

THERMAGE INC  
Form 10-Q  
May 15, 2007  
Table of Contents

---

**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, 2007

**.. 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  
(State or other jurisdiction of  
incorporation or organization)

68-0373593  
(I.R.S. Employer  
Identification No.)

25881 Industrial Boulevard, Hayward, California 94545

(Address of principal executive offices) (Zip Code)

(510) 782-2286

Edgar Filing: THERMAGE INC - Form 10-Q

(Registrant's telephone number, including area code)

---

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

Indicate by check mark whether the registrant is a Large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated Filer  Accelerated filer  Non-accelerated filer

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

As of April 30, 2007, 23,027,556 shares of the registrant's common stock were outstanding.

---

**Table of Contents**

**THERMAGE, INC.**

**INDEX**

	<b>Page</b>
<b>PART I</b>	
<b><u>FINANCIAL INFORMATION</u></b>	
<b>ITEM 1. <u>CONDENSED FINANCIAL STATEMENTS (unaudited)</u></b>	3
<u>Condensed Balance Sheets as of March 31, 2007 and December 31, 2006</u>	3
<u>Condensed Statements of Operations for the three months ended March 31, 2007 and March 31, 2006</u>	4
<u>Condensed Statements of Cash Flows for the three months ended March 31, 2007 and March 31, 2006</u>	5
<u>Notes to Condensed Financial Statements</u>	6
<b>ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	10
<b>ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	15
<b>ITEM 4. <u>CONTROLS AND PROCEDURES</u></b>	15
<b>PART II</b>	
<b><u>OTHER INFORMATION</u></b>	
<b>ITEM 1. <u>LEGAL PROCEEDINGS</u></b>	15
<b>ITEM 1A. <u>RISK FACTORS</u></b>	16
<b>ITEM 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	28
<b>ITEM 3. <u>DEFAULTS UPON SENIOR SECURITIES</u></b>	28
<b>ITEM 4. <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></b>	29
<b>ITEM 5. <u>OTHER INFORMATION</u></b>	29
<b>ITEM 6. <u>EXHIBITS</u></b>	29
<b><u>SIGNATURES</u></b>	30

**Table of Contents****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,	December 31,
	2007	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 43,508	\$ 45,915
Accounts receivable, net	5,289	3,285
Inventories, net	5,581	5,219
Prepaid expenses and other current assets	1,497	1,717
Total current assets	55,875	56,136
Property and equipment, net	3,501	3,638
Other assets	119	101
Total assets	\$ 59,495	\$ 59,875
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Liabilities		
Accounts payable	\$ 1,367	\$ 1,398
Accrued liabilities	5,395	7,372
Current portion of deferred revenue	1,436	1,151
Customer deposits	76	62
Total current liabilities	8,274	9,983
Deferred revenue, net of current portion	739	716
Other liabilities	136	55
Total liabilities	9,149	10,754
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 23,026,723 and 22,906,851 issued and outstanding	23	23
Additional paid-in capital	94,684	93,418
Deferred stock-based compensation	(6)	(6)
Notes receivable from stockholders	(125)	(125)
Accumulated deficit	(44,230)	(44,189)
Total stockholders' equity	50,346	49,121

Edgar Filing: THERMAGE INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 59,495	\$ 59,875
--	-----------	-----------

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

**Table of Contents****Thermage, Inc.****CONDENSED STATEMENTS OF OPERATIONS***(in thousands of dollars, except share and per share data)***(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Net revenue	\$ 15,155	\$ 12,431
Cost of revenue	4,152	3,778
<b>Gross margin</b>	<b>11,003</b>	<b>8,653</b>
<b>Operating expenses</b>		
Sales and marketing	6,374	5,849
Research and development	2,466	2,377
General and administrative	2,683	2,264
Total operating expenses	11,523	10,490
Loss from operations	(520)	(1,837)
Interest and other income	586	114
Interest and other expense		(1,049)
Income (loss) before income taxes	66	(2,772)
Provision for income taxes	(7)	
Net income (loss)	\$ 59	\$ (2,772)
Net income (loss) allocable to common stockholders	\$ 59	\$ (2,772)
Net income (loss) per share:		
Basic and diluted	\$ 0.00	\$ (0.68)
Weighted average shares outstanding used in calculating net income (loss) per common share:		
Basic	22,978,331	4,058,082
Diluted	24,792,543	4,058,082

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

**Table of Contents****Thermage, Inc.****CONDENSED STATEMENTS OF CASH FLOWS***(in thousands of dollars)***(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows used in operating activities</b>		
Net income (loss)	\$ 59	\$ (2,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	402	506
Interest receivable on stockholder notes		(4)
Amortization of warrants on notes payable		28
Changes in preferred stock warrant liability		847
Stock-based compensation	1,261	1,228
Allowance for doubtful accounts	(24)	
Reserve for excess and obsolete inventory	(9)	27
Change in assets and liabilities		
Accounts receivable	(1,980)	(597)
Inventories	(653)	121
Prepaid expenses and other current assets	220	149
Other non-current assets	(18)	
Accounts payable	(31)	(564)
Accrued and other liabilities	(1,613)	(182)
Deferred revenue	308	(43)
Customer deposits	14	(24)
Deferred rent	(19)	(13)
<b>Net cash used in operating activities</b>	<b>(2,083)</b>	<b>(1,293)</b>
<b>Cash flows used in investing activities</b>		
Acquisition of property and equipment	(9)	(146)
Change in restricted cash		107
<b>Net cash used in investing activities</b>	<b>(9)</b>	<b>(39)</b>
<b>Cash flows from financing activities</b>		
Repayments on equipment leases		(2)
Proceeds from exercise of stock options	94	186
Payments of capitalized IPO related costs	(409)	
<b>Net cash provided by (used in) financing activities</b>	<b>(315)</b>	<b>184</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(2,407)</b>	<b>(1,148)</b>
Cash and cash equivalents at beginning of period	45,915	10,121
<b>Cash and cash equivalents at end of period</b>	<b>\$ 43,508</b>	<b>\$ 8,973</b>

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





---

**Table of Contents**

**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 4, 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 results for the three months ended March 31, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 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, 2006 included in the Company's Annual Report 10-K, as amended to date.

***Adoption of FIN 48***

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured, and de-recognized in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim-period guidance, among other provisions. At the adoption date of January 1, 2007, the Company had approximately \$800 of unrecognized tax benefit, of which \$100 would have affected the Company's effective tax rate if recognized. Accordingly, the Company recognized a liability for income taxes associated with uncertain tax positions of \$100, with a corresponding charge to beginning balance of accumulated deficit as of January 1, 2007. Additionally, the company decreased deferred tax asset and its associated valuation allowance by \$700. In accordance with FIN 48, the Company will recognize interests and penalties, when they occur, related to unrecognized tax benefits as a component of income taxes. Interest and penalties are immaterial at the date of adoption. The Company does not anticipate a significant change to the total amount of unrecognized tax benefits within the next twelve months.

The Company is subject to taxation in the U.S. and in various states. Generally, with a few exceptions, the tax years 2003 to 2006 remain open to examination by the major taxing jurisdictions to which the Company is subject. The Company is currently under examination with the State of California for the years 2003 and 2004. The final outcome of the examination is not yet known; however, management does not anticipate any adjustments which would result in material changes to the Company's results of operations, financial condition or liquidity.

**Table of Contents****Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the Company's Annual Report on 10-K filed on March 30, 2007 as amended to date, and have not changed since December 31, 2007, with the exception of adoption of FIN 48.

**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.

The following table summarizes net revenue by product:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
RF generators	\$ 3,892	\$ 3,259
ThermaTips and other consumables	10,840	8,821
<b>Net revenue from products</b>	<b>14,732</b>	<b>12,080</b>
Services and other	423	351
<b>Total net revenue</b>	<b>\$ 15,155</b>	<b>\$ 12,431</b>

The following table summarizes net revenue by geographic region:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
United States	\$ 7,633	\$ 6,528
Asia Pacific	3,228	3,164
Europe/Middle East	2,655	1,653
Rest of the world	1,639	1,086
<b>Total net revenue</b>	<b>\$ 15,155</b>	<b>\$ 12,431</b>

**NOTE 2 NET EARNINGS (LOSS) PER SHARE**

Basic net earnings (loss) per share attributed to common shares is computed by dividing the net earnings (loss) attributable to common shares 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 earnings (loss) per share attributed to common shares is computed by dividing the net earnings (loss) attributable to common shares 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 and upon conversion of preferred stock and incremental shares of common stock issuable under employee stock purchase plans and restricted stock units.

**Table of Contents**

	Three Months Ended	
	2007	March 31, 2006
<b>Historical net income (loss) per share:</b>		
Numerator		
Net income (loss)	\$ 59	\$ (2,772)
Net income (loss) allocable to preferred stockholders		
Net income (loss) allocable to common stockholders	\$ 59	\$ (2,772)
Denominator		
Weighted-average common shares outstanding	22,983,956	4,107,770
Less: weighted-average unvested common shares subject to repurchase	(5,625)	(49,688)
Denominator for basic net income (loss) per share	22,978,331	4,058,082
Dilutive potential common shares used in computing diluted net income per share	1,814,212	
Denominator for diluted net income (loss) per share	24,792,543	4,058,082
Basic net income (loss) per share	\$ 0.00	\$ (0.68)
Diluted net income (loss) per share	\$ 0.00	\$ (0.68)

The following outstanding options, common stock subject to repurchase, convertible preferred stock and convertible preferred stock warrants were excluded from the computation of diluted net loss per common share for the periods presented because including them would have had an antidilutive effect:

	Three Months Ended	
	2007	March 31, 2006
Options to purchase common stock		3,149,782
Common stock subject to repurchase		41,250
Convertible preferred stock		12,042,274
Convertible preferred stock warrants		628,718
Restricted stock units	46,128	

**NOTE 3 RECENT ACCOUNTING PRONOUNCEMENTS**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This statement clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. 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 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 chose, 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 will be applied prospectively. The Company is currently evaluating the impact of adopting SFAS No. 159 on its financial statements.

**Table of Contents****NOTE 4 BALANCE SHEET DETAIL***Inventories, Net*

Inventories, net consist of the following:

	March 31,	December 31,
	2007	2006
Raw materials	\$ 2,176	\$ 2,134
Work-in-process	1,221	710
Finished goods	2,184	2,375
	\$ 5,581	\$ 5,219

*Accrued Liabilities*

Accrued liabilities consist of the following:

	March 31,	December 31,
	2007	2006
Marketing expenses	\$ 198	\$ 226
Travel and entertainment	188	191
Warranty	438	329
Sales and use tax	238	171
Payroll and related expenses	2,823	3,947
Professional fees	297	269
Fixed assets	262	283
IPO expenses		409
Accrued claims	406	477
Accrued inventory purchases	176	294
Other	369	776
	\$ 5,395	\$ 7,372

**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,	March 31,
	2007	2006
Balance at beginning of period	\$ 329	\$ 296
Accruals for warranties issued during the period	153	68
	29	

Edgar Filing: THERMAGE INC - Form 10-Q

Accruals related to pre-existing warranties (including changes in estimates)		
Settlements made during the period	(73)	(57)
Balance at end of period	\$ 438	\$ 307

**Table of Contents*****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:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>March 31,</b>
	<b>2007</b>	<b>2006</b>
Balance at beginning of period	\$ 1,646	\$ 1,442
Payments received	319	310
Revenue recognized	(278)	(230)
Balance at end of period	\$ 1,687	\$ 1,522

The Company incurred costs of \$126 and \$160 under extended warranty contracts during the three month periods ended March 31, 2007 and 2006, 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 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.

In accordance with its certificate of incorporation, bylaws and individual indemnification agreements, the Company has indemnification obligations to its officers and directors 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 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 was allocated to cost of revenue, sales and marketing, research and development and general and administrative expense as follows:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>March 31,</b>
	<b>2007</b>	<b>2006</b>
Cost of revenue	\$ 99	\$ 32
Sales and marketing	482	509

## Edgar Filing: THERMAGE INC - Form 10-Q

Research and development	312	151
General and administrative	368	536
Total stock-based compensation expense	\$ 1,261	\$ 1,228

### NOTE 8 SUBSEQUENT EVENTS

On April 26, 2007, Alma Lasers, Ltd. and Alma Lasers, Inc. (together 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.

### 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*

**Table of Contents**

*increase as a percentage of revenue versus generator sales, while generator sales increase in absolute terms; increase in ThermaTip revenue as a result of greater demand; number of systems expected to be placed worldwide; sales organization growth; growth in international sales and expansion into new international markets; and our belief that our cash and cash equivalents 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 through the third quarter of 2002, we were principally engaged in development and regulatory clearance activities. We received FDA clearance to market our ThermaCool system for treatment of periorbital wrinkles and rhytids in the fourth quarter of 2002 and for the treatment of facial wrinkles and rhytids in June 2004. 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. 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 and cooling module with a reusable handpiece, a variety of consumable, single-use ThermaTips that attach to the handpiece, and several other consumable accessories. Since 2002, we have developed several 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. Our customers primarily consist of dermatologists and plastic surgeons. As of March 31, 2007, we had an installed base of over 2,100 ThermaCool RF generators and had sold over 375,000 ThermaTips.

**Significant Business Trends**

We commercially launched our ThermaCool system in the fourth quarter of 2002. From that time until the end of 2003, demand for our product increased as a result of rapid uptake by early adopters. During 2004, we slightly increased the average selling price of our RF generator and significantly increased the average selling price of our ThermaTips. In addition, we began implementation of a new procedure algorithm and focused our sales force on the time-consuming and difficult process of re-training and certifying our customers on the revised algorithm to the detriment of system sales. These factors contributed to a trend of declining unit sales beginning in the second half of 2004. During the years ended December 31, 2005 and 2006, we responded to the declining sales trends by implementing several changes, including lowering ThermaTip prices, providing a wider array of ThermaTip product options, including introduction of a larger treatment tip that reduced procedure time, and reorganizing our sales and marketing organization. Beginning with the last quarter of 2005, we experienced a reversal in the negative unit sales trends that were experienced in the previous twelve months. This improved performance and market penetration continued through the first three months of 2007.

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, 2005, 2006 and first three months of 2007 we derived 66%, 73% and 71% respectively, of our revenue from ThermaTip and other consumable sales, and 31%, 24% and 26% respectively, of our revenue from ThermaCool RF generator sales. As the installed base of ThermaCool RF generators has grown, so too have grown the number of physicians performing our Thermage procedure, and, consequently, sales of disposable ThermaTips have increased as a percentage of revenue versus generator sales. We expect this trend to continue, and we expect to derive a greater percentage of our revenue from sales of ThermaTips and other consumables in the future. During the years ended December 31, 2004 and 2005, sales of RF generators declined, not only on a percentage basis, but also on an absolute basis. This reflects our decision to prioritize our limited resources towards servicing existing customers' demands, rather than seeking new customers, because we believe we maximize operating results by emphasizing repeat ThermaTip sales over one time RF generator sales. With growth in our sales organization, we believe that the sale of RF generators will grow in absolute terms, but continue to decline as a percentage of revenue. 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 clinician comfort compared to our prior generator. Customer demand for the product was higher than expected, which resulted in an increase in systems sales as a percentage of total sales. We will continue to service our prior generation generator. During 2007, we expect to sell over 400 ThermaCool NXT systems to new customers worldwide. The balance of our revenue is derived from product service and shipping. Variations in unit sales of ThermaTips and our ThermaCool RF generator may significantly impact revenue in a given quarter.



**Table of Contents**

We market the ThermaCool system, including our single-use ThermaTips, in the United States to physicians through a direct sales force and internationally through a network of 32 distributors in 79 countries. In the year ended December 31, 2005, 2006 and first quarter of 2007, we derived 56%, 52% and 50%, respectively, of our revenue from sales of our products and services within the United States. For the year ended December 31, 2005, 2006 and first three months of 2007, we derived 44%, 48% and 50%, respectively, of our revenue from sales of our products and services outside the United States. 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. The percentages of our revenue by region are presented in the below table:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
United States	50%	53%
Asia Pacific	21%	25%
Europe/Middle East	18%	13%
Rest of the world	11%	9%
<b>Total net revenue</b>	<b>100%</b>	<b>100%</b>

We expect our operating expenses to increase in the future as a result of increased sales and marketing activity to promote revenue growth and geographic expansion, continued research and development of new products and technologies, and increased general and administrative expenses to support our overall anticipated growth and public company 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 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. We have in the past noticed brief increases both in demand for our products and in demand for our Thermage procedure, as well as in traffic to our website, following positive national media coverage, such as when Thermage was featured on *Oprah* in 2003 and on subsequent rebroadcasts. However, we believe that, conversely, negative media exposure has adversely impacted potential sales. 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.

**Results of Operations*****Three Months Ended March 31, 2007 and March 31, 2006***

**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 \$2.8 million, or 22%, from \$12.4 million to \$15.2 million for the three months ended March 31, 2007, as compared to the same period in 2006. Sales of ThermaTips and other consumables increased \$2.0 million, or 23%, from \$8.8 million to \$10.8 million for the three months ended March 31, 2007. Sales of ThermaCool RF generator increased \$0.6 million, or 20%, from \$3.3 million to \$3.9 million for the three months ended March 31, 2007. International sales to distributors accounted for 50% of revenue for the three months ended March 31, 2007, as compared to 47% in the same period in 2006. The increase in revenue was driven by increased demand of our ThermaTip and other consumables, which represented 71% of our first quarter 2007 revenue, continued expansion into new international markets, and higher than expected demand for the new ThermaCool NXT generator launch during the first three months of 2007. During the first

## Edgar Filing: THERMAGE INC - Form 10-Q

quarter of 2007, we sold 103 new systems with customers and our installed base grew from 2,104 at December 31, 2006 to 2,147 units at March 31, 2007.

**Table of Contents**

*Cost of Revenue.* Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. Cost of revenue increased \$0.4 million, or 10%, from \$3.8 million to \$4.2 million for the three months ended March 31, 2006 and 2007, respectively. Gross margin was 73% and 70% of revenue for the three months ended March 31, 2007 and 2006, respectively. Improvements in gross margins in the three months ended March 31, 2007 were primarily due to mix towards the higher margin ThermoTips products, increased average selling price of ThermoTips and continued improvement in costs of systems.

*Sales and Marketing.* Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops and trade shows, marketing, customer service and business development. Sales and marketing expenses increased \$0.5 million, or 9%, from \$5.9 million to \$6.4 million for the three months ended March 31, 2006 and 2007, respectively. The increase in the three months ended March 31, 2007 was primarily attributable to an increase of \$0.2 million in discretionary marketing expenses in support of the launch of the new ThermoCool NXT product, as well as additional personnel and related travel and entertainment 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 remained fairly constant in the three months ended March 31, 2006 and 2007 at \$2.5 million. Higher stock-based compensation costs and discretionary research and development costs including outside services in the three months ended March 31, 2007 compared to a year ago period was partially offset by lower clinical study costs in 2007.

*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 \$0.4 million, or 19%, from \$2.3 million to \$2.7 million for the three months ended March 31, 2006 and 2007, respectively. The increase in the three months ended March 31, 2007 was primarily attributable to higher professional fees and insurance in connection with being a public company, which was partially offset by \$0.2 million lower stock-based compensation charges.

*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 increased \$0.5 million from \$0.1 million to \$0.6 million in the three months ended March 31, 2006 and 2007, due to higher average cash balances resulting from the proceeds of our initial public offering,

*Interest and Other Expense.* Interest and other expense of \$1.0 million for the three months ended March 31, 2006 consists primarily of \$0.8 million of expense related to changes in the fair value of our convertible preferred stock warrants under FSP 150-5 and \$0.2 million of interest expenses on our GE Capital borrowing. Subsequent to our initial public offering, we repaid the GE Capital borrowing. The majority of the convertible preferred stock warrants were exercised upon our initial public offering, with an additional preferred stock warrants for 27,778 shares of preferred stock converted into warrants for common stock. As a result, we incurred no interest expense nor charges related to change in the fair value of our convertible preferred stock warrants during the three months ended March 31, 2007.

**Stock-Based Compensation**

For the three months March 31, 2007 and 2006, employee and non-employee stock-based compensation expense has been allocated as follows:

	Three Months Ended	
	March 31,	
	2007	2006
Cost of revenue	\$ 99	\$ 32
Sales and marketing	482	509
Research and development	312	151
General and administrative	368	536
<b>Total stock-based compensation expense</b>	<b>\$ 1,261</b>	<b>\$ 1,228</b>

We recorded employee stock-based compensation expense of \$1.2 million and \$1.2 million in the three months ended March 31, 2007 and 2006, respectively. As of March 31, 2007, the total compensation cost related to stock-based awards granted or modified under SFAS 123R to employees and directors but not yet recognized was approximately \$8.3 million, net of estimated forfeitures. We will amortize this cost on a straight-line basis over a weighted average period of approximately 3.1 years.

## Edgar Filing: THERMAGE INC - Form 10-Q

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line basis. The options generally vest ratably over four years. The values attributable to these options are amortized over the service period and

**Table of Contents**

the unvested portion of these options are remeasured as the services are provided and the options are earned. The stock-based compensation expense will fluctuate as the deemed fair value of the common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of \$65,000 and \$46,000 for the three months ended March 31, 2007 and 2006, respectively.

**Liquidity and Capital Resources**

We have not achieved sustained profitability since the introduction of our ThermaCool system in 2002. Prior to our initial public offering in November 2006, we have funded our operations principally from the issuance of our preferred stock that resulted in aggregate net proceeds of \$45.2 million. In addition, in 2005, we obtained a working capital line with GE Capital on which we drew \$2.5 million in November 2005, bearing interest at the rate of 10.2% per annum, and \$2.5 million in December 2005, bearing interest at the rate of 10.6% per annum. On November 9, 2006, we completed an initial public offering of 6,000,000 shares of our common stock at \$7.00 per share. Additionally, on December 4, 2006, the underwriters partially exercised their over-allotment option and purchased 150,000 shares at \$7.00 per share. We raised approximately \$38.3 million, net of underwriting discounts, commissions and other offering costs. Upon the closing of the offering, all of our outstanding shares of preferred stock converted on a one-to-one basis into 12,406,134 shares of common stock. Upon the completion of our initial public offering, we repaid the outstanding balance and interest on the working capital line.

On March 31, 2007, we had working capital of \$47.6 million, which consists primarily of \$43.5 million in cash and cash equivalents.

*Net Cash Used in Operating Activities.* Net cash used in operating activities was \$2.1 million and \$1.2 million for the three months ended March 31, 2007 and 2006, respectively. During 2007, net cash used by operating activities primarily resulted from an increase in accounts receivables of \$2.0 million, an increase in inventories of \$0.7 million and a decrease in accrued liabilities of \$1.6 million, offset by non-cash amortization of stock-based compensation of \$1.3 million, increase in deferred revenue of \$0.3 million, and non-cash depreciation and amortization of \$0.4 million. The increase in accounts receivable was the result of increased revenues. The decrease in accrued liabilities was primarily from payment of annual bonuses. During 2006, net cash used by operating activities primarily resulted from the \$2.8 million operating loss, an increase in accounts receivable of \$0.6 million, and a decrease in accounts payable of \$0.6 million, partially offset by non-cash amortization of stock-based compensation of \$1.2 million, changes in preferred stock warrant liability of \$0.8 million and non-cash depreciation and amortization of \$0.5 million.

*Net Cash Used in Investing Activities.* Net cash used in investing activities was \$9,000 and \$39,000 for the three months ended March 31, 2007 and 2006, respectively. Investing activities were primarily related to acquisition of property and equipment in both periods.

*Net Cash Provided by Financing Activities.* Net cash used in financing activities was \$321,000 in the three months ended March 31, 2007. During 2007, cash was used for payment of capitalized IPO costs of \$409,000, partially offset by proceeds from exercise of stock options. Net cash provided by financing activities was \$184,000 in the three months ended March 31, 2006. During 2006, cash was primarily provided from proceeds of 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. If existing cash and cash generated from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research and development and selling and marketing efforts.

**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.

---

## **Table of Contents**

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This statement clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. We have not determined the effect, if any, the adoption of this statement will have on our results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS 115* ( SFAS No. 159 ). SFAS No. 159 allows companies to chose, 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 will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on our financial statements.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We invest our excess cash primarily in U.S. government securities and investment-grade marketable debt securities of financial institutions and corporations. These instruments have maturities of three months or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

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 4. 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.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

On April 26, 2007, Alma Lasers, Ltd. and Alma Lasers, Inc. (together, 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 intend to defend the action vigorously. We believe that we have meritorious defenses in this action. However, litigation is unpredictable and we may not prevail in successfully defending or asserting our position. If we do not prevail, we may lose certain patent protection, exposing us to increased direct competition.



## **Table of Contents**

### **ITEM 1A. RISK FACTORS**

**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;

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.

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

We incurred a loss of \$3.9 million in 2006 and a profit of \$0.1 million for the three months ended March 31, 2007. In the past, with increasing revenue, we have expanded our business and increased our expenses to meet anticipated increased demand for our ThermaCool system. We expect this trend to continue for the foreseeable future. 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 and require us to seek additional financing for our business.

**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 expand our line of ThermaTips in the near future 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.

**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 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 seeking a declaratory judgment of non-infringement, and also seeking a judgment that our patents are invalid. We currently intend to file a patent infringement lawsuit against Alma. 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.

---

## **Table of Contents**

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, 2007, we had 29 issued U.S. patents and 17 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.

### **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 U.S. Food and Drug Administration, or FDA, clearance in the United States to market our ThermaCool system for the non-invasive treatment of wrinkles and rhytids, and for the temporary improvement in the appearance of cellulite and for therapeutic massage. 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.

### **We may not be successful in, or may be delayed in, commercializing a product for cellulite.**

We recently received FDA clearance to market the TherMassager, an accessory to our ThermaCool system, for the temporary improvement in the appearance of cellulite and for therapeutic massage, which we currently intend to commercially launch in the second half of 2007. The timing and success of our launch depends on our current effort at demonstrating compelling evidence of meaningful clinical effect. We have not previously marketed our ThermaCool 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. In addition, integrating a new accessory into our existing ThermaCool system will require additional physician training as well as manufacturing and technical support. As a result of these factors, we may incur significant clinical, marketing and development expenses relating to this new product opportunity without achieving commercial success, which could harm our business and our competitive position.

---

## **Table of Contents**

**Performing clinical studies on, and collecting data from, the Thermage procedure is inherently subjective, and we have limited data regarding the efficacy of our ThermoCool 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 ThermoCool 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 ThermoCool 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<sup>2</sup> ThermoTip 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 ThermoCool 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 ThermoCool 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 ThermoCool system may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

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

Most procedures performed using our ThermoCool 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, which 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;

general consumer sentiment about the benefits and risks of aesthetic procedures; and

consumer confidence, which may be impacted by economic and political conditions.

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

**Negative publicity 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

## Edgar Filing: THERMAGE INC - Form 10-Q

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. There are under 200 such medical device reports, excluding duplicate reports, on the FDA's website related to the Thermage procedure. Based upon an estimated 375,000 Thermage procedures performed to date, the rate of such reports is under 0.1%, with over

---

## **Table of Contents**

99.9% of procedures performed without an adverse event reported. Despite this safety record, 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.

### **The failure of our ThermoCool 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 ThermoCool system and continued use of our ThermoTips.**

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 ThermoCool system depends on the success of our clinical and sales and marketing efforts. Our business model involves both a capital equipment purchase of our ThermoCool RF generator and continued purchases by our customers of single-use ThermoTips. This may be a novel business model for many potential 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 ThermoCool 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 ThermoCool system and use of our ThermoTips, 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 ThermoCool system effectively could have a material adverse effect on our business.**

We rely on a direct sales force to sell our ThermoCool system in the United States. In order to meet our anticipated sales objectives, we expect to grow our domestic sales organization significantly over the next several years. 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 ThermoCool 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 ThermoCool 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 ThermoCool system, causing our revenue to be lower than expected and harming our results of operations.

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

## Edgar Filing: THERMAGE INC - Form 10-Q

International sales accounted for 48% of our revenue for the year ended December 31, 2006, and 50% of our revenue for the quarter ended March 31, 2007. 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;

**Table of Contents**

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.

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

We currently depend exclusively 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;



---

**Table of Contents**

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.

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

We outsource the repair of our first generation RF generator to a single contract manufacturer, Stellartech. If Stellartech's operations are interrupted, we may be limited in our ability to repair equipment at customer sites. 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;

Edgar Filing: THERMAGE INC - Form 10-Q

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;

---

**Table of Contents**

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.

**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.

**If the ThermaCool System malfunctions or if we discover a manufacturing defect that could lead to a malfunction, we may have to initiate a product recall, which could adversely impact 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. For example, in December 2002, we initiated our only recall to date following a change we had made in the seal around the edge of the treatment tip. We discovered that the newly-designed seal could fail to hold, resulting in leakage of cryogen and the possibility of skin damage. Burns, including one classified as third degree, were reported in five patients and we filed Medical Device Reports, or MDRs, with the FDA for each of these injuries. The problem was resolved within two weeks and did not have a significant impact on our ability to supply products to our customers or, more generally, on our results of operations. However, 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 more significant recall or significant 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 first generation and ThermaCool NXT RF generators relies upon a hydrofluorocarbon, 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 on the import of R134a, and new products that utilize R134a beginning July 4, 2007. If we are unable to develop an alternative cooling system for our device which is not dependent on R134a

## Edgar Filing: THERMAGE INC - Form 10-Q

in a timely or cost-effective manner, our ThermaCool system may not be in compliance with environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

In addition, the impending restrictions on HFCs may reduce their availability, as suppliers have lower incentive to expand production capacity or maintain existing capacity. This change in supply could expose us to supply shortages or increased prices for R134a, which could impair our ability to support our current or future customers.

---

## **Table of Contents**

**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, but cannot prevent an otherwise qualified physician from contracting with a rental company in violation of their purchase agreement with us. The 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 is working to implement 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,



---

## **Table of Contents**

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. We do not have employment contracts with any of our officers or other key employees. Any of our officers and other key employees may terminate their employment at any time. 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.

### **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 premarketing 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 three to 12 months, but it can last significantly longer. The process of obtaining premarketing 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;

## Edgar Filing: THERMAGE INC - Form 10-Q

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



---

**Table of Contents**

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 third-party manufacturers fail to comply with the FDA's Quality System Regulation, our business would suffer.**

We and our third-party manufacturers 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 third-party manufacturers, 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.

**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 all 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**

**Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price and Nasdaq listing.**

As a public company, we will require greater financial resources than we have had as a private company. We cannot provide you with assurance that our finance department has or will maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors, including:

Edgar Filing: THERMAGE INC - Form 10-Q

faulty human judgment and simple errors, omissions or mistakes;

fraudulent action of an individual or collusion of two or more people;

---

**Table of Contents**

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 fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to Nasdaq delisting, Securities and Exchange Commission investigation and civil or criminal sanctions.

**We must implement additional and expensive procedures and controls in order to grow our business and organization and to satisfy new reporting requirements, which will increase our costs and require additional management resources.**

As a public reporting company, we will be required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including the requirements that we maintain disclosure controls and procedures and adequate internal control over financial reporting. Upon approval for listing as a public company on Nasdaq, we will also be required to comply with marketplace rules and the heightened corporate governance standards of Nasdaq. Compliance with the Sarbanes-Oxley Act and other SEC and Nasdaq requirements will increase our costs and require additional management resources. We recently have begun upgrading our procedures and controls and will need to continue to implement additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act or if we fail to maintain internal control over financial reporting, our ability to produce timely, accurate and reliable periodic financial statements could be impaired. We have previously restated our fiscal 2004 financial statements to reflect an adjustment to the calculation of net income allocable to common stockholders and the calculation of basic and diluted net income per share available to common stockholders as further described in Note 1 to the financial statements included in our Amendment No. 5 to Form S-1 filed on November 9, 2006. If we do not maintain adequate internal control over financial reporting, investors could lose confidence in the accuracy of our periodic reports filed under the Exchange Act. Additionally, our ability to obtain additional financing could be impaired. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert management's time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies or products. If we decide to expand our product offerings beyond radiofrequency technologies, 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.

**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 intend to provide guidance to the investing community regarding our anticipated future operating performance. 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 this prospectus. 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.

**Table of Contents**

**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;

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, upon the expiration of lock-up agreements approximately 180 days following our initial public offering, 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.**

## Edgar Filing: THERMAGE INC - Form 10-Q

Our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control approximately 63% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control 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;

---

**Table of Contents**

a supermajority stockholder vote requirement for amending certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws;

limitations on stockholder actions by written consent; and

the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

These provisions 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 77.0 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 your 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.

We registered for the initial public offering of our common stock, par value \$0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-136501), which was declared effective on November 9, 2006. On November 15, 2006 we completed the initial public offering of our common stock by selling 6.0 million shares at \$7.00 per share. Additionally, on December 4, 2006, the underwriters partially exercised their over-allotment option and purchased 150,000 shares at \$7.00 per share. Gross proceeds from the offering were \$43.0 million. Total expenses from the offering were \$4.7 million, which included underwriting discounts and commissions of \$3.0 million, and \$1.7 million in other offering-related expenses. Net offering proceeds, after deducting total expenses were \$38.3 million.

Of the \$38.3 million in net proceeds, through March 31, 2007, we have spent approximately \$5.0 million for repayment of our working capital line with GE Capital, \$9.0 million for sales and marketing initiatives, \$3.4 million for research and development activities and \$3.6 million for operating and general corporate purposes. In addition, we invested the proceeds from the offering primarily in U.S. government securities and investment-grade marketable debt securities of financial institutions and corporations.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**Table of Contents**

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

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

**Exhibit No. Description**

3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Amended and Restated Bylaws.
4.1*	Specimen Common Stock Certificate.
4.2*	Amended and Restated Investor Rights Agreement dated March 12, 2002 by and among Thermage and certain of its stockholders.
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).

---

\* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-136501), which was declared effective on November 9, 2006.



**Table of Contents**

**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 15, 2007

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

Date: May 15, 2007

/s/ Lauren DeBuono  
Lauren DeBuono  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Table of Contents**

**INDEX TO EXHIBITS**

**Exhibit No. Description**

3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Amended and Restated Bylaws.
4.1*	Specimen Common Stock Certificate.
4.2*	Amended and Restated Investor Rights Agreement dated March 12, 2002 by and among Thermage and certain of its stockholders.
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).

---

\* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-136501), which was declared effective on November 9, 2006.