litigation lawsuit was filed against the Company in July 2009 in the United States District Court for the Northern District of California by a former sales representative at the Company. The complaint alleges that the employee was wrongfully terminated, that the Company violated Florida's Private Sector Whistleblower Act by retaliating against him and that the Company breached a contract that it had with him. The complaint seeks unspecified damages, reimbursement of costs, expenses and legal fees, and requests a jury trial. The Company denies the allegations in the complaint and intends to defend this case vigorously. Although the Company has insurance coverage for this matter, there is no assurance that such insurance will cover the claims that are made or will insure the Company fully for all losses on covered claims. Since the Company does not believe that a significant adverse result in this litigation is probable, and since the amount of potential damages in the event of an adverse result is not reasonably estimable, no expense has been recorded in the Company's Condensed Consolidated Financial Statements with respect to the contingent liability associated with this matter.

Other Legal Matters

In addition to the foregoing lawsuits, the Company is named from time to time as a party to product liability, employment and other lawsuits in the normal course of its business. As of September 30, 2009, the Company is not a party to any other material pending litigation.

Indemnifications

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

Note 9. Subsequent Events

Management evaluated all activity of the Company through November 2, 2009 (the issue date of these Condensed Consolidated Financial Statements) and concluded that no subsequent events have occurred that would require

recognition in the Condensed Consolidated Financial Statements or disclosure in Notes to Condensed Consolidated Financial Statements.

14

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Caution Regarding Forward-Looking Statements

The following discussion should be read in conjunction with the attached financial statements and notes thereto, and with our audited financial statements and notes thereto for the fiscal year ended December 31, 2008 as contained in our annual report on Form 10-K filed with the SEC on March 16, 2009. 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 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 30, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. We caution you to not place undue reliance on these forward-looking statements, which reflect management's analysis and expectations only as of the date of this report. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-Q.

Introduction

The Management's Discussion and Analysis, or MD&A, is organized as follows:

- **Executive Summary.** This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.
- **Critical Accounting Policies and Estimates.** This section describes the key accounting policies that are affected by critical accounting estimates.
- **Recent Accounting Guidance.** This section describes the issuance and effect of new accounting pronouncements that are and may be applicable to us.
- **Results of Operations.** This section provides our analysis and outlook for the significant line items on our Consolidated Statements of Operations.
- **Liquidity and Capital Resources.** This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of September 30, 2009.

Executive Summary

Company Description. We are a global medical device company engaged in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetics systems for practitioners worldwide. We offer products on three platforms—Xeo, CoolGlide, and Solera— for use by physicians and other qualified practitioners to allow our customers to offer safe and effective aesthetic treatments to their customers.

15

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

International sales are generally made through direct sales employees and through a worldwide distributor network in over 30 countries. Outside the United States, we have a direct sales presence in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom.

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

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

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

Our U.S. revenue decreased 49% for the three months and 54% for the nine months ended September 30, 2009, compared to the same periods in 2008, and our international revenue decreased 24% for the three months and 28% for the nine months ended September 30, 2009, compared to the same periods in 2008. International revenue as a percent of total revenue was 60% for the three months and 59% for the nine months ended September 30, 2009, compared with 50% for the three months and 48% for the nine months ended September 30, 2008. We believe that the decline in U.S. and international revenue was primarily attributable to the global recession that has caused our prospective customers to be reluctant to spend significant amounts of money on capital equipment during these unstable economic times. Historically a significant portion of our U.S. revenue was sourced from the non-core market of practitioners

such as primary care physicians, gynecologists and physicians offering aesthetic treatments in spa environments. We believe our U.S. revenue declined greater than our international revenue, because the recession impacted the U.S. market and particularly the non-core market more severely than our international market. Further, we also believe that those prospective customers who do not have established medical offices, are finding it more difficult to obtain credit financing, which also contributed to the reduced U.S. revenue.

Our service revenue increased 10% for the three months and 19% for the nine months ended September 30, 2009, compared to the same periods in 2008. Service contract amortization is the primary component of our total service revenue. Due to an increasing installed base of customers, our revenue from contract amortization has consistently increased. However, our deferred service revenue balance decreased by \$3.0 million, or 26%, to \$8.6 million as of September 30, 2009, compared to December 31, 2008. We believe, this decline was primarily attributable to: (i) fewer customers purchasing extended service contracts in response to improved product liability and the tougher economy, (ii) a decrease in unit sales volume in the U.S. that historically included an element of deferred revenue for service contracts beyond our standard warranty terms; (iii) a shift by customers towards purchasing more quarterly, rather than annual or multi-year, service contracts and (iv) a reduction of our service contract pricing, but including prorated charges for hand piece usage, which resulted in a reduction of our deferred service revenue balance as of September 30, 2009. With the reconfiguring of our service contracts to include prorated charges for hand piece usage during the service coverage period, we expect that in the long term, there will be an increase in revenue derived from hand piece sales which would offset the service contract amortization decline resulting from lower priced contracts being sold.

Our gross margin increased slightly to 60% for the three months ended September 30, 2009, compared to 59% for the same period in 2008, and decreased to 58% for the nine months ended September 30, 2009, compared to 61% for the same period in 2008. This decrease in gross margin for the nine months ended September 30, 2009, was due primarily to: (i) lower overall revenue, due to lower volume, which resulted in reduced leverage of our manufacturing and service department expenses; (ii) higher Service and Titan refill revenue as a percentage of our total revenue, which has a lower gross margin than our total revenue; and (iii) higher international distributor revenue as a percentage of total revenue, which has a lower gross margin than our direct business; partially offset by (iv) reduced manufacturing expenses resulting primarily from headcount reductions and improved product reliability.

Our sales and marketing expenses, as a percentage of net revenue, remained flat at 42% for the three months ended September 30, 2009, compared to the same period in 2008, and increased to 47% for the nine months ended September 30, 2009, compared to 44% for the same period of 2008. This increase in expenses as a percentage of net revenue for the nine months ended September 30, 2009, was due primarily to lower revenue in the nine months ended September 30, 2009, compared to the same period in 2008. In absolute dollars, sales and marketing expenses decreased by \$3.0 million to \$5.1 million for the three months and decreased by \$10.6 million to \$18.2 million for the nine months ended September 30, 2009, compared to same periods in 2008. These decreases in absolute dollars were due primarily to reduced personnel expenses in the United States, attributable to lower headcount, and reduced sales commission expenses resulting from lower revenue.

Our research and development (R&D) expenses, as a percentage of net revenue, increased to 14% for the three months ended September 30, 2009, compared to 10% for the same period in 2008, and increased to 13% for the nine months ended September 30, 2009, compared to 9% for the same period in 2008. These increases in expenses as a percentage of net revenue were due primarily to lower revenue in the three and nine months ended September 30, 2009, compared to the same period in 2008. In absolute dollars, R&D expenses decreased by \$144,000 to \$1.7 million for the three months and decreased by \$695,000 to \$4.9 million for the nine months ended September 30, 2009, compared to the same periods in 2008. These decreases in absolute dollars were due primarily to lower material spending resulting from one of our products under development in our R&D pipeline nearing commercialization. During the initial phases of the development of a product, material expenditure is significantly higher due to the design and development of a prototype, however, in the later stages of the product development efforts are mostly labor intensive.

General and administrative (G&A) expenses, as a percentage of net revenue, increased to 17% for the three months ended September 30, 2009, compared to 13% for the same period in 2008, and increased to 22% for the nine months ended September 30, 2009, compared to 13% for the same period in 2008. These increases in expenses as a percentage of net revenue was due primarily to lower revenue in the three and nine months ended September 30, 2009, compared to the same period in 2008. In absolute dollars, G&A expenses decreased by \$462,000 to \$2.1 million for the three months and decreased by \$290,000 to \$8.3 million for the nine months ended September 30, 2009, compared to the

same periods in 2008. The decrease in G&A expenses for the three months ended September 30, 2009, was due primarily to a decrease in personnel expenses and legal, audit, tax, and consulting fees. The decrease in G&A expenses for the nine months ended September 30, 2009, was due primarily to a decrease in legal, audit, tax, and consulting fees, and other legal expense.

We are a defendant in a Telephone Consumer Protection Act class action lawsuit. See Part II, Item 1 – Legal Proceedings below. We have included \$850,000 in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2009 for the estimated cost of the tentative settlement, net of administrative expenses and amounts that may be recoverable from our insurance carrier.

In response to the current economic environment, we reduced our company-wide workforce by approximately 12% in April 2009 and implemented other cost-reduction measures in the first half of 2009. The headcount reductions impacted all departments and functions and resulted in restructuring charges of approximately \$646,000 in our second quarter ended June 30, 2009. As of June 30, 2009, there were no service requirements outstanding from the employees who were affected. As a result of these cost-reduction measures our third quarter 2009 quarterly operating expenses declined, compared to our first and second quarter 2009 operating expenses.

We recognized an income tax provision of \$12.1 million and \$9.2 million for the three months and nine months ended September 30, 2009, respectively, despite losses before taxes. The year-to-date provision is primarily due to the recording of a valuation allowance of \$10.2 million on our U.S. deferred tax assets as of September 30, 2009. The valuation allowance was recorded at the end of the third quarter of 2009 to reduce certain U.S. federal and state net deferred tax assets to their anticipated realizable value. The valuation allowance was offset by \$969,000 of certain tax benefits resulting from losses generated during fiscal 2009 that can be carried-back to prior periods. Also, included in the third quarter 2009 provision is the reversal of \$3.1 million tax benefit primarily related to net operating losses previously recognized in the first and second quarters of 2009. See “Provision (Benefit) for Income Taxes” below for further discussion.

Factors that May Impact Future Performance.

Our industry is impacted by numerous competitive, regulatory and other significant factors. Our industry is highly competitive and our future performance depends on our ability to compete successfully. Additionally, our future performance is dependent upon our ability to continue to develop new products and innovative technologies, obtain regulatory clearances for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost effectively, and successfully market and distribute our products in a profitable manner. If we fail to 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” below.

Critical Accounting Policies and Estimates.

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

Critical accounting policy and 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 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, 2008 filed with SEC on March 16, 2009. There have been no significant changes to those accounting policies and estimates disclosed in our Form 10-K, except for the following policies that were adopted in 2009 and discussed below.

Fair Value Measurement of our Long Term Auction Rate Securities Investments

We hold a variety of interest bearing auction rate securities (ARS) that represent investments in pools of student loan assets. At the time of acquisition, these ARS investments were intended to provide liquidity through an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over

their holdings or gain immediate liquidity by selling such interests at par. Since February 2008, uncertainties in the credit markets affected our ARS investments and auctions for some of ARS have continued to fail to settle on their respective settlement dates while some have been redeemed in full at their respective par values. The current portfolio of investments shown as “Long term investments” in our Condensed Consolidated Financial Statements represents those investments that are not currently liquid and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the issuer refinances their debt. Maturity dates for these ARS investments range from to 2028 to 2043.

At September 30, 2009, total financial assets measured and recognized at fair value were \$101.8 million and of these assets, \$7.3 million, or 7%, were ARS that were measured and recognized using significant unobservable inputs (Level 3). During the nine months ended September 30, 2009, as a result of the redemption of \$4.1 million at their full par value, we transferred \$2.2 million of Level 3 assets into cash and cash equivalents (Level 1) and \$155,000 of Level 3 assets into marketable investments (Level 2). This redemption resulted in a gain of \$1.9 million being recorded to accumulated comprehensive income (loss) for the nine months ended September 30, 2009.

As of September 30, 2009, we had \$8.9 million par value (\$7.3 million fair value) of long-term ARS investments and \$155,000 par value of ARS recorded in marketable investments. The aggregate loss in value is included as an unrealized loss in accumulated other comprehensive income (loss). Given observable market information was not available to determine the fair values of our ARS portfolio, we valued these investments based on a discounted cash flow model. While our ARS valuation model was based on both Level 2 (credit quality and interest rates) and Level 3 inputs, we determined that the Level 3 inputs were the most significant to the overall fair value measurement, particularly the estimates of risk adjusted discount rates. The expected future cash flows of the ARS were discounted using a risk adjusted discount rate that compensated for the illiquidity. Projected future cash flows over the economic life of the ARS were modeled based on the contractual penalty rates for the security added to a tax adjusted LIBOR interest rate curve. The discount rates that were applied to the cash flows were based on a premium over the projected yield curve and included an adjustment for credit, illiquidity, and other risk factors. See Note 2 "Balance Sheet Details-Fair Value of Financial Instruments" in Notes to Condensed Consolidated Financial Statement in Part I, Item 1 of this Form 10-Q for more information.

The valuation of our investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the valuation include duration of time that the ARS remain illiquid, changes to credit ratings of the securities, rates of default of the underlying assets, changes in the underlying collateral value, market discount rates for similar illiquid investments, and ongoing strength and quality of credit markets. If the auctions for our ARS investments continue to fail, and there is a further decline in their valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk; and (iii) record an other-than-temporary-impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings and harm our business.

We had no non-financial assets or liabilities measured at fair value as of September 30, 2009.

Recognition and Presentation of Other-Than-Temporary-Impairments

We review our impairments on a quarterly basis in order to determine the classification of the impairment as "temporary" or "other-than-temporary." Beginning April 1, 2009, impairment recognition applies only to fixed maturity investments that are subject to the other-than-temporary impairments. If an entity intends to sell or if it is more likely than not that it will be required to sell an impaired security prior to recovery of its cost basis, the security is other-than-temporarily impaired and the full amount of the impairment is required to be recognized as a loss through earnings. Otherwise, losses on securities which are other-than-temporarily impaired are separated into: (i) the portion of loss which represents the credit loss; or (ii) the portion which is due to other factors.

The credit loss portion is recognized as a loss through earnings while the loss due to other factors is recognized in other comprehensive income (loss), net of taxes and related amortization.

With respect to the ARS that we held as of April 1, 2009, we determined that the cumulative effect adjustment required to reclassify the non-credit portion of previously recognized other-than-temporarily impaired adjustments was \$3.5 million. Therefore, we increased our accumulated earnings and decreased our accumulated other comprehensive income (loss) by the \$3.5 million cumulative effect adjustment. With respect to the \$9.1 million of par

value ARS investments held as of September 30, 2009, the unrealized losses included in accumulated comprehensive income (loss) was \$1.6 million.

Recently Adopted and Recently Issued Accounting Guidance

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

Results of Operations

The following table sets forth selected consolidated financial data for the periods indicated, expressed as a percentage of net total revenue.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Operating Ratio:				
Net revenue	100%	100%	100%	100%
Cost of revenue	40%	41%	42%	39%
Gross profit	60%	59%	58%	61%
Operating expenses:				
Sales and marketing	42%	42%	47%	44%
Research and development	14%	10%	13%	9%
General and administrative	17%	13%	22%	13%
Litigation settlement	—%	—%	2%	—%
Total operating expenses	73%	65%	84%	66%
Loss from operations	(13%)	(6%)	(26%)	(5%)
Interest and other income, net	2%	3%	4%	4%
Other-than-temporary impairment on long term investments	—%	(12%)	—%	(3%)
Loss before income taxes	(11%)	(15%)	(22%)	(4%)
Provision (benefit) for income taxes	100%	(1%)	24%	0%
Net loss	(111%)	(14%)	(46%)	(4%)

Net Revenue

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
Revenue mix by geography:						
United States	\$ 4,825	(49%)	\$ 9,498	\$ 15,721	(54%)	\$ 34,266
International	7,346	(24%)	9,612	22,545	(28%)	31,216
Consolidated total revenue	\$ 12,171	(36%)	\$ 19,110	\$ 38,266	(42%)	\$ 65,482
United States as a percentage of total revenue						
	40%		50%	41%		52%
International as a percentage of total revenue						
	60%		50%	59%		48%
Revenue mix by product category:						
Products	\$ 6,322	(51%)	\$ 12,920	\$ 20,024	(57%)	\$ 46,610
Upgrades	1,352	(31%)	1,948	4,307	(32%)	6,333
Service	3,210	10%	2,920	9,860	19%	8,311

Edgar Filing: CUTERA INC - Form 10-Q

Titan hand piece refills	1,287	(3%)	1,322	4,075	(4%)	4,228
Consolidated total revenue	\$ 12,171	(36%)	\$ 19,110	\$ 38,266	(42%)	\$ 65,482

20

Our U.S. revenue decreased 49% for the three months and 54% for the nine months ended September 30, 2009, compared to the same periods in 2008, and our international revenue decreased 24% for the three months and 28% for the nine months ended September 30, 2009, compared to the same periods in 2008. International revenue as a percent of total revenue was 60% for the three months and 59% for the nine months ended September 30, 2009, compared with 50% for the three months and 48% for the nine months ended September 30, 2008. We believe that the decline in U.S. and international revenue was primarily attributable to the global recession that has caused our prospective customers to be reluctant to spend significant amounts of money on capital equipment during these unstable economic times. Historically a significant portion of our U.S. revenue was sourced from the non-core market of practitioners such as primary care physicians, gynecologists and physicians offering aesthetic treatments in spa environments. We believe our U.S. revenue declined greater than our international revenue, because the recession impacted the U.S. market and particularly the non-core market more severely than our international market. Further, we also believe that those prospective customers who do not have established medical offices, are finding it more difficult to obtain credit financing, which also contributed to the reduced U.S. revenue.

Our product revenue decreased 51% for the three months and 57% for the nine months ended September 30, 2009, compared to the same periods in 2008. We believe the decrease in Product and Upgrade revenue in 2009 was primarily driven by the global recession that has caused our prospective customers to be reluctant on spending significant amounts of money on capital equipment during these unstable economic times. We also believe that those prospects who do not have established medical offices are finding it more difficult to obtain credit financing.

Our service revenue increased 10% for the three months and 19% for the nine months ended September 30, 2009, compared to the same periods in 2008. Service contract amortization is the primary component of our total service revenue. Due to an increasing installed base of customers, our revenue from contract amortization has consistently increased. However, our deferred service revenue balance decreased by \$3.0 million, or 26%, to \$8.6 million as of September 30, 2009, compared to December 31, 2008. We believe, this decline was primarily attributable to: (i) fewer customers purchasing extended service contracts in response to improved product liability and the tougher economy, (ii) a decrease in unit sales volume in the U.S. that historically included an element of deferred revenue for service contracts beyond our standard warranty terms; (iii) a shift by customers towards purchasing more quarterly, rather than annual or multi-year, service contracts and (iv) a reduction of our service contract pricing, but including prorate charges for hand piece usage, which resulted in a reduction of our deferred service revenue balance as of September 30, 2009. With the reconfiguring of our service contracts to include prorate charges for hand piece usage during the service coverage period, we expect that in the long term, there will be an increase in revenue derived from hand piece sales which would offset the service contract amortization decline resulting from lower priced contracts being sold.

Our Titan hand piece refill revenue decreased 3% for the three months and 4% for the nine months ended September 30, 2009, compared to the same periods in 2008. We believe that these slight decreases were due primarily to a decline in consumer spending on Titan procedures in response to the global recession.

Gross Profit

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
Gross profit	\$ 7,261	(36%)	\$ 11,287	\$ 22,290	(45%)	\$ 40,169
As a percentage of total revenue	60%		59%	58%		61%

Our cost of revenue consists primarily of material, labor, stock-based compensation, royalty expense, warranty and manufacturing overhead expenses. Gross margin as a percentage of net revenue was 60% for the three months ended September 30, 2009 compared to 59% for the same period in 2008, and 58% for the nine months ended September 30, 2009, compared to 61% for the same period in 2008. We believe this decrease in gross margin in 2009, was primarily attributable to:

- (i) Lower overall revenue, due to lower volume, which resulted in reduced leverage of our manufacturing and service department expenses;
- (ii) Higher Service and Titan refill revenue, as a percentage of our total revenue, which has a lower gross margin than our total revenue; and
- (iii) Higher international distributor revenue, as a percentage of total revenue, which has a lower gross margin than our direct business; partially offset by
- (iv) Reduced manufacturing expenses resulting primarily from headcount reductions and improved product reliability.

Sales and Marketing

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
Sales and marketing	\$ 5,112	(37%)	\$ 8,076	\$ 18,186	(37%)	\$ 28,786
As a percentage of total revenue	42%		42%	47%		44%

Sales and marketing expenses consist primarily of labor, stock-based compensation, expenses associated with customer-attended workshops and trade shows, and advertising. Sales and marketing expenses decreased by \$3.0 million in the three months and \$10.6 million for the nine months ended September 30, 2009, compared to the same periods in 2008. This decrease was mainly attributable to the following:

- (i) A decrease in personnel expenses of \$1.5 million for the three months and \$5.7 million for the nine months ended September 30, 2009, compared to the same periods in 2008, due primarily to lower headcount and reduced sales commission expenses resulting from lower revenue;
- (ii) A decrease in marketing expenses associated with workshop, advertising and other promotional activities of \$258,000 for the three months and \$1.9 million for the nine months ended September 30, 2009, compared to the same periods in 2008; and
- (iii) A decrease in travel and related expense of \$449,000 for the three months and \$1.6 million for the nine months ended September 30, 2009, compared to the same periods in 2008, due primarily to lower headcount.

Sales and marketing expenses, as a percentage of net revenue, remained flat at 42% for the three months ended September 30, 2009, compared to the same period in 2008, and increased to 47% for the nine months ended September 30, 2009, compared to 44% for the same period of 2008. This increase in expenses as a percentage of net revenue for the nine months ended September 30, 2009, was due primarily to lower revenue in the nine months ended September 30, 2009, compared to the same period in 2008.

Research and Development

Edgar Filing: CUTERA INC - Form 10-Q

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
Research and development	\$ 1,684	(8%)	\$ 1,828	\$ 4,922	(12%)	\$ 5,617
As a percentage of total revenue	14%		10%	13%		9%

22

R&D expenses consist primarily of labor, stock-based compensation, clinical, regulatory and material costs. R&D expenses decreased by \$144,000 in the three months and \$695,000 for the nine months ended September 30, 2009, compared to the same periods in 2008. These decreases were due primarily to lower material spending resulting from one of our products under development in our R&D pipeline nearing commercialization. During the initial phases of the development of a product, material expenditure is significantly higher due to the design and development of a prototype, however, in the later stages of the product development efforts are mostly labor intensive.

R&D expenses, as a percentage of net revenue, increased to 14% for the three months ended September 30, 2009, compared to 10% for the same period in 2008, and increased to 13% for the nine months ended September 30, 2009, compared to 9% for the same period in 2008. These increases in expenses as a percentage of net revenue was due primarily to lower revenue in the three and nine months ended September 30, 2009, compared to the same period in 2008.

General and Administrative (G&A)

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
General and Administrative	\$ 2,121	(18%)	\$ 2,583	\$ 8,257	(3%)	\$ 8,547
As a percentage of total revenue	17%		13%	22%		13%

General and administrative expenses consist primarily of labor, stock-based compensation, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses.

G&A expenses decreased by \$462,000 in the three months ended September 30, 2009, compared to the same period in 2008, due primarily to:

- (i) A decrease in personnel expenses of \$174,000, primarily attributable to lower headcount in the United States;
- (ii) A decrease in legal, audit and tax consulting fees of \$121,000, due to reduced fees from the consulting firms, partially offset by higher consulting fees related to our 2009 Option Exchange Program;
- (iii) A decrease in bad debt expense by \$91,000, a decrease in travel and related expenses of \$38,000, and a decrease in facility and equipment expenses of \$38,000.

G&A expenses decreased by \$290,000 for the nine months ended September 30, 2009, compared to the same periods in 2008, due primarily to:

- (i) A decrease in legal, audit and tax consulting fees of \$354,000, due to reduced fees from the consulting firms, partially offset by higher consulting fees related to our 2009 Option Exchange Program; and
- (ii) A decrease in product litigation settlement expense of \$78,000, a decrease in facility and equipment expenses of \$73,000, and a decrease in travel and related expenses of \$66,000, partly offset by;
- (iii) An increase in bad debt expense of \$363,000, resulting primarily from one leasing company that defaulted on its payment in the second quarter of 2009 due to it having

significant financial problems.

23

G&A expenses, as a percentage of net revenue, increased to 17% for the three months ended September 30, 2009, compared to 13% for the same period in 2008, and increased to 22% for the nine months ended September 30, 2009, compared to 13% for the same period in 2008. These increases in expenses as a percentage of net revenue was due primarily to lower revenue in the three and nine months ended September 30, 2009, compared to the same period in 2008.

Litigation Settlement

We are a defendant in a Telephone Consumer Protection Act class action lawsuit. See "Litigation" in Note 8 of Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report of Form 10-Q. We have included \$850,000 in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2009 for the estimated cost of the tentative settlement, net of administrative expenses and amounts that may be recoverable from our insurance carrier.

Interest and Other Income, Net

Interest and other income, net consist of the following:

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	% Change	2008	2009	% Change	2008
Interest income	\$ 288	(61%)	\$ 741	\$ 1,148	(54%)	\$ 2,485
Other income (expense), net	—	N/A	(8)	250	N/A	6
Total Interest and other income, net	\$ 288	(61%)	\$ 733	\$ 1,398	(44%)	\$ 2,491

Interest and other income, net decreased by \$445,000 for the three months and \$1.1 million for the nine months ended September 30, 2009, compared to the same period in 2008. These decreases were the result of:

- (i) A decrease in interest income of \$453,000 for the three months and \$1.3 million for the nine months ended September 30, 2009, compared to the same periods in 2008, due primarily to reduced tax-exempt interest yields as a result of the Federal Reserve cutting interest rates; which was partially offset by
- (ii) An increase in net foreign exchange gains of \$223,000 for the nine months ended September 30, 2009, compared to the same period in 2008, due primarily to translation gains resulting from the devaluation of the US dollar relative to the currencies of our foreign subsidiaries.

Other-Than-Temporary Impairment of Long Term Investments

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

Provision (Benefit) for Income Taxes

(Dollars in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	Change	2008	2009	Change	2008
	\$ (1,368)	\$ 1,471	\$ (2,839)	\$ (8,527)	\$ (5,865)	\$ (2,662)

Edgar Filing: CUTERA INC - Form 10-Q

Loss before income taxes						
Provision (benefit) for income taxes	12,126	12,212	(86)	9,159	9,187	(28)
Effective tax rate	N/A		3%	N/A		1%

24

We recognized an income tax provision of \$12.1 million and \$9.2 million for the three months and nine months ended September 30, 2009, respectively, despite losses before taxes. The year-to-date provision is primarily due to the recording of a valuation allowance of \$10.2 million on our U.S. deferred tax assets as of September 30, 2009. The valuation allowance was recorded at the end of the third quarter of 2009 to reduce certain U.S. federal and state net deferred tax assets to their anticipated realizable value. The valuation allowance was offset by \$969,000 of certain tax benefits resulting from losses generated during fiscal 2009 that can be carried-back to prior periods. Also, included in the third quarter 2009 provision is the reversal of \$3.1 million tax benefit primarily related to net operating losses previously recognized in the first and second quarters of 2009.

ASC 740 requires the consideration of a valuation allowance to reflect the likelihood of realization of 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, we considered available positive and negative evidence, giving greater weight to our recent cumulative losses and our ability to carry-back losses against prior taxable income and lesser weight to its projected financial results due to the challenges of forecasting future periods. We also considered, commensurate with its objective verifiability, the forecast of future taxable income including the reversal of temporary differences. We performed this evaluation as of the year ended December 31, 2008 and the quarters ended March 31, 2009 and June 30, 2009. At that time we continued to have sufficient positive evidence, including recent cumulative profits, a reduction in operating expenses, the ability to carry-back losses against prior taxable income and an expectation of improving operating results, showing a valuation allowance was not required. At the end of the quarter ended September 30, 2009, changes in previously anticipated expectations and continued operating losses necessitated a valuation allowance against the tax benefits recognized in this quarter and prior quarters since they are no longer “more-likely-than-not” realizable. Under current tax laws, this valuation allowance will not limit our ability to utilize federal and state deferred tax assets provided we can generate sufficient future taxable income in the U.S.

We anticipate we will continue to record a valuation allowance against the losses of certain jurisdictions, primarily federal and state, until such time as we are able to determine it is “more-likely-than-not” the deferred tax asset will be realized. Such position is dependent on whether there will be sufficient future taxable income to realize such deferred tax assets. We expect our future tax provisions (benefits), during the time such valuation allowances are recorded, will consist primarily of the tax expense of our non-US jurisdictions that are profitable. Our effective tax rate may vary from period to period based on changes in estimated taxable income or loss by jurisdiction, changes to the valuation allowance, changes to federal, state or foreign tax laws, future expansion into areas with varying country, state, and local income tax rates, deductibility of certain costs and expenses by jurisdiction.

Liquidity and Capital Resources

Liquidity is the measurement of our ability to meet potential cash requirements, fund the planned expansion of our operations and acquire businesses. Our sources of cash include operations and stock option exercises. We actively manage our cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet our daily needs. The majority of our cash and investments are held in U.S. banks and our foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short-term operating expenses.

Cash, Cash Equivalents and Marketable Investments Summary

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

	September 30, 2009	December 31, 2008	Change
Cash and cash equivalents	\$ 34,302	\$ 36,540	\$ (2,238)
Marketable investments	62,572	60,653	1,919
Long-term investments	7,339	9,627	(2,288)

Edgar Filing: CUTERA INC - Form 10-Q

Total	\$	104,213	\$	106,820	\$	(2,607)
-------	----	---------	----	---------	----	---------

25

Cash Flows

(Dollars in thousands)	Nine Months Ended September 30,	
	2009	2008
Net cash flow provided by (used in):		
Operating activities	\$ (3,135)	\$ 5,870
Investing activities	461	9,496
Financing activities	436	263
Net increase (decrease) in cash and cash equivalents	\$ (2,238)	\$ 15,629

Cash Flows from Operating Activities

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

- \$2.3 million used by the net loss of \$17.7 million after adjusting for non-cash related items of \$15.4 million- consisting primarily of valuation allowance on our deferred tax asset of \$12.3 million as of December 31, 2008, stock-based compensation expense of \$3.4 million, net increase in the allowance for doubtful accounts of \$550,000 due primarily to one leasing company that has defaulted on its payment and an increase in the provision for excess and obsolete inventories of \$247,000 resulting from the reduced future demand for our products;
- \$3.0 million used as a result of a decrease in deferred revenue due primarily to a decrease in unit sales volume of Products and Upgrades that included purchases of extended service contracts, a reduction in our service contract pricing beginning in 2009, a shift by customers towards purchasing shorter term contracts, and fewer customers purchasing extended service contracts in response to improved product reliability and to a tougher economy; and
- \$1.7 million used to pay down the higher 2008 year-end accrued liabilities relating primarily to: (i) lower accrued personnel expenses of \$679,000 due primarily to reduced accruals for commissions and employee benefit expenses; (ii) reduction of accrued warranty expenses of \$827,000 due primarily to fewer units remaining under warranty; (iii) reduction of the income taxes payable balance by \$285,000; and (iv) net reduction of \$245,000 of accrued royalties due to the reduced revenue in the third quarter of 2009. This was partially offset by higher accrued legal settlement expense of \$850,000 relating to our TCPA litigation matter (see "Litigation" in Note 8 of Notes to the Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report of Form 10-Q); partially offset by
- \$2.6 million of cash generated by the decrease in gross accounts receivable balance from December 31, 2008 to September 30, 2009 that resulted from the collection of the higher 2008 year-end accounts receivable balances; and
- \$1.8 million generated by the decrease in gross inventory balance from December 31, 2009 to September 30, 2009, that resulted from slowing our inventory build to better match the reduced sales of our products.

Net cash provided by operating activities was \$5.9 million in the nine months ended September 30, 2008, which was due primarily to:

- \$4.7 million generated from net loss of \$2.6 million after adjusting for non-cash related items primarily consisting of \$4.0 million of stock-based compensation, other-than-temporary

impairment of long term investments of \$2.4 million, and depreciation and amortization of \$671,000;

- \$4.1 million of cash generated from the collection of the higher accounts receivable balance as of December 31, 2007;
- \$1.6 million of cash generated due to an increase in deferred revenue resulting primarily from higher service contract revenue; partially offset by
- \$3.6 million used to pay down the higher year-end accrued liabilities relating primarily to personnel expenses of \$410,000, net reduction of \$1.1 million of the income tax payable due to the payment of the 2007 year-end income tax liability, net reduction of \$1.0 million of royalty accrual, and \$528,000 relating to the reduction in accrued warranty costs due primarily to fewer units remaining under warranty; and

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

Cash Flows from Investing Activities

Net cash provided by investing activities was \$461,000 in the nine months ended September 30, 2009, which was due primarily to:

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

Net cash provided by investing activities was \$9.5 million in the nine months ended September 30, 2008, which was due primarily to:

- \$68.1 million in net proceeds from the sale and maturity of marketable investments and long-term investments; partially offset by
- \$58.1 million of cash used to purchase marketable investments; and
- \$538,000 cash used to purchase property and equipment primarily for the research and development function.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$436,000 in the nine months ended September 30, 2009 and \$263,000 for the nine months ended September 30, 2008, which represented cash generated by the issuance of stock through our stock option and employee stock purchase plan.

Adequacy of cash resources to meet future needs

We had cash, cash equivalents, marketable investments and long-term investments of \$104.2 million as of September 30, 2009. Of this amount, we had \$7.5 million invested in student loan auction rate securities that were rated Aaa to A3 by a major credit rating agency and are guaranteed by The Federal Family Education Loan Program (FFELP). These securities were classified under the caption of "Long-term investments" in the Condensed Consolidated Balance Sheet as auctions for these securities have been failing since February 2008 due to the current overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security prospectus, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our ARS into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. Based on our ability to access our cash, cash equivalents and other short term marketable investments and our expected operating cash flows, we do not anticipate the current lack of liquidity on these investments will affect our ability to operate our business as usual over the next twelve months.

Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of September 30, 2009, we were not involved in any unconsolidated transactions.

Contractual Obligations

We believe that there were no significant changes during the three and nine months ended September 30, 2009 in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

Commitments and Contingencies

We are party to various legal proceedings. For a discussion of these contingencies and a schedule of our minimum commitments, see Note 8, "Commitments and Contingencies," in Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report on Form 10-Q.

Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, we have entered into indemnification agreements with each of our directors and executive officers. Our executive officers are named as defendants in securities class action litigation – See “Litigation” in Note 8 of Notes to the Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report of Form 10-Q. Our exposure under the various indemnification obligations, including those under the indemnification agreements with our directors and officers, is unknown since the outcome of the securities litigation is unpredictable and the amount that could be payable thereunder is not reasonably estimable, and since other indemnification obligations involve future claims that may be made against us. We have not accrued or paid any amounts for any such indemnification obligations. However, we may record charges in the future as a result of these potential indemnification obligations, including those related to the securities class action litigation.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and municipal bonds, and, by policy, restrict our exposure to any single type of investment or issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity (interest reset date for ARS) of generally less than eighteen months. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio would have potentially declined by approximately \$389,000 as of September 30, 2009.

We hold interest bearing ARS that represent investments in pools of student loans issued by the Federal Family Education Loan Program. At the time of acquisition, these ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. Since February 2008, uncertainties in the credit markets affected our holdings in ARS investments and auctions for all of our investments in these securities failed until December 31, 2008. In the first nine months of 2009, approximately \$4.3 million of our original \$13.4 million par value portfolio has been redeemed in full and as of September 30, 2009 we had \$8.9 million par value (fair value of \$7.3 million) of long-term ARS, whose auctions continue to fail. These investments are not currently liquid and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument. Maturity dates for these ARS investments range from 2028 to 2043. We currently classify all of these investments as long-term investments in our Condensed Consolidated Balance Sheet because of our continuing inability to determine when these investments will settle. We have also modified our current investment strategy and increased our investments in more liquid money market investments, United States Treasury securities, municipal bonds, and eliminated investments in corporate debt. The valuation of our ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact its valuation include, duration of time that the ARS remain illiquid, changes to credit ratings of the securities, rates of default of the underlying assets, changes in the underlying collateral value, market discount rates for similar illiquid investments, ongoing strength and quality of credit markets. If the auctions for our ARS investments continue to fail, and there is a further decline in the valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk; and (iii) record an other-than-temporary-impairment charge in our Consolidated Statement of Operations for the loss

in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings and harm our business.

28

Foreign Currency Exchange Risk

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. Although the majority of our revenue and purchases are denominated in U.S. dollars, we have revenue to certain international customers and expenses denominated in the Japanese Yen, Euro, Pounds Sterling, Australian Dollars, Swiss Francs and Canadian Dollars. The net gains and losses from the revaluation of foreign denominated assets and liabilities was a gain of approximately \$32,000 for the three months and a gain of approximately \$142,000 for the nine months ended September 30, 2009, which is included in our Condensed Consolidated Statements of Operations. Movements in currency exchange rates could cause variability in our revenues, expenses or interest and other income (expense). Though to date our exposure to exchange rate volatility has not been significant, we cannot assure that there will not be a material impact in the future. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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) 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 our CFO have concluded that as of the end of the period covered by this report the Company's disclosure controls and procedures were effective at a reasonable assurance level.

Definition of Disclosure Controls

Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in 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 our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Our Disclosure Controls include components of its internal control over financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the U.S. To the extent that components of our internal control over financial reporting are included within its Disclosure Controls, they are included in the scope of our annual controls evaluation.

Limitations on the Effectiveness of Controls

The Company's management, including the CEO and CFO, does not expect that the Company's disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no

evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

We are in a difficult economic period, and the uncertainty in the economy may further reduce customer demand for our products, cause potential customers to delay their purchase decisions and make it more difficult for some potential customers to obtain credit financing, all of which would adversely affect our business and may increase the volatility of our stock price.

Our revenue decreased by 36% and 42% in the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008. The general economic difficulties being experienced by our customers, reduced end consumer demand for procedures, the lack of availability of consumer credit for some of our customers, and the general reluctance of many of our current and prospective customers to spend significant amounts of money on capital equipment during these unstable economic times, are adversely affecting the market in which we operate. In times of economic uncertainty individuals often reduce the amount of money that they spend on discretionary items, including aesthetic procedures. This economic uncertainty may cause potential customers to further delay their capital equipment purchase decisions, and may make it more difficult for some potential customers to obtain credit financing necessary to purchase our products or make timely payments to us, each of which can have a material adverse effect on our revenue, profitability and business and may increase the volatility of our stock price.

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

Our success largely depends on our ability to manage and improve the productivity levels of our sales professionals worldwide. If we experience significant levels of attrition, or reductions in productivity among our sales professionals or our sales managers, our revenue and profitability may be adversely affected and this could materially harm our business.

Measures we implement in an effort to retain, train and manage our sales professionals and improve their productivity may not be successful. Our direct sales professionals have a material portion of their compensation based on commissions. Unless revenue improves, their total compensation may remain low, which could result in higher turnover. In response to reduced commission earnings resulting from the decrease in revenue, some of our sales professionals left the industry entirely or left our company to work for competitors. We are selectively hiring new sales professionals in key territories to fill vacant positions. The replacement of seasoned sales professionals with new sales professionals or the absence of a sales professional in a certain territory may adversely affect our revenue. Following the resignation of our Vice President of Sales in June 2009, we promoted our General Manager for our Japan operations to the Vice President of North American Sales position in July 2009. If the North American sales team does not align with our new Vice President of North American Sales, we could experience more turnover in the future.

The initiatives that we are implementing in an effort to improve revenue and profitability could be unsuccessful, which could harm our business.

For the three and nine months ended September 30, 2009, our total revenue decreased 36% and 42%, U.S. revenue decreased by 49% and 54% and international revenue decreased by 24% and 28%, respectively, compared to the same periods in 2008. In an effort to improve our revenue and profitability, we have implemented several strategic initiatives focusing on our worldwide sales and marketing infrastructure, product introductions and expense management. For example, we had company-wide reductions in force in January 2009 and April 2009 resulting in a total net reduction of approximately 22% of our workforce from December 31, 2008, and we reduced or eliminated certain employee benefit programs. Further, following the resignation of our Vice President of Sales in June 2009, we promoted our General Manager for our Japan operations to the Vice President of North American Sales position. These initiatives are intended to improve our revenue and profitability; however, they may instead contribute to employee turnover, instability to our operations, or further reduction in our revenue and harm to our business.

A lack of customer demand for our products in any of our markets would harm our revenue.

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

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

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

At recent industry conferences, we announced plans to release a new body contouring product called True Sculpt. We can provide no assurance that such a product launch will be successfully or be widely adopted by our customers. If we do not achieve anticipated demand for our products our revenue may be adversely impacted.

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

While we qualify customers to whom we offer credit terms (generally net 30 to 60 days), we cannot provide any assurance that the financial position of these customers will not change adversely before we receive payment. For example, in the second quarter ended June 30, 2009, one leasing company that owed us approximately \$472,000 defaulted on its payment due to significant financial difficulties they experienced. As a result, our general and administrative expenses, and therefore net loss, for the three months ended June 30, 2009, and the nine months ended September 30, 2009, was negatively impacted by an increase in the allowance for doubtful accounts. In the event that there is a default by any other customers to whom we have provided credit terms, this could further negatively affect our earnings and results of operations.

We may have exposure to additional tax liabilities which could negatively impact our income tax provision (benefit), net income (loss) and cash flow.

We are subject to income taxes and other taxes in both the U.S. and the foreign jurisdictions in which we currently operate or have historically operated. The determination of our worldwide provision for income taxes and current and deferred tax assets and liabilities requires judgment and estimation. In the ordinary course of our business, there are

many transactions and calculations where the ultimate tax determination is uncertain. We are subject to regular review and audit by both domestic and foreign tax authorities and to the prospective and retrospective effects of changing tax regulations and legislation. Although we believe our tax estimates are reasonable, the ultimate tax outcome may materially differ from the tax amounts recorded in our Condensed Consolidated Financial Statements and may materially affect our income tax provision (benefit), net income (loss), and cash flows in the period in which such determination is made.

Deferred tax assets are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. A valuation allowance reduces deferred tax assets to estimated realizable value, which assumes that it is more likely than not that we will be able to generate sufficient future taxable income in certain tax jurisdictions to realize the net carrying value. We review our deferred tax assets and valuation allowance on a quarterly basis. As part of our review, we consider positive and negative evidence, including cumulative results in recent years. As a result of our review for the quarter ended September 30, 2009, we provided for a valuation allowance of \$10.2 million on the deferred tax assets as of December 31, 2008 and reversed \$3.1 million tax benefit primarily related to net operating losses previously recognized in the first and second quarters of 2009. This resulted in a material income tax charge.

We anticipate we will continue to record a valuation allowance against the losses of certain jurisdictions, primarily federal and state, until such time as we are able to determine it is “more-likely-than-not” the deferred tax asset will be realized. Such position is dependent on whether there will be sufficient future taxable income to realize such deferred tax assets. We expect our future tax provisions (benefits), during the time such valuation allowances are recorded, will consist primarily of the tax expense of our non-US jurisdictions that are profitable.

Healthcare reform legislation and changes occurring at U.S. Food and Drug Administration, or FDA, could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, the current administration and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. Our products are not reimbursed by insurance companies or federal or state governments and some of this proposed legislation will therefore not affect us. This proposed legislation, however, includes a tax on manufacturers of medical devices and diagnostic products which would be applicable to us and, if passed, would decrease our net income.

In addition, there are several changes occurring at FDA that may lengthen the regulatory approval process for medical devices and require additional clinical data to support regulatory clearance for the sale and marketing of products such as ours. These changes in the FDA regulatory approval process may delay or prevent the approval of new products and could result in lost market opportunity. Changes in FDA regulations may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have an adverse effect on our financial condition and results of operations.

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

Our international revenue was \$7.3 million and \$22.5 million for the three and nine months ended September 30, 2009, respectively, which represented 60% and 59% of our total revenue for the three and nine months ended September 30, 2009, respectively. International revenue is a material component of our business strategy. We depend on third-party distributors and a direct sales force to sell our products internationally, and if they underperform we may be unable to increase or maintain our level of international revenue. To grow our business, we will need to

improve productivity in current sales territories and expand into new territories. However, direct sales productivity may not improve and distributors may not accept our business or commit the necessary resources to market and sell our products to the level of our expectations. As a result, we may not be able to increase or maintain international revenue growth.

We believe that an increasing amount of our future revenue will come from international sales as we expand our overseas operations and develop opportunities in additional international territories. International sales are subject to a number of risks, including:

- Difficulties in staffing and managing our foreign operations;
- Export restrictions, trade regulations and foreign tax laws;
- Fluctuating foreign currency exchange rates;
- Foreign certification and regulatory requirements;
- Lengthy payment cycles and difficulty in collecting accounts receivable;
- Customs clearance and shipping delays;
- Political and economic instability;
- Lack of awareness of our brand in international markets;
- Preference for locally-produced products; and
- Reduced protection for intellectual property rights in some countries.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation; and if we were unsuccessful at finding a solution, we may not be able to sell our products in a particular market and, as a result, our revenue may decline.

We compete against companies that have longer operating histories, newer and different products, and greater resources, each of which may result in a competitive disadvantage to us and harm our business.

Our industry is subject to intense competition. Our products compete against similar products offered by public companies, such as Candela, Cynosure, Elen (in Italy), Iridex, Palomar, Solta, and Syneron and as well as private companies such as Aesthera, Alma, Lumenis, Sciton and several other companies. 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. We also face competition from medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include sclerotherapy, a procedure involving the injection of a solution into the vein to collapse it, electrolysis, a procedure involving the application of electric current to eliminate hair follicles, and chemical peels. We may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products, and includes such factors as:

- Success and timing of new product development and introductions;
- 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 products are attractive alternatives to other devices and treatments by differentiating our products on the basis of such factors as performance, brand name, service and price, and this is difficult to do 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 achieve continued market penetration, we will be unable to compete effectively and our business will be harmed.

In addition, some of our current and potential competitors have greater financial, research and development, business development, manufacturing, and sales and marketing resources than we have. Our competitors could utilize their greater financial resources to acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing product lines. Recently there has been some consolidation in the aesthetic industry leading to companies combining their resources. For example, Thermage acquired Reliant in December 2008 and renamed the combined company, Solta. In addition, in September 2009, Syneron agreed to acquire Candela. Our competitors could also form strategic alliances with other companies to develop products and solutions that effectively compete with our products. For example, Syneron has entered into agreements with Procter and Gamble for the proposed development of home-use aesthetic devices. Business combinations and alliances by our competitors could increase competition, which could harm our business.

The aesthetic equipment market is characterized by rapid innovation. To compete effectively, we must develop and acquire new products, market them successfully, and identify new markets for our technology.

We have created products to apply our technology to hair removal, treatment of veins and skin rejuvenation, including the treating of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and pigmented lesions. Currently, these applications represent the majority of offered laser and other energy-based aesthetic procedures. To grow in the future, we must develop and acquire new and innovative aesthetic applications, identify new markets for our existing technologies, and develop and acquire new technologies for various platforms. 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 products;
- Convince our customers and prospects that our new products or upgrades would be an attractive revenue-generating addition to their practices;
- Sell our products to a broad customer base;
- Identify new markets and alternative applications for our technology;
- Protect our existing and future products with defensible intellectual property; and
- Satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, except for year-to-date 2009, we have introduced at least one new product. Historically, these introductions have generally been a significant component of our financial performance. Our business strategy is

based, in part, on our expectation that we will continue to make regular product introductions that we can sell to new customers as systems and to existing customers as upgrades to their existing systems. 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, which could adversely affect our business.

In addition, our former Executive Vice President of Research & Development, who is also one of our founders, resigned from his employment with us effective March 2009 to pursue personal interests. Although we have appointed a new Vice President of Research & Development and our founder continues to provide consulting services to us, our founder's full-time employment, experience and leadership was critical to our historical product development initiatives. As a result, we may not be able to continue our trend of regular new product introductions. Also, we may need additional research and development resources to make new product introductions, which may be more costly and time consuming to our organization.

Some of our competitors release new products more often and more successfully than we do. We believe that, to increase revenue from sales of new products and related upgrades, we need to continue to develop our clinical support, further expand and nurture relationships with industry thought leaders and increase market awareness of the benefits of our new products. If we fail to successfully commercialize any of our new products, our business could be harmed.

While we attempt to protect our products through patents and other intellectual property, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with ours. For example, while our CoolGlide product was the first long-pulse Nd:YAG, or long wavelength, laser system cleared by the FDA for permanent hair reduction on all skin types, competitors have subsequently introduced systems that utilize Nd:YAG lasers, and received FDA clearances to market these products as treating all skin types. We expect that any competitive advantage we may enjoy from other current and future innovations, such as combining multiple hand pieces in a single system to perform a variety of applications, may diminish over time, as companies successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue could decline as our customers and prospects purchase our competitors' products.

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.

If PSS World Medical fails to perform to our expectations, we may fail to achieve anticipated operating results.

We have a distribution agreement with PSS World Medical. PSS sales professionals work in coordination with our sales force to locate new customers for our products throughout the United States. Revenue from PSS declined significantly in the nine months ended September 30, 2009, compared with the same period in 2008. PSS revenue represented approximately 14% of our worldwide revenue in 2008 and 2007 and 7% of total revenue in the nine months ended September 30, 2009. In addition, our revenue from PSS as a percentage of U.S. revenue was 16% in the nine months ended September 30, 2009, compared to 29% in 2008 and 23% in 2007. Although we continue to work closely with, and focus our attention on, our PSS relationship, there is no assurance that this will translate into increased revenue for us. Further, if PSS does not perform adequately under the arrangement, or terminates our relationship, it may have a material adverse effect on our business, financial condition and results of operations.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers and other key employees. Except for Change of Control and Severance Agreements for our executive officers, we do not have employment contracts with any of our officers or other key employees. Any of our officers and other key employees may terminate their employment at any time. We do not have a succession plan in place for each of our officers and key employees. In addition, we do not maintain “key person” life insurance policies covering any of our employees. The loss of any of our senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees are critical factors in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We may face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

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

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against us in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, Ltd., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that we violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, we removed the case to federal court in the Northern District of Illinois. On August 25, 2009, following negotiations between the parties, the parties entered into a settlement agreement that would resolve the case on a class-wide basis. The Court gave its preliminary approval to the proposed settlement on August 27, 2009, and a final hearing on the settlement is scheduled for April 6, 2010. Under the terms of the settlement, we will cause to be paid a total of \$950,000 in exchange for a full release of facsimile-related claims. We included in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2009, \$850,000 for the estimated cost of the settlement, net of administrative expenses and amounts that are expected to be recoverable from our insurance carrier. If the proposed settlement does not receive final approval, we intend to defend this case vigorously.

Two securities class action lawsuits were filed against us in April and May 2007, respectively, based upon the decreases in our stock price following the announcement of our preliminary first quarter 2007 revenue and earnings, and the announcement of our revised 2007 guidance. Defending ourselves against this litigation could distract management and harm our business.

Two class action lawsuits were filed against us following declines in our stock price in the spring of 2007. On November 1, 2007, the court ordered the two cases consolidated. These consolidated cases have been on appeal since November 2008 after our motion to dismiss the plaintiffs’ complaint was granted. See “Litigation” set forth in Note 8 of Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this quarterly report on Form 10-Q for further details.

Although we retain director and officer liability insurance, there can be no guarantee that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims. This litigation may distract our management and consume resources that would otherwise have been directed toward operating our business. Each of these factors could harm our business.

We are exposed to fluctuations in the market values of our portfolio of investments, specifically auction rate securities (ARS), and due to interest rates changes. Due to failed auctions for some of our ARS since February 2008, we are unable to readily liquidate them into cash, and in 2008, we took impairment charges. If the auctions for our ARS investments continue to fail, and there is a further decline in their valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk; and (iii) record an other-than-temporary-impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings, harm our business and cause our stock price to decline.

We invest our excess cash primarily in money market funds and in highly liquid debt instruments of the U.S. government and its agencies, U.S. municipalities (including ARS). As of September 30, 2009, our balance in marketable securities was \$101.8 million. The longer the duration of a security, the more susceptible it is to changes in market interest rates and bond yields. As yields increase, those securities with a lower yield-at-cost show a mark-to-market unrealized loss. For example, assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of September 30, 2009 would have potentially decreased by approximately \$389,000, 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).

Included under the caption of "Long-term investments" in the Condensed Consolidated Balance Sheet as of September 30, 2009, are \$7.3 million of ARS. These ARS are designed to provide liquidity through an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days. Though approximately \$4.3 million (par value) of our original holdings of \$13.4 million (par value) of ARS, have been redeemed at full par value since December 31, 2008, auctions for the remaining ARS in our portfolio at September 30, 2009 have continued to fail since February 2008 due to the lack of liquidity and overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our ARS into cash until a future auction of these investments is successful, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument.

If the auctions for our ARS investments continue to fail, and there is a further decline in the valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk; and (iii) record an other-than-temporary-impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings, harm our business and cause our stock price to decline.

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

As of June 30, 2009, approximately 58% of our outstanding shares of common stock were held by 10 institutional investors. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

- 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;
- Regulatory developments or delays concerning our, or our competitors' products; and
- The initiation of litigation by us or against us.

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

We may be involved in future costly intellectual property litigation, which could impact our future business and financial performance.

Our competitors or other patent holders may assert that our present or future products and the methods we employ are covered by their patents. In addition, we do not know whether our competitors own or will obtain patents that they may claim prevent, limit or interfere with our ability to make, use, sell or import our products. Although we may seek to resolve any potential future claims or actions, we may not be able to do so on reasonable terms, or at all. If, following a successful third-party action for infringement, we cannot obtain a license or redesign our products, we may have to stop manufacturing and selling the applicable products and our business would suffer as a result. In addition, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition.

We may become involved in litigation not only as a result of alleged infringement of a third party's intellectual property rights but also to protect our own intellectual property. For example, we have been, and may hereafter become, involved in litigation to protect the trademark rights associated with our company name or the names of our products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management's attention from our core business.

Intellectual property rights may not provide adequate protection for some or all of our products, which may permit third parties to compete against us more effectively.

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and products. At September 30, 2009, we had twelve issued U.S. patents. Some of our components, such as our laser module, electronic control system and high-voltage electronics, are not, and in the future may not be, protected by patents. Additionally, our patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we obtain may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products and use manufacturing processes that are substantially similar to, or superior to, ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

The absence of complete intellectual property protection exposes us to a greater risk of direct competition. Competitors could purchase one of our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected against competitors' products and methods, our competitive position and our business could be adversely affected.

38

If we fail to obtain or maintain necessary FDA clearances for our products and indications, if clearances for future products and indications are delayed or not issued, if there are federal or state level regulatory changes or if we are found to have violated applicable FDA marketing rules, our commercial operations would be harmed.

Our products are medical devices that are subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or labeling claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. In the event that we do not obtain FDA clearances or approvals for our products, our ability to market and sell them in the United States and revenue derived there from may be adversely affected.

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

We have obtained 510(k) clearance for the indications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. We also are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. Our products are also subject to state regulations, which are, in many instances frequently changing. Changes in state regulations may impede sales. For example, federal regulations allow our products to be sold to, or on the order of, "licensed practitioners," as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase our products. However, a state could change its regulations at any time, thereby disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

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

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

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

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

We are currently required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

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

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

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

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

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

Any acquisitions that we make could disrupt our business and harm our financial condition.

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects. We may not be able to identify appropriate acquisition

candidates or strategic partners, or successfully negotiate, finance or integrate any businesses, products or technologies that we acquire. Furthermore, the integration of any acquisition and management of any collaborative project may divert management's time and resources from our core business and disrupt our operations and we may incur significant legal, accounting and banking fees in connection with such a transaction. In addition, if we purchase a company that is not profitable, our cash balances may be reduced or depleted. We do not have any experience as a team with acquiring companies or products. If we decide to expand our product offerings beyond laser and other energy-based products, we may spend time and money on projects that do not increase our revenue. Any cash acquisition we pursue would diminish our available cash balances to us for other uses, and any stock acquisition could be dilutive to our stockholders.

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

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

Some of our customers and prospective customers have had difficulty in procuring or maintaining liability insurance to cover their operation and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing laser and other energy based products due to the cost or inability to procure insurance coverage. The unavailability of insurance coverage for our customers and prospects could adversely affect our ability to sell our products, and that could harm our financial condition.

Because we do not require training for users of our products, and sell our products at times to non-physicians, there exists an increased potential for misuse of our products, which could harm our reputation and our business.

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

Product liability suits could be brought against us due to a defective design, material or workmanship or misuse of our products and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our products or failing to adhere to operating guidelines could cause significant eye and skin damage, and underlying tissue damage. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. We have been involved, and may in the future be involved, in litigation related to the use of our products. Product liability claims could divert management’s attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all future claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce product sales. In addition, we have been experiencing steep increases in our product liability insurance premiums. If our premiums continue to rise, we may no longer be able to afford adequate insurance coverage.

If we are unable to maintain adequate insurance coverage, or we have product liability claims in excess of our insurance coverage, claims would be paid out of cash reserves, thereby harming our financial condition, operating results and profitability.

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

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

- Interruption of supply resulting from modifications to or discontinuation of a supplier's operations;

41

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

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

Any defects in the design, material or workmanship of our products may not be discovered prior to shipment to customers, which could result in warranty obligations that may reduce our future revenue and increase our cost.

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, 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 compromised.

If our products contain defects that cannot be repaired easily and inexpensively, we may experience:

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

The occurrence of any one or more of the foregoing could materially harm our business.

We forecast sales to determine requirements for components and materials used in our products and if our forecasts are incorrect, we may experience either delays in shipments or increased inventory costs.

We keep limited materials and components on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to twelve months in advance and enter into purchase orders on the basis of these requirements. Our experience of materials usage may not provide us with enough data to accurately predict future demand. If our sales demand decreases significantly, or if we

overestimate our component and material requirements, we will have excess inventories and incur costs associated with the termination of existing purchase order obligations, which would increase our expenses. If our business expands, or if we underestimate our component and material requirements, we may have inadequate inventories, which could interrupt, delay or prevent delivery of our products to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

Our gross and operating margins may vary over time.

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

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

As a result of recent fluctuations in currency markets and the strong dollar relative to many other major currencies, our products priced in U.S. dollars may be more expensive relative to products of our foreign competitors, which could result in lower sales. We do not actively hedge our exposure to currency rate fluctuations. While we transact business primarily in U.S. Dollars, and a significant proportion of our revenue is denominated in U.S. Dollars, a portion of our costs and revenue is denominated in other currencies, such as the Euro, Japanese Yen, Australian Dollar, Canadian Dollar and British Pound Sterling. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our net income (loss).

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

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

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

These provisions, as well as Change of Control and Severance Agreements entered into with each of our executive officers, might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

43

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.2(1)	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4(1)	Bylaws of the Registrant.
4.1(2)	Specimen Common Stock certificate of the Registrant.
10.14(3)	Cutera, Inc. 2004 Equity Incentive Plan, as amended by its Board of Directors on April 25, 2008
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

-
- (1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.
 - (2) Incorporated by reference from our Annual Report on Form 10-K filed with the SEC on March 25, 2005.
 - (3) Incorporated by reference from our Definitive Proxy Statement on Form 14A filed with the SEC on April 28, 2008.

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 November, 2009.

CUTERA, INC.

/S/ RONALD J. SANTILLI

Ronald J. Santilli

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

