THERMAGE INC
Form 10-Q
May 12, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2008

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 001-33123

THERMAGE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0373593**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

25881 Industrial Boulevard, Hayward, California 94545

(Address of principal executive offices) (Zip Code)

(510) 782-2286

(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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a small reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated Filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

As of April 30, 2008, 23,808,988 shares of the registrant s common stock were outstanding.

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THERMAGE, INC.

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Thermage, ThermaCool, ThermaCool TC, NXT and ThermaCool NXT are registered trademarks in the United States and several other countries. ThermaTip, Body by Thermage, Face by Thermage, Eyes by Thermage, Tummy by Thermage, Hands by Thermage and Cellulite Procedures by Thermage are unregistered trademarks. All other trademarks, trade names and service marks appearing in this document are the property of their respective owners.

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PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

Thermage, Inc.

CONDENSED BALANCE SHEETS

(in thousands of dollars, except share and per share data)

(Unaudited)

	March 31, 2008	December 31, 2007 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,691	$ 13,650
Marketable investments	40,520	38,707
Accounts receivable, net	6,630	4,809
Inventories, net	6,069	6,639
Prepaid expenses and other current assets	1,870	1,782
Total current assets	64,780	65,587
Property and equipment, net	3,070	3,000
Other assets	139	140
Total assets	$ 67,989	$ 68,727
LIABILITIES AND STOCKHOLDERS EQUITY		
Liabilities:		
Accounts payable	$ 1,808	$ 1,341
Accrued liabilities	6,628	6,850
Current portion of deferred revenue	1,582	1,544
Customer deposits	12	18
Total current liabilities	10,030	9,753
Deferred rent, net of current portion	93	47
Deferred revenue, net of current portion	563	601
Other liabilities	215	208
Total liabilities	10,901	10,609
Contingencies (Note 6)		
Stockholders equity:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized none issued and outstanding		
Common stock, $0.001 par value: 100,000,000 shares authorized 23,695,617 and 23,605,415 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	24	24
Additional paid-in capital	100,670	99,588
Deferred stock-based compensation	(3)	(4)
Accumulated other comprehensive income	143	19
Accumulated deficit	(43,746)	(41,509)
Total stockholders equity	57,088	58,118

Total liabilities and stockholders equity	$ 67,989	$ 68,727

(1) December 31, 2007 condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

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

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Thermage, Inc.

CONDENSED STATEMENTS OF OPERATIONS

(in thousands of dollars, except share and per share data)

(Unaudited)

	Three Months Ended March 31,	
	2008	**2007**
Net revenue	$ 16,231	$ 15,155
Cost of revenue	4,358	4,152
Gross margin	11,873	11,003
Operating expenses		
Sales and marketing	7,422	6,374
Research and development	2,731	2,466
General and administrative	4,552	2,683
Total operating expenses	14,705	11,523
Loss from operations	(2,832)	(520)
Interest and other income	603	586
Income (loss) before income taxes	(2,229)	66
Provision for income taxes	(8)	(7)
Net income (loss)	$ (2,237)	$ 59
Net income (loss) per share:		
Basic and diluted	$ (0.09)	$ 0.00
Weighted average shares outstanding used in calculating net income (loss) per common share:		
Basic	23,630,842	22,978,331
Diluted	23,630,842	24,792,543

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

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Thermage, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands of dollars)

(Unaudited)

	Three Months Ended March 31,	
	2008	**2007**
Cash flows used in operating activities		
Net income (loss)	$ (2,237)	$ 59
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	331	402
Amortization of premium on marketable investments	50	
Loss on disposal on property, plant and equipment	2	
Stock-based compensation	979	1,261
Allowance for doubtful accounts	23	(24)
Reserve for excess and obsolete inventory	69	(9)
Change in assets and liabilities		
Accounts receivable	(1,844)	(1,980)
Inventories	473	(653)
Prepaid expenses and other current assets	(88)	220
Other non-current assets	1	(18)
Accounts payable	467	(31)
Accrued and other liabilities	(242)	(1,613)
Deferred revenue		308
Customer deposits	(6)	14
Deferred rent	46	(19)
Net cash used in operating activities	(1,976)	(2,083)
Cash flows used in investing activities		
Acquisition of property and equipment	(351)	(9)
Purchase of marketable investments	(6,689)	
Proceeds from sale of marketable investments	4,950	
Net cash used in investing activities	(2,090)	(9)
Cash flows provided by (used in) financing activities		
Proceeds from exercise of stock options	107	94
Payments of capitalized IPO related costs		(409)
Net cash provided by (used in) financing activities	107	(315)
Net decrease in cash and cash equivalents	(3,959)	(2,407)
Cash and cash equivalents at beginning of period	13,650	45,915
Cash and cash equivalents at end of period	$ 9,691	$ 43,508

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

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Thermage, Inc.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(in thousands of dollars, except share and per share amounts)

(Unaudited)

NOTE 1 THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Thermage, Inc. (the Company) develops, manufactures, and markets radiofrequency-based equipment and disposable products for non-invasive treatment of wrinkles. The Company was incorporated in California on January 11, 1996 and reincorporated in Delaware on September 10, 2001. The Company commercially launched its first products in October 2002. On November 9, 2006, the Company completed an initial public offering (IPO) of 6,000,000 shares of its common stock at $7.00 per share. Additionally, on December 8, 2006, the underwriters partially exercised their over-allotment option and purchased 150,000 shares at $7.00 per share. The Company raised approximately $38.3 million, net of underwriting discounts, commissions and other offering costs. Upon the closing of the offering, all of the Company s outstanding shares of redeemable convertible preferred stock converted on a one-to-one basis into 12,406,134 shares of common stock.

Basis of Presentation

The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company s financial position as of the date of the interim balance sheet and results of operations and cash flows for the interim periods. The condensed balance sheet at December 31, 2007 was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles. The results for the three months ended March 31, 2008 are not necessarily indicative of the results to be expected for the year ending December 31, 2008 or for any other interim period or for any future year.

These unaudited interim condensed financial statements should be read in conjunction with the financial statements and notes for the year ended December 31, 2007 included in the Company s Annual Report on Form10-K.

Adoption of SFAS No. 157 and SFAS No. 159

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* (SFAS No. 157). This statement clarifies the definition of fair value, establishes a framework for measuring fair value and expands the disclosure on fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157*, which deferred the effective date of SFAS No. 157 for one year, as it relates to non-financial assets and liabilities. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact to the Company s financial position, results of operations or cash flow. See Note 4 under the caption of cash, cash equivalents and marketable investments for further discussion and disclosure.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115* (SFAS No. 159). SFAS No. 159 allows companies to choose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and is applied prospectively. The Company has not expanded its eligible items subject to the fair value option under SFAS No. 159.

Significant Accounting Policies

The Company s significant accounting policies are disclosed in the Company s Annual Report on Form 10-K filed on March 14, 2008, and have not changed since December 31, 2007, with the exception of adoption of SFAS No. 157 and SFAS No. 159.

Segment Information

The Company operates in one business segment, which encompasses the developing, manufacturing and marketing of radiofrequency based equipment for the aesthetics market. Management uses one measurement of profitability and does not segregate its business for internal

reporting. All long-lived assets are maintained in the United States.

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The following table summarizes net revenue by product:

	Three Months Ended March 31,	
	2008	2007
RF generators	$ 4,418	$ 3,892
ThermaTips and other consumables	11,394	10,840
Net revenue from products	15,812	14,732
Services and other	419	423
Total net revenue	$ 16,231	$ 15,155

The following table summarizes net revenue by geographic region:

	Three Months Ended March 31,	
	2008	2007
United States	$ 8,237	$ 7,633
Asia Pacific	3,521	3,228
Europe/Middle East	3,056	2,655
Rest of the world	1,417	1,639
Total net revenue	$ 16,231	$ 15,155

NOTE 2 NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period as reduced by the weighted average unvested common shares subject to repurchase by the Company.

Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and potential common shares outstanding during the period, if the effect of each class of potential common shares is dilutive. Potential common shares include common stock subject to repurchase rights, incremental shares of common stock issuable upon the exercise of stock options and warrants, incremental shares of common stock issuable under employee stock purchase plans and restricted stock units. The dilutive effect of potential common shares is reflected in diluted net income (loss) per share by application of the treasury stock method, which includes consideration of stock-based compensation required by Statement of Financial Accounting Standards No. 123R, *Share-Based Payment (revised 2004)*, or (SFAS 123R), and SFAS No. 128, *Earnings Per Share.*

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	Three Months Ended March 31,	
	2008	2007
Historical net income (loss) per share:		
Numerator		
Net income (loss)	$ (2,237)	$ 59
Denominator		
Weighted-average common shares outstanding	23,630,842	22,983,956
Less: weighted-average unvested common shares subject to repurchase		(5,625)
Denominator for basic net income (loss) per share	23,630,842	22,978,331
Dilutive potential common shares used in computing diluted net income per share		1,814,212
Denominator for diluted net income (loss) per share	23,630,842	24,792,543
Basic net income (loss) per share	$ (0.09)	$ 0.00
Diluted net income (loss) per share	$ (0.09)	$ 0.00

The following outstanding options, warrants, common stock issuable under the Employee Stock Purchase Plan and restricted stock units were excluded from the computation of diluted net income (loss) per common share for the periods presented because including them would have had an antidilutive effect:

	Three Months Ended March 31,	
	2008	2007
Options to purchase common stock	4,559,058	1,210,264
Warrants to purchase common stock	27,778	
Common stock issuable under Employee Stock Purchase Plan	60,781	
Restricted stock units	5,000	46,128

NOTE 3 RECENT ACCOUNTING PRONOUNCEMENTS

In February 2008, the FASB issued FASB Staff Position FAS 157-2, which deferred the effective date of SFAS No. 157 for one year, effective for fiscal years beginning after November 15, 2008, as it relates to non-financial assets and liabilities. The Company has not determined the effect, if any, the adoption of this statement will have on its results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133* (SFAS No. 161). SFAS No. 161 establishes, among other things, the disclosure requirements for derivative instruments and for hedging activities. This statement amends and expands the disclosure requirements of SFAS No. 133 with the intent to provide users of financial statements with an enhanced understanding of: a. How and why an entity uses derivative instruments, b. How derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and c. How derivative instruments and related hedged items affect an entity s financial position, financial performance and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008, with early adoption encouraged. The Company has not determined, the effect, if any, the adoption of this statement will have on its results of operations or financial position.

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NOTE 4 BALANCE SHEET DETAIL

Cash, Cash Equivalent and Marketable 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 held for use in current operations and are classified in current assets as Marketable Investments . Cash, cash equivalents and marketable investments consist of the following:

March 31, 2008	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Checking and money market accounts	$ 9,691	$	$	$ 9,691
Corporate and Euro dollar bonds	18,396	127		18,523
Medium and short term notes	19,480	9		19,489
Certificates of deposit	2,501	7		2,508
	$ 50,068	$ 143	$	$ 50,211
Reported as:				
Cash and cash equivalents	$ 9,691	$	$	$ 9,691
Marketable investments	40,377	143		40,520
	$ 50,068	$ 143	$	$ 50,211

December 31, 2007	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Checking and money market accounts	$ 13,650	$	$	$ 13,650
Corporate and Euro dollar bonds	15,517	9		15,526
Medium and short term notes	15,719	10		15,729
Certificates of deposit	2,502			2,502
Auction rate securities	4,950			4,950
	$ 52,338	$ 19	$	$ 52,357
Reported as:				
Cash and cash equivalents	$ 13,650	$	$	$ 13,650
Marketable investments	38,688	19		38,707
	$ 52,338	$ 19	$	$ 52,357

On January 1, 2008, the Company adopted the provisions of SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, the Company measures its cash, cash equivalents and marketable investments at fair value.

The Company s cash equivalents and marketable investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

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Fair value hierarchy of the Company s cash equivalents and marketable investments at fair value in connection with our adoption of SFAS No. 157 is as follows:

	Fair Market Value	Fair Value Measurements at Reporting Date using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)
Money market accounts	$ 8,728	$ 8,728	$
Corporate and Euro dollar bonds	18,523		18,523
Medium and short term notes	19,489		19,489
Certificates of deposit	2,508		2,508

Inventories, Net

Inventories, net consist of the following:

	March 31, 2008	December 31, 2007
Raw materials	$ 2,556	$ 2,382
Work-in-process	440	931
Finished goods	3,073	3,326
	$ 6,069	$ 6,639

Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2008	December 31, 2007
Marketing expenses	$ 255	$ 282
Travel and entertainment	234	276
Warranty	586	577
Sales and use tax	247	162
Payroll and related expenses	2,868	4,181
Professional fees	1,324	447
Fixed assets	53	30
Accrued claims	336	331
Accrued inventory purchases	154	48
Other	571	516
	$ 6,628	$ 6,850

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NOTE 5 WARRANTY AND SERVICE CONTRACTS

Standard Warranty

The Company currently accrues for the estimated cost to repair or replace products under warranty at the time of sale. A summary of standard warranty accrual activity is shown below:

	Three Months Ended March 31,	
	2008	2007
Balance at beginning of period	$ 577	$ 329
Accruals for warranties issued during the period	121	153
Accruals related to pre-existing warranties (including changes in estimates)		29
Settlements made during the period	(112)	(73)
Balance at end of period	$ 586	$ 438

Extended Warranty Contracts

The Company sells extended warranty contracts to its customers. At the time of sale, the Company defers the amounts billed for such service contracts. Deferred service contract revenue is recognized on a straight-line basis over the period of the applicable extended warranty contract. A summary of extended warranty contract activity is shown below:

	Three Months Ended March 31,	
	2008	2007
Balance at beginning of period	$ 1,471	$ 1,646
Payments received	193	319
Revenue recognized	(239)	(278)
Balance at end of period	$ 1,425	$ 1,687

The Company incurred costs of $114 and $126 under extended warranty contracts during the three months ended March 31, 2008 and 2007, respectively.

NOTE 6 CONTINGENCIES

Contingencies

From time to time, the Company is involved in litigation relating to claims arising from the ordinary course of business. Management does not believe the final disposition of these matters will have a material adverse effect on the financial statements and future cash flows of the Company.

The Company advised Alma Lasers, Ltd. and Alma Lasers, Inc. (together Alma) in February 2006 that Alma s Accent product infringed numerous Thermage patents. On April 26, 2007, Alma filed a lawsuit against the Company in the United States District Court for the District of Delaware requesting declaratory judgment that Alma s Accent product does not infringe Thermage s patents and that Thermage s patents are invalid. Management believes that the Company has meritorious defenses in this action and intends to defend the action vigorously. On June 20, 2007, the Company filed counterclaims in the United States District Court for the District of Delaware asserting that Alma s Accent[XL] and Harmony devices infringe 10 Thermage U.S. patents. The counterclaims were amended on December 10, 2007 to include a claim of infringement of an eleventh Thermage patent. In addition to damages and attorney fees, the Company is asking the Court to enjoin Alma from further infringement. The case is active and discovery is ongoing. Management does not believe the final disposition of these matters will have a

material adverse effect on the financial statements and future cash flows of the Company.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representation and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves future claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

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In accordance with its certificate of incorporation, bylaws and individual indemnification agreements, the Company has indemnification obligations to its officers and directors and certain key employees for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such a capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amount paid for future claims.

NOTE 7 COMPREHENSIVE INCOME (LOSS)

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

	Three Months Ended March 31,	
	2008	2007
Net income (loss)	($ 2,237)	$ 59
Unrealized gain on marketable investments, net of tax	124	
Comprehensive income (loss)	($ 2,113)	$ 59

NOTE 8 STOCK-BASED COMPENSATION

Stock-based compensation expense recorded under APB No. 25, SFAS No. 123R and EITF No. 96-18 related to options granted to employees and non-employees, Employee Stock Purchase Plan and restricted stock unit awards was allocated to cost of revenue, sales and marketing, research and development and general and administrative expense as follows:

	Three Months Ended March 31,	
	2008	2007
Cost of revenue	$ 43	$ 99
Sales and marketing	418	482
Research and development	133	312
General and administrative	385	368
Total stock-based compensation expense	$ 979	$ 1,261

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning our expectations that ThermaTip sales will continue to increase as a result of greater demand; introduction of new treatment procedures and associated treatment tips in the future; increase in average selling price; sales organization growth; growth in international sales and expansion into new international markets; increase operating expenses for research and development; increase general and administrative expenses to support overall business and for regulatory compliance requirements; proportionately larger increase in sales and marketing expenses; and our belief that our cash, cash equivalents and marketable investments will be sufficient to satisfy our anticipated cash requirements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Risk Factors section in Item 1A of this Quarterly Report on Form 10-Q. We caution the reader not to place undue reliance of these forward-looking statements, which reflect management s analysis only as of the date of this Form 10-Q. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-Q.

Overview

We design, develop, manufacture and market medical devices for the non-invasive treatment of wrinkles. We were incorporated in 1996 and received FDA clearance for treatment of periorbital wrinkles and commercially launched our ThermaCool system in 2002. In June 2004, we received FDA clearance for the treatment of facial wrinkles and rhytids. In December 2005, we received FDA clearance to market our ThermaCool system for the treatment of wrinkles and rhytids, without limitation to particular areas of the body. In October 2006, we received FDA clearance to market our system for the temporary improvement in the appearance of cellulite. In June 2007, we received FDA clearance to market our ThermaCool system for treatment of wrinkles and rhytids for the upper and lower eyelids. In January 2008, we received FDA clearance to market a multiplex treatment tip and associated handpiece. Our patented and FDA-cleared ThermaCool system uses radiofrequency, or RF, energy to heat and shrink collagen and tighten tissue while simultaneously cooling and protecting the surface of the skin. The ThermaCool system consists primarily of an RF generator with cooling capability and a reusable handpiece, a variety of consumable, single-use ThermaTips that attach to the handpiece, and several other consumable accessories. We offer a variety of ThermaTips that a physician can select based on the area of the body being treated. We currently offer four ThermaTip sizes in several configurations of pulse counts, pulse durations and heating profiles for efficient implementation of treatment guidelines. As of March 31, 2008, we had an installed base of 2,485 ThermaCool RF generators and had sold approximately 516,000 ThermaTips.

Significant Business Trends

We derive revenue primarily from the sale of ThermaTips and other consumables and sales of our ThermaCool RF generator. For the years ended December 31, 2006 and 2007 and the three months ended March 31, 2007 and 2008, we derived 73%, 71%, 72% and 70% respectively, of our revenue from ThermaTip and other consumable sales, and 24%, 26%, 26% and 27% respectively, of our revenue from ThermaCool RF generator sales. The balance of our revenue is derived from product service and shipping. In February 2007, we introduced and began shipment of the ThermaCool NXT, our next generation system. The ThermaCool NXT is designed to save time, reduce procedure cost, simplify the treatment experience and improve patient comfort compared to our prior generator. Since the introduction of the ThermaCool NXT generator, customer demand for upgrade from the older generation product was higher than expected. During the first quarter of 2007, we sold 147 generators, which included sales of 103 systems to new customers and sales of 44 systems as upgrades to existing customers. During the first quarter of 2008, we sold 163 generators, which included sales of 86 systems to new customers and sales of 77 systems as upgrades to existing customers. The 86 systems sold in 2008 to new customers is in line with our expectation to sell approximately 400 ThermaCool NXT systems to new customers worldwide in 2008. During 2007, we launched four new procedures and associated treatment tips, including *Hands by Thermage, Lips by Thermage*, the premium ThermaTip STC for skin tightening and contouring, and ThermaTip DC for deep contouring and body shaping. In the first quarter of 2008, we introduced the *Cellulite Procedure by Thermage* and its associated treatment tip, ThermaTip CL. As a result of the introduction of new treatment tips in 2007 and the first quarter of 2008, we have seen a gradual increase in the average selling price of our treatment tips. In addition in the first quarter of 2008, we launched our Infinity Program, a purchasing plan that provides more flexibility for our U.S. customers. Under the Infinity Program, a customer may sign up for our Partner Plan, which is a six-month plan that provides a set number of monthly treatment tips and consumable products at a fixed monthly price. As a result of payment terms extended to certain of our U.S. customers under the Infinity Program, accounts receivable balance and associated days sales outstanding as of March 31, 2008 were higher than historical trends.

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We market the ThermaCool system, including our single-use ThermaTips in the United States to physicians, primarily dermatologists and plastic surgeons, through a direct sales force, and internationally in 83 countries through a network of 35 distributors. Our sales force trains physicians on the proper use of the ThermaCool system and maintains frequent interaction with these customers to promote repeat sales of our disposable ThermaTip products. In the years ended December 31, 2006 and 2007 and the three months ended March 31, 2007 and 2008, we derived 52%, 52%, 50% and 51%, respectively, of our revenue from sales of our products and services within the United States, and 48%, 48%, 50% and 49%, respectively, of our total sales outside of the United States. We believe that a significant portion of our business will continue to come from international sales through increased penetration in countries we currently sell our ThermaCool system, combined with expansion into new international markets. The percentages of our revenue by region are presented in the below table:

	Three Months Ended March 31,	
	2008	2007
United States	51%	50%
Asia Pacific	21%	21%
Europe/Middle East	19%	18%
Rest of the world	9%	11%
Total net revenue	100%	100%

During the last quarter of 2007, we began to execute our plans to expand our U.S. sales force to better address customer needs. Our plan included expansion of our U.S. sales force by about 50% in headcount and its segmentation into two groups, with about two-thirds of the sales force focusing on existing customers on sales of treatment tips, upgrades and training, and the remainder focusing on securing new accounts. Consequently, we expect a proportionately larger increase in sales and marketing expenses to promote revenue growth and geographic expansion. We continue to expect our operating expenses to increase in the future for research and development of new products and technologies, and increased general and administrative expenses to support our overall business and for regulatory compliance requirements.

Future operating results are difficult to predict accurately. We anticipate that our quarterly results of operations may fluctuate for the foreseeable future due to several factors, including the timing of introduction and the degree of acceptance of future product offerings, unanticipated interruptions and expenses related to our manufacturing operations, and the performance of our direct sales force and international distributors.

Significant Industry Factors

The growth of our business relies on continued growth of the industry, our ability to continue to develop new products, applications and innovative technologies, obtain and maintain regulatory clearances for our products, protect our proprietary technology and products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products. Our industry is characterized by seasonally lower demand during the third calendar quarter of the year, when both physicians and prospective patients take summer vacations. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. Our business is sensitive to a number of factors that influence the levels of consumer spending, including political and economic conditions such as recessionary environments, the level of disposable consumer income, consumer debt, interest rates and consumer confidence. Declines in consumer spending on aesthetic procedures could have an adverse effect on our operating results. We have in the past noticed brief fluctuations both in demand for our products and in demand for our Thermage procedure, as well as in traffic to our website, following media coverage and promotional campaigns. We experience frequent positive, negative and neutral media coverage throughout a fiscal quarter. Our sales are also impacted by other factors outside of our control, such as prior patient and practicing physician recommendations. Consequently, while we believe that media exposure and other factors outside of our direct control play a role in our long-term success, to date we have not been able to quantify the impact of particular media exposure or media exposure in general, and have not observed any material effect, positive or negative, on our quarterly financial results of operations. A detailed discussion of these and other factors that impact our business is provided in the Risk Factors section in this Form 10-Q.

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Results of Operations

Three Months Ended March 31, 2007 and 2008

Net Revenue. Revenue is derived from the sale of single-use ThermaTips and other consumables, ThermaCool RF generator sales, and service and other revenue. Net revenue increased $1.0 million, or 7%, from $15.2 million to $16.2 million for the three months ended March 31, 2007 and 2008, respectively. The increase in sales was primarily driven by sales of ThermaCool RF generators. Sales of ThermaCool RF generators increased $0.5 million, or 14%, from $3.9 million to $4.4 million for the three months ended March 31, 2007 and 2008, respectively. The increase in revenue in systems was primarily due to an increase in total quantity of systems sold, as well as a slight increase in average selling price of such systems. Sales of ThermaTips and other consumable products increased $0.6 million, or 5% from $10.8 million to $11.4 million for the three months ended March 31, 2007 and 2008, respectively. The increase in revenue was primarily due to higher average selling price of ThermaTips, driven by the recently launched premium ThermaTip STC for skin tightening and contouring, the ThermaTip DC for deep contouring and body shaping and the newly launched ThermaTip CL, for Cellulite, partially offset by lower quantity of ThermaTips sold during the three months ended March 31, 2008. During the three months ended March 31, 2008, revenue derived from sales under the Partner Plan totaled more than 30% of the U.S. ThermaTips and other consumables revenue.

Cost of Revenue. Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. Gross margin was 73.2% of revenue in the first quarter of 2008, compared with 72.6% of revenue in the first quarter of 2007. The increase in gross margin as a percent of revenue in 2008 was primarily due to higher margins realized in ThermaTip sales, driven by higher average selling price, which was partially offset by sales of more lower-margin upgrades to systems and unfavorable overhead absorption due to lower than planned production volume.

Sales and Marketing. Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops and user meetings, trade shows and advertising, as well as marketing and customer service expenses. Sales and marketing expenses increased $1.0 million, or 16%, from $6.4 million to $7.4 million for the three months ended March 31, 2007 and 2008, respectively. The increase in 2008 was primarily attributable to increased headcount and related personnel and travel and entertainment expenses as a result of our expansion of the U.S. sales force, which was partially offset by lower discretionary marketing expenses and stock-based compensation expenses.

Research and Development. Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, material costs and regulatory and quality assurance costs not directly related to the manufacturing of our products. Research and development expenses increased $0.2 million, or 11%, from $2.5 million to $2.7 million for the three months ended March 31, 2007 and 2008, respectively. The increase in research and development expenses was primarily from higher employee-related expenses and clinical study, partially offset by lower stock-based compensation expenses.

General and Administrative. General and administrative expenses consist primarily of personnel costs, legal and accounting fees, information technology costs, human resources costs and other general operating expenses. General and administrative expenses increased by $1.9 million, or 70%, from $2.7 million to $4.6 million for the three months ended March 31, 2007 and 2008, respectively. During the three months ended March 31, 2008, we reached an advanced stage of negotiations with a potential acquisition target and had performed significant due diligence on the project before negotiations were terminated. We incurred approximately $1.0 million in outside advisory fees pursuing this acquisition. The remaining increase from the prior year quarter were due to an increase of $0.4 million in professional fees associated with compliance, and an increase of $0.3 million in legal fees incurred related to patents.

Interest and Other Income. Interest and other income consist primarily of interest income generated from our cash and cash equivalent balances. Interest and other income remained at $0.6 million during the three months ended March 31, 2007 and 2008.

Provision for Income Taxes. Provision for income taxes was $7,000 and $8,000 for the three months ended March 31, 2007 and 2008, respectively. The provision for income taxes for the three months ended March 31, 2008 represented additions to FIN 48 reserves. We did not recognize any tax benefits in relation to the loss before income taxes as we maintained a full valuation allowance for deferred taxes.

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Stock-Based Compensation

For the three months ended March 31, 2007 and 2008, employee and non-employee stock-based compensation expense has been allocated as follows (in thousands):

	Three Months Ended March 31,	
	2008	2007
Cost of revenue	$ 43	$ 99
Sales and marketing	418	482
Research and development	133	312
General and administrative	385	368
Total stock-based compensation expense	$ 979	$ 1,261

Liquidity and Capital Resources

On March 31, 2008, we had working capital of $54.8 million, which consists primarily of $9.7 million in cash and cash equivalents and $40.5 million in marketable investments.

We have not demonstrated sustained profitability even though we had five consecutive quarters of profitable results through 2007. Prior to our initial public offering in November 2006, we funded our operations principally from the issuance of our preferred stock that resulted in aggregate net proceeds of $45.2 million and from working capital lines totaled approximately $5.0 million. We raised approximately $38.3 million, net of underwriting discounts, commissions and other offering costs from our initial public offering. Upon the completion of our initial public offering, we repaid the outstanding balance and interest on the working capital lines.

Net Cash Used in Operating Activities. Net cash used in operating activities was $2.0 million in the three months ended March 31, 2008, compared with net cash used of $2.1 million in the same period a year ago. During 2008, $0.8 million net cash was used in net loss after adjusting for non-cash items. An additional $1.2 million of net cash was used in changes in assets and liabilities. Cash used in changes in assets and liabilities was primarily from $1.8 million of increased accounts receivable, which was partially offset by $0.5 million cash provided as a result of a decrease in inventory and $0.5 million cash provided as a result of an increase in accounts payable. The increase in accounts receivable was due to a higher percentage of sales volume that occurred towards in the latter part of the quarter, as well as the impact of providing more flexible payment terms to certain U.S. customers under our Infinity Program in the first quarter of 2008. During 2007, $1.7 million of net cash was provided from net income after adjusting for non-cash items, which was fully offset by $3.8 million of net cash used in changes in assets and liabilities. Cash used in changes in assets and liabilities was primarily from $2.0 million of increased accounts receivable, the result of increased revenue; $1.6 million decrease in accrued and other liabilities, due to payment of annual bonuses; $0.7 million increase in inventory, to support the new ThermaCool NXT generator launch; offset by $0.3 million increase in deferred revenue, a result of deferral of revenue on sales of our predecessor generators with rights to upgrade to the new ThermaCool NXT generator.

Net Cash Used in Investing Activities. Net cash used in investing activities was $2.1 million and $9,000 for the three months ended March 31, 2008 and 2007, respectively. The Company began to purchase marketable investments during the third quarter of 2007.

Net Cash Provided by (Used in) Financing Activities. Net cash provided by financing activities was $0.1 million in the three months ended March 31, 2008 compared with net cash used of $0.3 million in the three months ended March 31, 2007. During the first quarter of 2008, cash was provided by proceeds from exercise of stock options. During the first quarter of 2007, cash was used for payment of capitalized IPO costs of $0.4 million, partially offset by proceeds from exercise of stock options.

We believe that our current cash, cash equivalents, and investments, along with the cash we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

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Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance 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. In addition, we do not have any undisclosed borrowings or debt, and we have not entered into any synthetic leases. We are, therefore, not materially exposed to any financing, liquidity, market or credit risk that could arise if we engaged in such relationships.

Recent Accounting Pronouncements

In February 2008, the FASB issued FASB Staff Position FAS 157-2, which deferred the effective date of SFAS No. 157 for one year, effective for fiscal years beginning after November 15, 2008, as it relates to non-financial assets and liabilities. We have not determined the effect, if any, the adoption of this statement will have on our results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133* (SFAS No. 161). SFAS No. 161 establishes, among other things, the disclosure requirements for derivative instruments and for hedging activities. This statement amends and expands the disclosure requirements of SFAS No. 133 with the intent to provide users of financial statements with an enhanced understanding of: a. How and why an entity uses derivative instruments, b. How derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and c. How derivative instruments and related hedged items affect an entity s financial position, financial performance and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008, with early adoption encouraged. We have not determined, the effect, if any, the adoption of this statement will have on our results of operations or financial position.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to credit and interest rate risk relates primarily to our investment portfolio. Our investment portfolio primarily includes fixed rate debt instruments of corporate issuers, fixed rate Euro bonds and certificates of deposit. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of March 31, 2008 would have potentially declined by $350,000. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity of generally one year or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

Although, currently, all of our sales and purchases are denominated in U.S. dollars, 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.

ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to management as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We advised Alma Lasers, Ltd. and Alma Lasers, Inc. (together, Alma) as early as February 2006 that its Accent product infringed numerous Thermage patents.

On April 26, 2007, Alma filed a lawsuit against us in the United States District Court for the District of Delaware requesting declaratory judgment that Alma s Accent product does not infringe Thermage s patents and that Thermage s patents are invalid. We believe that we have meritorious defenses in this action and intend to defend the action vigorously.

On June 20, 2007, we filed patent infringement counterclaims against Alma in the United States District Court for the District of Delaware asserting that Alma s Accent^{XL} and Harmony systems infringe 10 Thermage U.S. patents. The counterclaims were amended on December 10, 2007 to include a claim of infringement of an eleventh Thermage patent. In addition to damages and attorney fees, we are asking the Court to enjoin Alma from further infringement. The case is active and discovery is ongoing.

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We may not be able to achieve sustainable profitability even if we are able to generate significant revenue.

While we have had five consecutive quarters of profitable results through the end of 2007, we incurred a loss of $2.2 million in the three months ended March 31, 2008. In the past, we have expanded our business and increased our expenses in order to grow revenue. We expect this trend to continue for the foreseeable future. For example, in order to promote revenue growth and geographic expansion, during the fourth quarter of 2007, we began to execute a plan to increase our U.S. sales force by about 50% in headcount. We will have to increase our revenue while effectively managing our expenses in order to achieve sustained profitability. Our failure to achieve sustained profitability could negatively impact the market price of our common stock.

It is difficult to forecast future performance, which may cause our financial results to fluctuate unpredictably.

Our limited operating history makes it difficult for us to predict future performance. Historically, the demand for our ThermaCool system has varied from quarter to quarter. A number of factors, over which we have limited or no control, may contribute to fluctuations in our financial results, such as:

- delays in receipt of anticipated purchase orders;
- seasonal variations in patient demand for aesthetic procedures;
- the potential impact of general economic conditions on the demand for aesthetic procedures;
- performance of our independent distributors;
- positive or negative media coverage of our ThermaCool system, the Thermage procedure or products of our competitors or our industry;

our ability to obtain further regulatory clearances or approvals;

delays in, or failure of, product and component deliveries by our subcontractors and suppliers;

changes in the length of the sales process;

customer response to the introduction of new product offerings; and

fluctuations in foreign currency.

Our operating performance has in the past been negatively impacted as we have attempted to determine the proper sales prices for our ThermaCool radiofrequency, or RF, generator and our single-use ThermaTips. Establishing appropriate pricing for our capital equipment and components has been challenging because there have not existed directly comparable competitive products. We may experience similar pricing challenges in the future as we introduce new products, which could have an unanticipated negative impact on our financial performance.

In addition, we expect to continue to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We incurred approximately $1.0 million pursuing such a strategic acquisition in the three months ended March 31, 2008, which negatively impacted our financial performance during the quarter. We may incur similar expenses in future periods as we continue to evaluate potential strategic transactions. Such expenditures could negatively impact our financial performance in future periods.

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If there is not sufficient patient demand for Thermage procedures, practitioner demand for our ThermaCool system, including our single-use ThermaTips, could drop, resulting in unfavorable operating results.

Most procedures performed using our ThermaCool system are elective procedures, the cost of which must be borne by the patient, and are not reimbursable through government or private health insurance. The decision to undergo a Thermage procedure is thus driven by consumer demand. Our business is sensitive to a number of factors that influence the level of consumer spending, including political and economic conditions such as recessionary environments, the levels of disposable consumer income, consumer debt, interest rates and consumer confidence. Declines in consumer spending on aesthetic procedures could have an adverse effect on our operating results. Consumer demand may be influenced by a number of factors, such as:

- our sales and marketing efforts directed toward consumers, as to which we have limited experience and resources;
- the extent to which physicians recommend our procedures to their patients;
- the cost, safety and effectiveness of a Thermage procedure versus alternative treatments; and
- general consumer sentiment about the benefits and risks of aesthetic procedures.

Our financial performance could be materially harmed in the event that any of the above factors discourage patients from seeking Thermage procedures.

We may not be successful in selling and marketing our product for cellulite.

In October 2006, we received FDA clearance to market our system for the temporary improvement in the appearance of cellulite. We commercially introduced the *Cellulite Procedure by Thermage ™* and ThermaTip CL product in the first quarter of 2008. We have not previously marketed our system to reduce the appearance of cellulite, and our anticipated marketing and training efforts may not be successful in encouraging physicians and patients to adopt this new procedure in commercially meaningful numbers. We expect to face significant competition in the area of cellulite products, in some cases from companies that are more established, market more widely known products and have greater resources than we do. We may not be able to differentiate our cellulite product sufficiently from our competitors products to achieve significant market penetration. As a result of these factors, we may incur significant sales and marketing expenses relating to this new product opportunity without achieving commercial success, which could harm our business and our competitive position.

We are totally dependent upon the success of our ThermaCool system, which has a limited commercial history. If the ThermaCool system fails to increase market acceptance, our business will suffer.

We introduced our ThermaCool system in 2002, and expect that sales of our ThermaCool system, including our line of single-use ThermaTips, will account for substantially all of our revenue for the foreseeable future. We expect to continue to expand our line of ThermaTips for new applications. This may not occur when expected, or at all, which would negatively affect our anticipated revenue. Our ThermaCool system may not significantly penetrate current or new markets. If demand for the ThermaCool system does not increase as we anticipate, or declines, our business, financial condition and results of operations will be harmed.

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 incurred approximately $1.0 million pursuing such a strategic acquisition in the three months ended March 31, 2008, which negatively impacted our financial performance during the quarter. We may incur similar expenses in future periods as we continue to evaluate potential strategic transactions. Such expenditures could negatively impact our financial performance in future periods. In addition, we may not be able to successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the evaluation, negotiation and 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. We have not acquired companies or products in the past. If we decide to expand our product offerings, we may spend time and money on projects that do not increase our revenue. Any cash

acquisition we pursue would diminish funds available to us for other uses, and any stock acquisition would dilute our stockholders ownership. 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 acquisitions or collaborative projects.

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

We advised Alma Lasers Ltd. and Alma Lasers, Inc. (together Alma) as early as February 2006 that its Accent product infringed numerous Thermage patents. A number of these patents are the same as those at issue in our 2004 litigation against Syneron, which was settled in 2005 with Syneron acknowledging the validity of these patents in a paid license. In April 2007, Alma filed a complaint in federal court in Delaware seeking a declaratory judgment of non-infringement, and invalidity of nine of Thermage s U.S. patents. On June 20, 2007, we filed an answer to this complaint and counterclaims, alleging that Alma infringed one or more claims of ten of Thermage s U.S. patents. Our counterclaims were subsequently amended on December 10, 2007 to include a claim of infringement of an eleventh Thermage patent. Among other things, our counterclaim alleges that both Alma s Harmony and Accent XL systems infringe our patents. In addition to damages and attorney fees, we have asked the court to enjoin Alma from engaging in further infringement. Alma has responded to all our counterclaims by denying infringement and alleging invalidity of all eleven U.S. patents asserted by us. The litigation is active and discovery is ongoing. Our intellectual property has not been tested at trial. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and could divert management s attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our ThermaCool system, any of which would have a material adverse effect on our business, results of operations and financial condition. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our ThermaCool system or processes to avoid infringement.

Our industry has been characterized by frequent intellectual property litigation. Our competitors or other patent holders may assert that our ThermaCool system and the methods we employ are covered by their patents. If our ThermaCool system or methods are found to infringe, we could be prevented from marketing our ThermaCool system. In addition, we do not know whether our competitors or potential competitors have applied for, or will apply for or obtain, patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our ThermaCool system. Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our ThermaCool system in one or more countries.

In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our company name or the names used with our ThermaCool system. Names used with our ThermaCool system and procedures may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or ThermaCool system, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

Intellectual property rights may not provide adequate protection for our ThermaCool system, 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 ThermaCool system. As of March 31, 2008, we had 32 issued U.S. patents and 19 issued foreign patents outside of the United States, mostly covering our ThermaCool system. Some of our system components 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, we do not have patent rights in all foreign countries in which a market may exist, and where we have applied for foreign patent rights, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

In addition, competitors could purchase our ThermaCool system and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, 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 so as to protect our market against competitors products and methods, our competitive position could be adversely affected, as could our business.

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Our ability to market our ThermaCool system in the United States is limited. If we want to expand our marketing claims, we will need to obtain additional FDA clearances or approvals, which may not be granted.

Developing and promoting new applications for our ThermaCool system are elements of our growth strategy. We currently have FDA clearance in the U.S. to market our system for the non-invasive treatment of wrinkles and rhytids, and for the temporary improvement in the appearance of cellulite. These clearances restrict our ability to market or advertise our ThermaCool system for many specific indications, which could affect our growth. We intend to expand our line of ThermaTips for new applications and conditions. We are in the process of seeking, and intend to continue to seek, clearances from the FDA to expand our marketing efforts. We cannot predict whether we will receive such clearances. Future indications may be more difficult to obtain. The FDA may require us to conduct clinical trials to support a regulatory clearance or approval, which trials may be time-consuming and expensive, and may produce results that do not result in approval of our FDA application. In the event that we do not obtain additional FDA clearances, our ability to promote our ThermaCool system in the United States and to grow our revenue may be adversely affected.

Performing clinical studies on, and collecting data from, the Thermage procedure is inherently subjective, and we have limited data regarding the efficacy of our ThermaCool system. If future data is not positive or consistent with our prior experience, rates of physician adoption will likely be harmed.

We believe that in order to significantly grow our business, we will need to conduct future clinical studies of the effectiveness of the ThermaCool system. Clinical studies of aesthetic wrinkle treatments and cellulite are subject to a number of limitations. First, these studies do not involve well-established objective standards for measuring the effectiveness of treatment. Subjective, before and after, evaluation of the extent of change in the patient s appearance, performed by a medical professional or by the patient, is the most common method of evaluating effectiveness. A clinical study may conclude that a treatment is effective even if the change in appearance is subtle and not long-lasting. Second, as with other non-invasive, energy-based devices, the effect of the Thermage procedure varies from patient to patient and can be influenced by a number of factors, including the area of the body being treated, the age and skin laxity of the patient and operator technique.

Most published studies of our ThermaCool system have investigated the tissue-tightening effect of our monopolar RF technology in procedures on the face, using a single treatment with our first generation 1.0 cm^2 ThermaTip and our prior procedure protocol, which involved the use of fewer energy pulses at a higher power than our current procedure protocol. We have not conducted any head-to-head clinical studies that compare results from treatment with our ThermaCool system to surgery or treatment with other aesthetic devices. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase our ThermaCool system. If we decide to pursue additional studies in the future, they could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians expectations, our ThermaCool system may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

The failure of our ThermaCool system to meet patient expectations or the occurrence of unpleasant side effects from the Thermage procedure could impair our financial performance.

Our future success depends upon patients having a positive experience with the Thermage procedure in order to increase physician demand for our products, as a result of both individual patients repeat business and as a result of word-of-mouth referrals. We believe that patients may be dissatisfied with the Thermage procedure if they find it to be too painful. Furthermore, Thermage patients may experience temporary swelling or reddening of the skin as a procedure side effect. In rare instances patients may receive burns, blisters, skin discoloration or skin depressions. Experiencing excessive pain, any of these side effects or adverse events could discourage a patient from having a Thermage procedure or discourage a patient from having additional procedures or referring Thermage procedures to others. In order to generate repeat and referral business, we also believe that patients must be satisfied with the effectiveness of the Thermage procedure. Results obtained from a Thermage procedure are subjective and may be subtle. A Thermage treatment may produce results that may not meet patients expectations. If patients are not satisfied with the procedure or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

Our success depends on growing physician adoption of our ThermaCool system and continued use of our ThermaTips.

Our target physician customers typically already own one or more aesthetic device products. Our ability to grow our business and convince physicians to purchase our ThermaCool system depends on the success of our clinical and sales and marketing efforts. Our business model involves both a capital equipment purchase of our ThermaCool RF generator and continued purchases by our customers of single-use ThermaTips. This may be a novel business model for many potential

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customers who may be used to competing products that are either exclusively capital equipment, such as many laser-based systems, or that are exclusively single-use products, such as Botox or dermal fillers. We must be able to demonstrate that the cost of our ThermaCool system and the revenue that the physician can derive from performing procedures using our product are compelling when compared to the cost and revenue associated with alternative products. When marketing to plastic surgeons, we must also, in some cases, overcome a bias against non-invasive aesthetic procedures. If we are unable to increase physician adoption of our ThermaCool system and use of our ThermaTips, our financial performance will be adversely affected.

We have limited sales and marketing experience and failure to build and manage our sales force or to market and distribute our ThermaCool system effectively could have a material adverse effect on our business.

We rely on a direct sales force to sell our ThermaCool system in the United States. During the fourth quarter of 2007, we began to expand and realign our U.S. sales force to better address customer needs. We began to execute our plan to increase our U.S. sales force by about 50% in headcount and realign resources into two groups, with about two-thirds of the sales force focusing on existing customers on sales of treatment tips, upgrades and training, and the remainder focusing on securing new accounts. As the Company grows, we expect to grow or realign, if necessary, our sales organization to meet our anticipated sales objectives. There are significant risks involved in building and managing our sales organization, including risks related to our ability to:

- hire qualified individuals as needed;
- provide adequate training for the effective sale of our ThermaCool system; and
- retain and motivate our sales employees.

In addition, sales to non-traditional practitioners of aesthetic procedures is a key element of our growth strategy. However, our sales force historically has sold primarily to dermatologists and plastic surgeons. Also, our ThermaCool system competes with products that are well-established in the market. Accordingly, it is difficult for us to predict how well our sales force will perform. Our failure to adequately address these risks could have a material adverse effect on our ability to sell our ThermaCool system, causing our revenue to be lower than expected and harming our results of operations.

To successfully market and sell our ThermaCool system internationally, we must address many issues with which we have limited experience.

International sales accounted for 48% of our revenue for the year ended December 31, 2007, and 49% of our revenue for the three months ended March 31, 2008. We believe that a significant portion of our business will continue to come from international sales through increased penetration in countries where we currently sell our ThermaCool system, combined with expansion into new international markets. However, international sales are subject to a number of risks, including:

- difficulties in staffing and managing our international operations;
- difficulties in penetrating markets in which our competitors products are more established;
- reduced or no protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;

fluctuating foreign currency exchange rates;

foreign certification and regulatory clearance or approval requirements;

difficulties in developing effective marketing campaigns for unfamiliar, foreign countries;

customs clearance and shipping delays;

political and economic instability; and

preference for locally produced products.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and if we are unable to find a solution, our revenue may decline.

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To market and sell our ThermaCool system internationally, we depend on distributors, and they may not be successful.

We currently depend primarily on third-party distributors to sell and service our ThermaCool system internationally and to train our international customers, and if these distributors terminate their relationships with us or under-perform we may be unable to maintain or increase our level of international revenue. We will also need to engage additional international distributors to grow our business and expand the territories in which we sell our ThermaCool system. Distributors may not commit the necessary resources to market, sell and service our ThermaCool system to the level of our expectations. If current or future distributors do not perform adequately, or if we are unable to engage distributors in particular geographic areas, our revenue from international operations will be adversely affected.

We compete against companies that have more established products, longer operating histories and greater resources, which may prevent us from achieving significant market penetration or increased operating results.

The aesthetics market is highly competitive and dynamic, and is marked by rapid and substantial technological development and product innovations. Demand for our ThermaCool system could be diminished by equivalent or superior products and technologies offered by competitors. Specifically, our ThermaCool system competes against a variety of offerings in the aesthetics market, including laser and other light-based medical devices, pharmaceutical products such as Botox, filler injections, chemical peels, microdermabrasion, liposuction, cosmetic surgical procedures and less invasive surgical solutions such as implanted sutures. Our closest competitors are makers of laser and other light-based devices, which include public companies such as Candela, Cutera, Cynosure, Lumenis, Palomar Medical Technologies and Syneron Medical, as well as many private companies.

Competing in the aesthetics market could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. Our ability to compete effectively depends upon our ability to distinguish our company and our ThermaCool system from our competitors and their products, and on such factors as:

- safety and effectiveness;
- product pricing;
- success of our marketing initiatives;
- compelling clinical data;
- intellectual property protection;
- quality of customer support; and
- development of successful distribution channels, both domestically and internationally.

Some of our competitors have more established products and 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 expensive products that they have already purchased from our competitors and thus may decide not to purchase our ThermaCool system, or to delay such purchase. 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 significantly greater financial, research and 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

line. Given the relatively few competitors currently in the market, any business combination could exacerbate any existing competitive pressures, which could harm our business.

Competition among providers of devices for the aesthetics market is characterized by rapid innovation, and we must continuously develop new products or our revenue may decline.

While we attempt to protect our ThermaCool system through patents and other intellectual property rights, 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 we believe our monopolar RF technology maintains a strong intellectual property position, there are other companies employing competing technologies which claim to have a similar clinical effect to ours. Additionally, there are others who may market monopolar RF technology for competing purposes in a direct challenge to our intellectual property position. As we continue to create market demand for a non-surgical, non-invasive way to treat wrinkles, competitors will enter the market with other products making similar or superior claims. We expect that any competitive advantage we may enjoy from our current and future innovations may diminish over time, as companies successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our ThermaCool system and technology to compete successfully. If we are unable to innovate successfully, our ThermaCool system could become obsolete and our revenue will decline as our customers purchase competing products.

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Negative publicity and other publicly-available information regarding our Thermage procedure could harm demand, which would adversely affect sales and our financial performance.

We have in the past experienced, and expect that in the future we will experience, negative media exposure. Such publicity may present negative individual physician or patient experience regarding the safety or effectiveness of the Thermage procedure. Competitors could attempt to use such publicity to harm our reputation and disrupt current or potential future customer relationships. While, to date, we have not observed a material impact on our quarterly financial results of operations from negative publicity, future results could be negatively impacted. Additionally, while we believe that obtaining positive publicity is important to our success, and it is an important component of our marketing efforts, we have also not observed a material impact on our quarterly financial results of operations from positive publicity.

Our reputation and competitive position may be harmed not only by negative media exposure, but also by other publicly-available information suggesting that our Thermage procedure is not safe. For example, we file adverse event reports with the FDA that are publicly available on the FDA s website if our product may have caused or contributed to a serious injury or malfunctioned in a way that would likely cause or contribute to a serious injury if it were to recur. Competitors may attempt to harm our reputation by pointing to isolated injuries that have been reported or publicized, or by claiming that their product is superior because they have not filed as many adverse event reports with the FDA. Such negative publicity and competitor behavior could harm our reputation and our future sales.

We outsource the repair of key elements of our ThermaCool RF generator to a single repair subcontractor.

We outsource the repair of our first generation RF generator to a single repair subcontractor, Stellartech. If Stellartech s operations are interrupted, we may be limited in our ability to repair equipment. Stellartech is dependent on trained technical labor to effectively repair our ThermaCool RF generator. In addition, Stellartech is a medical device manufacturer and is required to demonstrate and maintain compliance with the FDA s Quality System Regulation, or QSR. If Stellartech fails to comply with the FDA s QSR, its repair operations could be halted and our ability to repair first generation ThermaCool systems would be impaired.

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

Several components and materials that comprise our ThermaCool system are currently manufactured by a single supplier or a limited number of suppliers. In many of these cases, we have not yet qualified alternate suppliers and rely upon purchase orders, rather than long-term supply agreements. A supply interruption or an increase in demand beyond our current suppliers capabilities could harm our ability to manufacture our ThermaCool system until new sources of supply are identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier s variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially 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;

delay in delivery due to our suppliers prioritizing other customer orders over ours;

damage to our brand reputation caused by defective components produced by our suppliers;

increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and

fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

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.

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If, in the future, we decide to perform additional manufacturing functions internally that we currently outsource, our business could be harmed by our limited manufacturing experience and related capabilities.

We currently perform certain value-added and proprietary manufacturing processes internally at our principal facility, and we outsource the manufacture of components, subassemblies and certain finished products to a limited number of third parties. For financial or operational purposes, we may elect to perform additional component or system manufacturing functions internally. In that event, we may face a number of challenges beyond those that we currently address in our internal assembly, inspection, testing and certification activities. Implementing complex or specialized manufacturing processes could lead to difficulties in producing sufficient quantities of manufactured items that meet our quality standards and that comply with applicable regulatory requirements in a timely and cost-effective manner. In addition, if we experience these types of internal manufacturing difficulties, it may be expensive and time consuming to engage a new or previous subcontractor or supplier to fulfill our replacement manufacturing needs. The occurrence of any of these events could harm our business.

Problems in our manufacturing processes, or those of our manufacturing subcontractors, that lead to an actual or possible malfunction in the ThermaCool system, may require us to recall product from customers and could disrupt our operations. Our results of operations, our reputation and market acceptance of our products could be harmed if we encounter difficulties in manufacturing that result in a recall or patient injury, and delays in our ability to fill customer orders.

We may not be able to develop an alternative cooling system that will be in compliance with changing environmental regulations in a timely or cost-effective manner.

The cooling capability of our ThermaCool RF generators relies upon a hydroflurocarbon, or HFC, called R134a, to protect the outer layer of the skin from over-heating while our device delivers RF energy to the subcutaneous tissue. New environmental regulations phasing out certain HFCs over the next decade have been adopted or are under consideration in a number of countries, and recent European Union directives require the phase-out of certain HFCs and place certain restrictions which became effective in July 2007 on the import of R134a, and new products that utilize R134a. Our research and development staff continues to develop an alternative cooling system to address changing environmental regulations. We have also put in place a solution for the European Union import restrictions. If we are unable to develop an alternative cooling system for our device in a timely or cost-effective manner, our ThermaCool system may not be in compliance with changing environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

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

We keep limited materials, components and finished product 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 six months in advance and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand. If we overestimate our component and material requirements, we will have excess inventory, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of our ThermaCool system to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

Even though we require training for users of our ThermaCool system and do not sell our ThermaCool system to non-physicians, there exists a potential for misuse, which could harm our reputation and our business.

While we only sell our ThermaCool system to licensed physicians who have met our training requirements, Federal regulations allow us to sell our ThermaCool system to licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our ThermaCool system may be operated by licensed practitioners with varying levels of training, and in many states by non-physicians, including physician assistants, registered nurses and nurse practitioners. Thus, in some states, the definition of licensed practitioner may result in the legal use of our ThermaCool system by non-physicians. Outside the United States, our independent distributors sell in many jurisdictions that do not require specific qualifications or training for purchasers or operators of our ThermaCool system. We do not supervise the procedures performed with our ThermaCool system, nor can we be assured that direct physician supervision of our equipment occurs according to our recommendations. We, and our distributors, require purchasers of our ThermaCool system to undergo an initial training session as a condition of purchase, but do not require ongoing training. In addition, we prohibit the sale of our system to companies that rent our system to third parties without our approval, but cannot prevent an otherwise qualified physician from contracting with a rental company in violation of their purchase agreement with us. The

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use of our ThermaCool system by non-physicians, as well as noncompliance with the operating guidelines set forth in our training programs, may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

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

If our ThermaCool system is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our ThermaCool system or failing to adhere to operating guidelines could cause significant 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 and may, in the future, be involved in litigation related to the use of our ThermaCool system. 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 reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and reducing our operating results.

The dielectric material in our ThermaTips may degrade with prolonged operation of our device, which could, in turn, lead to skin burns. Our research and development staff continues to be innovative in designing and implementing strategies to mitigate the risks associated with breakdown of the dielectric material in our ThermaTips. If we are unable to address this issue effectively, we could be subject to product liability litigation, as well as damage to our reputation in the marketplace, as a result of potential injury to patients.

After-market modifications to our ThermaTips by third parties and the development of counterfeit treatment tips could reduce ThermaTip sales, expose us to product liability litigation and dilute our brand quality.

Third parties have introduced adulterated after-market modifications to our ThermaTips which have enabled re-use of our ThermaTips in multiple procedures. Because our ThermaTips are designed to withstand a finite number of firings, modifications intended to increase the number of firings could result in patient injuries caused by the use of worn-out or damaged ThermaTips. In addition, third parties may seek to develop counterfeit treatment tips that are compatible with our ThermaCool system and available to practitioners at lower prices than our own. If security features incorporated into the design of our ThermaCool system are unable to prevent after-market modifications to our ThermaTips or the introduction of counterfeit treatment tips, we could be subject to reduced ThermaTip sales, product liability lawsuits resulting from the use of damaged or defective goods and damage to our reputation for providing a quality product.

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. Many of our officers and key employees do not have employment contracts with us and can terminate their employment at any time. 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 will be a critical factor 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 will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use and benefits of our ThermaCool system. 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.

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Risks Related to Regulatory Matters

If we fail to obtain and maintain necessary FDA clearances for our ThermaCool system and indications, if clearances for future products and indications are delayed, not issued or rescinded or if there are federal or state level regulatory changes, our commercial operations would be harmed.

Our ThermaCool system is a medical device that is 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 claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or premarket approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. The FDA s 510(k) clearance process usually takes from one to three months, but it can last significantly longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process, and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the non-invasive treatment of wrinkles and rhytids. 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 product causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. Our ThermaCool system is also subject to state regulations which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations allow our ThermaCool system 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 and operate our ThermaCool system. However, a state could change its regulations at any time, 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. Our failure to comply with applicable regulatory requirements 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, refunds, recall or seizure of our product;

operating restrictions or partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to our existing product;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

If any of these events were to occur, our business could be harmed.

If we modify our FDA-cleared device, we may need to seek and obtain new clearances, which, if not granted, would prevent us from selling our modified product or require us to redesign our product.

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 premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing product in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. We have made modifications to our device in the past and may

make additional modifications in the future that we believe do not or will not require additional clearances 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 device, which could harm our operating results and require us to redesign our product.

If we or our repair subcontractor fail to comply with the FDA s Quality System Regulation, our business would suffer.

We and our repair subcontractor are 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 product. The FDA enforces the QSR through periodic unannounced inspections. We have been, and anticipate in the future to be, subject to such inspections. Our failure, or the failure of our repair subcontractor, to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our product, civil or criminal penalties or other sanctions, which would cause our sales and business to suffer.

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

Sales of our ThermaCool system outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. 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 primarily rely upon third-party distributors to obtain most regulatory clearances and approvals required in other countries, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications, which could increase the difficulty of attracting and retaining qualified distributors. If our distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if they 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. To support the registration of products outside the United States, we must comply with and be registered to the ISO 13485: 2003 Quality System Standard. Failure to adequately maintain our ISO 13485: 2003 registration may adversely impact or prevent the registration of our products in some foreign countries.

Risks Related to Our Capital Requirements and Finances

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to maintain disclosure controls and procedures and adequate internal control over financial reporting. Under such requirements, we much furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. The effectiveness of our controls and procedures may in the future be affected by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we are unable to assert that our internal control over financial reporting is effective in any future period, or if our auditors are unable to express an opinion on the effectiveness of our internal controls, or conclude that our internal controls are ineffective, or if we fail to maintain adequate and effective internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

Risks Related to Our Common Stock

If our public guidance or our future operating performance does not meet investor expectations, our stock price could decline.

We provide guidance to the investing community regarding our anticipated future operating performance. In the past we have updated guidance because our actual results were different than originally anticipated. Our business typically has a short sales cycle, so that we do not have

significant backlog of orders at the start of a quarter, and our ability to sell our ThermaCool system successfully is subject to many uncertainties, as discussed. In light of these factors, it is difficult for us to estimate with accuracy our future results. Our expectations regarding these results will be subject to numerous risks and uncertainties that could make actual results differ materially from those anticipated. If our actual results do not meet our public guidance or our guidance or actual results do not meet the expectations of third-party financial analysts, our stock price could decline significantly.

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We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- volume and timing of sales of our ThermaCool system;
- the introduction of new products or product enhancements by us or our competitors;
- disputes or other developments with respect to our intellectual property rights or the intellectual property rights of others;
- our ability to develop, obtain regulatory clearance or approval for and market new and enhanced products on a timely basis;
- hiring or departure of executive officers or key employees;
- product liability claims or other litigation;
- quarterly variations in our or our competitors results of operations;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- developments in our industry;
- media exposure of our ThermaCool system or products of our competitors;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other factors may make the price of our stock volatile and subject to unexpected fluctuation.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, for example, liquidation of shares held by our principal shareholders, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could decline. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control more than 40% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to significantly influence the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

Our 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

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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 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.

We have a large number of authorized but unissued shares of stock, which could negatively impact you if you purchase our common stock.

Our certificate of incorporation provides for 100,000,000 shares of authorized common stock, of which 76.2 million shares will be available for future issuance, and 10,000,000 shares of preferred stock, all of which will be available for future issuance. The issuance of additional shares of common stock may have a dilutive effect on earnings per share and relative voting power. We could use the shares of common stock that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

Our board of directors will be authorized, without further stockholder approval, to issue up to 10,000,000 shares of preferred stock with such rights, preferences and privileges as our board may determine. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights and liquidation rights that may be greater than the rights of our common stock. As a result, the rights of holders of our common stock will be subject to, and could be adversely affected by, the rights of holders of any preferred stock that may be issued in the future.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a return on investment will only occur if our stock price appreciates.

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

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.3	2006 Equity Incentive Plan, as amended by the Board of Directors on April 18, 2008.
31.1	Certification of Chief Executive Officer under Securities Exchange Act Rule 13a-14(a).
31.2	Certification of Chief Financial Officer under Securities Exchange Act Rule 13a-14(a).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S. C. 1350 and Securities Exchange Act Rule 13a-14(b).

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 12, 2008

/s/ Stephen J. Fanning
Stephen J. Fanning
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2008

/s/ John F. Glenn
John F. Glenn
Chief Financial Officer
(Principal Financial and Accounting Officer)

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