

THERMAGE INC
Form S-1/A
October 20, 2006
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As filed with the Securities and Exchange Commission on October 20, 2006

Registration No. 333-136501

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2

TO

FORM S-1

REGISTRATION STATEMENT

Under

The Securities Act of 1933

THERMAGE, INC.

(Exact name of Registrant as specified in its charter)

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

3845
*(Primary Standard Industrial
Classification Code Number)*
25881 Industrial Boulevard

Hayward, California 94545

(510) 782-2286

68-0373593
*(I.R.S. Employer
Identification Number)*

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(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Stephen J. Fanning

President and Chief Executive Officer

Thermage, Inc.

25881 Industrial Boulevard

Hayward, California 94545

(510) 782-2286

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the

Commission acting pursuant to said Section 8(a) may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell securities, and we are not soliciting offers to buy these securities, in any state where the offer or sale is not permitted.

Subject to Completion

Preliminary Prospectus dated October 20, 2006

PROSPECTUS

Shares

Common Stock

This is our initial public offering. We are selling _____ shares of our common stock.

We expect the initial public offering price to be between \$ _____ and \$ _____ per share of common stock. Currently, no public market exists for our common stock. After pricing of the offering, we expect that our common stock will be quoted on the Nasdaq Global Market under the symbol THRM.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 8 of this prospectus.

	Per Share	Total
Public offering price	\$ _____	\$ _____
Underwriting discount	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

The underwriters may also purchase up to an additional _____ shares of common stock from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallocments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares of common stock will be ready for delivery on or about _____, 2006.

Merrill Lynch & Co.

Thomas Weisel Partners LLC

Wachovia Securities

C. E. Unterberg, Towbin

Maxim Group LLC

The date of this prospectus is _____, 2006.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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PROSPECTUS SUMMARY

*This summary highlights the most important features of this offering and the information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under **Risk Factors** and our financial statements and related notes included in this prospectus.*

Our Company

We design, develop, manufacture and market medical devices for the non-invasive treatment of wrinkles. Our Thermage procedure can be performed on any part of the body where treatment of wrinkles is desired. Our ThermaCool system uses patented monopolar radiofrequency, or RF, energy to heat and shrink collagen and tighten the dermis and subcutaneous tissue while simultaneously cooling and protecting the surface of the skin. The heating and shrinking of the collagen can cause a healing process to begin, which may further tighten the skin and reduce wrinkles over the next two to six months. The Thermage procedure is normally performed in a medical office setting as a single treatment that takes from 20 minutes to two hours, depending on the treatment area. The Thermage procedure provides patients seeking wrinkle reduction a non-invasive alternative to more expensive surgical procedures that can involve weeks of recovery. We offer, and are continuing to develop, a variety of ThermaTips designed to optimize the Thermage procedure for new conditions and different parts of the body.

In 2002, we received U.S. Food and Drug Administration, or FDA, clearance for the treatment of wrinkles around the eyes, or periorbital wrinkles and rhytids, and commercially launched our ThermaCool system. We market the ThermaCool system, including our single-use ThermaTips, in the United States to physicians through a direct sales force and internationally in 70 countries through a network of distributors. Our sales force trains physicians on the proper use of the ThermaCool system and maintains frequent interaction with these customers to promote repeat sales of our ThermaTips. As of June 30, 2006, we had an installed base of over 1,800 ThermaCool RF generators and had sold over 275,000 ThermaTips, which we estimate represent an approximately equal number of Thermage procedures performed.

The Market for Aesthetic Procedures to Treat the Skin

The American Society for Aesthetic Plastic Surgery reports that in 2005, total expenditures for aesthetic procedures were approximately \$12.4 billion. From 2000 to 2005, the total number of aesthetic procedures increased from approximately 5.7 million to over 11.4 million procedures, representing a 15% compounded annual growth rate. Non-invasive aesthetic procedures were primarily responsible for the overall increase, rising from approximately 4.3 million to approximately 9.3 million procedures over the same period, representing a 17% compounded annual growth rate. Furthermore, patients are seeking treatment for wrinkles in larger numbers. For example, skin tightening, which represents the fastest growing segment of the aesthetic laser market, is projected to grow at a 31% compounded annual growth rate over the next five years, according to the Millennium Research Group. We believe there are several factors contributing to the rapid growth of non-invasive aesthetic and skin tightening procedures, including:

aging of the U.S. population;

emergence of non-traditional practitioners;

broader range of and accessibility to safe and effective treatments;

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market shift towards less-invasive procedures;

changing practitioner economics; and

increasing acceptance of aesthetic procedures.

Similar market trends also exist outside the United States, where demand for non-invasive aesthetic procedures has also experienced strong growth.

Widely-adopted treatment options for wrinkle reduction fall generally into one of two categories: either a single invasive procedure involving significant recovery time, but with a long-lasting, pronounced effect; or a procedure that is either minimally-invasive or non-invasive involving minimal recovery time, but requiring frequent repeat treatments for a modest effect. We believe that the ideal treatment option falls between these two extremes, providing lasting, noticeable effects from a single procedure that involves little or no downtime.

The Thermage Solution

We believe that our Thermage procedure provides a compelling alternative for the treatment of wrinkles that fills a need not met by currently available surgical procedures and minimally and non-invasive treatments. Our ThermoCool system consists of an RF generator, a cooling module to deliver cryogen to help protect the outer layer of the skin from over-heating and a handpiece that regulates epidermis cooling and monitors treatment data. Our system also includes a variety of single-use ThermoTips that attach to the handpiece and are selected by physicians based on the procedure to be performed and the size of the area to be treated. The Thermage procedure is typically performed in a medical office setting by, or under the supervision of, qualified physicians, including not only plastic surgeons and dermatologists, but also physicians who do not traditionally perform cosmetic surgery, such as general and family practitioners, obstetricians and gynecologists, and general and vascular surgeons.

Our solution provides a number of benefits for physicians and patients:

controlled heating of collagen;

non-invasive, non-ablative alternative to surgery;

single-procedure treatment;

compelling physician economics; and

ease of use.

Our Thermage Procedure

In order to perform our Thermage procedure, the physician chooses a single-use ThermoTip based on the procedure to be performed and the size of the area to be treated. We currently offer four treatment tip sizes with a combination of pulse counts, pulse durations and heating profiles for a variety of uses:

Body-By-Thermage, which involves the use of a larger tip, such as the 3.0 cm² tip, designed for the treatment of large areas;

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Eyes-By-Thermage, which involves the use of a small, 0.25 cm² tip, designed for the treatment of eyelids; and

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Face-By-Thermage, which involves the use of 3.0 cm², 1.5 cm² or 1.0 cm² tip sizes, designed for the treatment of the face and neck.

After choosing the tip and attaching it to the handpiece, the physician places the tip against the patient's skin and depresses the handpiece button. Information from the handpiece is sent to the console in order to control RF delivery. The ThermoTip device transmits RF energy to the skin while serving as a contact membrane for the delivery of cryogen, which cools and helps protect the skin's surface. Thermage procedure times vary with the size of the treatment area; a procedure for a full face typically requires multiple passes and takes approximately 60 minutes.

In our clinical studies of the Thermage procedure, performed primarily on the face, most patients displayed modest wrinkle reduction from a single treatment, over a measurement period of six months. Patients may notice immediate improvement in their appearance and are typically able to resume normal activities directly after having the procedure. Over the subsequent two to six months, patients may experience further tightening of the treated skin as new collagen strands grow.

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. Thermage patients may experience temporary swelling and reddening of the skin and, in rare instances, patients may experience burns, blisters, skin discoloration or skin depressions.

Business Strategy

Our goal is to become a leading provider of non-ablative medical devices to the aesthetics market by:

Driving Increased ThermoTip Usage. We maintain an active, continuous relationship with our customer base to generate and fulfill demand for our single-use ThermoTips. We work collaboratively with our customer base to increase ThermoTip usage by expanding clinical applications and augmenting and facilitating the marketing efforts of our physician customers.

Developing New Applications and ThermoTips. We intend to expand our line of ThermoTips for additional applications and conditions. We recently received FDA clearance to market the TherMassager, an accessory to our ThermoCool system, for the temporary improvement in the appearance of cellulite and for therapeutic massage, which we currently intend to commercially launch in 2007. We are in the process of seeking, and intend to continue to seek, clearances from the FDA to strengthen our marketing efforts with regard to specific areas of the body, such as arms, the abdomen, hands and other locations on the body where wrinkle reduction is desired.

Investing in Intellectual Property and Patent Protection. We will continue to invest in expanding our intellectual property portfolio in the aesthetics market, and we intend to file for additional patents to strengthen our intellectual property rights. When necessary, we will pursue companies that we believe infringe our patents.

Broadening our Physician Customer Base. We intend to continue to penetrate the traditional aesthetic practitioner specialties, which include dermatologists and plastic surgeons. We are also seeking to selectively expand our direct sales efforts in non-core physician specialties and physician-directed medi-spas with track records of safe and successful aesthetic treatments.

Expanding our International Presence. We are focused on increasing our market penetration overseas and building global brand-recognition. We intend to add distributors to increase sales and strengthen our relationships with physicians in international markets.

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Seeking Growth Opportunities via Complementary Products, Technologies or Businesses. We intend to pursue opportunities to expand our core business by identifying opportunities to offer complementary proprietary products for the aesthetics market.

Risks Associated with Our Business

Our business is subject to numerous risks, as discussed more fully in the section entitled *Risk Factors* immediately following this summary. We are wholly dependent upon the success of our ThermaCool system and our ThermaTip product line, have a limited operating history and may be unable to accurately predict our future performance. Our business currently is not profitable, and we may not be able to achieve profitability. We have limited regulatory clearances. To expand our marketing claims in the United States and abroad, we will need to obtain additional regulatory clearances, which may require the support of clinical trials, the success of which we cannot predict. Our growth will depend on both patient demand for our procedures and physician adoption of the ThermaCool system. Our industry is highly competitive, and we compete against many companies that are more established in the market and have greater resources. In order to keep pace with the rapid innovation in our industry, we must continuously develop compelling new products for which we can obtain intellectual property protection.

Company Information

We were incorporated in California in 1996. In September 2001, we reincorporated in Delaware. Our principal executive offices are located at 25881 Industrial Boulevard, Hayward, California 94545. Our telephone number is (510) 782-2286. Our website is located at www.thermage.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Unless the context requires otherwise, the terms *we*, *our*, *us*, *the Company* and *Thermage* in this prospectus refer to Thermage, Inc.

Thermage, ThermaCool and ThermaCool TC are registered trademarks in the United States and several other countries. ThermaTip is an unregistered trademark. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

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THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	We intend to use the net proceeds received by us from this offering for sales and marketing initiatives, research and development, repayment of existing debt and general corporate purposes. See Use of Proceeds.
Proposed Nasdaq Global Market symbol	THRM
The number of shares of common stock that will be outstanding after this offering is based on 16,370,450 shares outstanding as of June 30, 2006, and excludes:	

617,607 shares of common stock issuable upon the exercise of outstanding warrants at an exercise price of \$4.50 per share;

3,145,579 shares of common stock issuable upon the exercise of outstanding options under our 1997 Stock Option Plan at a weighted-average exercise price of \$1.70 per share;

234,756 shares of common stock reserved for issuance as of June 30, 2006 under our 1997 Stock Option Plan;

2,750,000 shares of common stock to be reserved for issuance under our 2006 Equity Incentive Plan; and

250,000 shares of common stock to be reserved for future issuance under our 2006 Employee Stock Purchase Plan.
Unless otherwise indicated, all information in this prospectus assumes:

the conversion of all outstanding shares of our preferred stock into shares of our common stock;

the filing of our amended and restated certificate of incorporation prior to completion of this offering; and

that the underwriters do not exercise their overallotment option.

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The summary financial data for each of the years ended December 31, 2003, 2004 and 2005 and the balance sheet data as of December 31, 2004 and 2005 are derived from our audited annual financial statements included elsewhere in this prospectus. The summary balance sheet data as of December 31, 2003 is derived from our audited financial statements not included in this prospectus. The summary financial data as of June 30, 2006 and for the six months ended June 30, 2005 and 2006 are derived from our unaudited interim financial statements included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as our audited annual financial statements and, in our opinion, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the results of operations for the six months ended June 30, 2005 and 2006. The historical results are not necessarily indicative of the results to be expected for any future periods and the results for the six months ended June 30, 2006 should not be considered indicative of results expected for the full fiscal year.

You should read the following financial information together with the information under Selected Financial Data, Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

The pro forma per share data give effect to the conversion of all outstanding convertible preferred stock into common stock prior to the closing of this offering and adjustments to eliminate charges associated with our preferred stock warrant liability.

Statements of Operations Data

<i>(in thousands of dollars, except share and per share data)</i>	Years Ended December 31,			Six Months Ended	
	2003	2004	2005	June 30,	
		(restated) ⁽¹⁾		2005	2006
Net revenue	\$ 24,910	\$ 50,384	\$ 40,655	\$ 22,817	\$ 27,062
Cost of revenue	12,566	12,452	12,309	6,286	7,679
Gross margin	12,344	37,932	28,346	16,531	19,383
Operating expenses					
Sales and marketing	8,945	15,596	19,997	10,118	12,150
Research and development	6,569	8,490	8,908	4,287	4,940
General and administrative	3,612	8,873	7,414	3,962	4,657
Litigation settlement gain			(1,646)	(1,646)	
Total operating expenses	19,126	32,959	34,673	16,721	21,747
Income (loss) from operations	(6,782)	4,973	(6,327)	(190)	(2,364)
Interest and other income	205	177	340	143	240
Interest and other expense	(7)	(14)	(1,549)	(13)	(1,628)
Income (loss) before income taxes and cumulative effect of change in accounting principle	(6,584)	5,136	(7,536)	(60)	(3,752)
Provision for income taxes		(103)			
Net income (loss) before cumulative effect of change in accounting principle	(6,584)	5,033	(7,536)	(60)	(3,752)
Cumulative effect of change in accounting principle			(697)		
Net income (loss)	\$ (6,584)	\$ 5,033	\$ (8,233)	\$ (60)	\$ (3,752)
Net income (loss) allocable to common stockholders	\$ (6,584)	\$ 313	\$ (8,233)	\$ (60)	\$ (3,752)
Net income (loss) per share basic and diluted:					
Before cumulative effect of change in accounting principle			\$ (2.06)	\$ (0.02)	
Cumulative effect of change in accounting principle			(0.19)		

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Net income (loss) per share basic	\$	(2.85)	\$	0.10	\$	(2.25)	\$	(0.02)	\$	(0.91)
Net income (loss) per share diluted	\$	(2.85)	\$	0.06	\$	(2.25)	\$	(0.02)	\$	(0.91)
Weighted average shares outstanding used in calculating net income (loss) per common share:										
Basic		2,307,238		3,023,225		3,664,990		3,562,659		4,132,187
Diluted		2,307,238		5,319,754		3,664,990		3,562,659		4,132,187
Pro forma net loss per share basic					\$	(0.39)			\$	(0.16)
Pro forma net loss per share diluted					\$	(0.39)			\$	(0.16)
Pro forma weighted average shares outstanding used in calculating net loss per share:										
Basic						15,707,264				16,174,461
Diluted						15,707,264				16,174,461

(1) See Note 1 to our financial statements regarding a correction of an error relating to the computation of basic and diluted net income per share in 2004.

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The following presents our summary balance sheet data as of June 30, 2006:

on an actual basis;

on a pro forma basis after giving effect to the automatic conversion of all outstanding shares of preferred stock into 12,042,274 shares of common stock and the reclassification of convertible preferred stock warrants from liabilities to stockholders' equity (deficit) upon completion of this offering; and

on a pro forma as adjusted basis to reflect the receipt of the net proceeds from our sale of shares of common stock at the initial public offering price of \$ _____ per share in this offering, the mid-point of the range on the front cover of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2006		
	Actual	Pro Forma (in thousands)	Pro Forma as Adjusted
Balance Sheet Data			
Cash and cash equivalents	\$ 10,175	\$ 10,175	\$
Working capital	11,176	11,176	
Total assets	23,947	23,947	
Borrowings, less current portion	3,814	3,814	
Preferred stock warrant liability	5,177		
Redeemable convertible preferred stock	45,169		
Total stockholders' equity (deficit)	(40,190)	10,156	

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before making an investment decision. If any of the possible events described below actually occurs, our business, results of operations or financial condition would likely suffer. In such an event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations.

Risks Related to 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 gain or loses 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.

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

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

Most published studies of our ThermaCool system have investigated the tissue-tightening effect of our monopolar RF technology in procedures on the face, using a single treatment with our first generation 1.0 cm² ThermaTip and our prior procedure protocol, which involved the use of fewer energy pulses at a higher power than our current procedure protocol. There are no published, peer-reviewed studies regarding the effectiveness of our latest generation 0.25 cm² and 3.0 cm² ThermaTips or our current procedure protocol, which have essentially replaced our first generation tip and procedure protocol, or for procedures on other parts of the body. Additionally, we have not conducted any head-to-head clinical studies that compare our ThermaCool system to other aesthetic devices. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase our ThermaCool system. If we decide to pursue additional studies in the future, they could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians' expectations, our ThermaCool system may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

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

Developing and promoting new applications for our ThermaCool system are elements of our growth strategy. We currently have 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.

Our business is not currently profitable, and we may not be able to achieve profitability even if we are able to generate significant revenue.

We incurred a loss of \$6.6 million in 2003, a profit of \$5.0 million in 2004, a loss of \$8.2 million in 2005 and a loss of \$3.8 million in the six months ended June 30, 2006. 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 profitability. We cannot predict if and when we will achieve profitability. Our failure to achieve and sustain profitability could negatively impact the market price of our common stock and require us to seek additional financing for our business.

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.

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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.

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

Most procedures performed using our ThermaCool system are elective procedures, the cost of which must be borne by the patient, and are not reimbursable through government or private health insurance. The decision to undergo a Thermage procedure is thus driven by consumer demand, 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 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 275,000 Thermage procedures performed to date, the rate of such reports is under 0.1%, with over 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.

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

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

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

Our target physician customers typically already own one or more aesthetic device products. Our ability to grow our business and convince physicians to purchase our ThermaCool system depends on the success of our sales and marketing efforts. Our business model involves both a capital equipment purchase of our ThermaCool RF generator and continued purchases by our customers of single-use ThermaTips. This may be a novel business model for many potential customers who may be used to competing products that are either exclusively capital equipment, such as many laser-based systems, or that are exclusively single-use products, such as Botox or dermal fillers. We must be able to demonstrate that the cost of our ThermaCool system and the revenue that the physician can derive from performing procedures using our product are compelling when compared to the cost and revenue associated with alternative products. When marketing to plastic surgeons, we must also, in some cases, overcome a bias against non-invasive aesthetic procedures. If we are unable to increase physician adoption of our ThermaCool system and use of our ThermaTips, our financial performance will be adversely affected.

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

We rely on a direct sales force to sell our ThermaCool system in the United States. 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 ThermaCool system; and

retain and motivate our sales employees.

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

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

International sales accounted for 44% of our revenue for 2005 and 48% of our revenue for the six months ended June 30, 2006. We believe that a significant portion of our business will continue to come from international sales through increased penetration in countries where we currently sell our ThermaCool system, combined with expansion into new international markets. However, international sales are subject to a number of risks, including:

difficulties in staffing and managing our international operations;

difficulties in penetrating markets in which our competitors' products are more established;

reduced or no protection for intellectual property rights in some countries;

export restrictions, trade regulations and foreign tax laws;

fluctuating foreign currency exchange rates;

foreign certification and regulatory clearance or approval requirements;

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

customs clearance and shipping delays;

political and economic instability; and

preference for locally produced products.

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

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.

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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

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system competes against a variety of offerings in the aesthetics market, including laser and other light-based medical devices, pharmaceutical products such as Botox, filler injections, chemical peels, microdermabrasion, liposuction, cosmetic surgical procedures and less invasive surgical solutions such as implanted sutures. Our closest competitors are makers of laser and other light-based devices, which include public companies such as Candela, Cutera, Cynosure, Lumenis, Palomar Medical Technologies and Syneron Medical, as well as many private companies.

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

safety and effectiveness;

product pricing;

success of our marketing initiatives;

compelling clinical data;

intellectual property protection;

quality of customer support; and

development of successful distribution channels, both domestically and internationally.

Some of our competitors have more established products and customer relationships than we do, which could inhibit our market penetration efforts. For example, we have encountered, and expect to continue to encounter, situations where, due to pre-existing relationships, potential customers decided to purchase additional products from our competitors. Potential customers also may need to recoup the cost of expensive products that they have already purchased from our competitors and thus may decide not to purchase our ThermaCool system, or to delay such purchase. If we are unable to achieve continued market penetration, we will be unable to compete effectively and our business will be harmed.

In addition, some of our current and potential competitors have significantly greater financial, research and development, manufacturing, and sales and marketing resources than we have. Our competitors could utilize their greater financial resources to acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing product line. Given the relatively few competitors currently in the market, any business combination could exacerbate any existing competitive pressures, which could harm our business.

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

While we attempt to protect our ThermaCool system through patents and other intellectual property rights, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with ours. For example, while we believe our monopolar RF technology maintains a strong intellectual property position, there are other companies employing competing technologies which claim to have a similar clinical effect to ours. Additionally, there are others who may market monopolar RF technology for competing purposes in a direct challenge to our intellectual property position. As we continue to create market demand for a non-surgical, non-invasive way to treat wrinkles, competitors will enter the market with

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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 may not be successful 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 2007. 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 marketing and development expenses relating to this new product opportunity without achieving commercial success, which could harm our business and our competitive position.

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

We outsource the manufacture and repair of our RF generator and cooling module to a single contract manufacturer, Stellartech. If Stellartech's operations are interrupted or if Stellartech is unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill new customer orders or to repair equipment at current customer sites. Stellartech has limited manufacturing capacity, is itself dependent upon third-party suppliers and 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 manufacturing and repair operations could be halted. In addition, both the availability of our product to support the fulfillment of new customer orders as well as our ability to repair those products installed at current customer sites 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.

The single source supply of our ThermaCool RF generator and cooling module from Stellartech could not be replaced without significant effort and delay in production. Also, several other 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;

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delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;

a lack of long-term supply arrangements for key components with our suppliers;

inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

difficulty locating and qualifying alternative suppliers for our components in a timely manner;

production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;

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

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

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

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

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

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, including our ThermaCool RF generator and cooling module, to a limited number of third parties. In the future, for financial or operational purposes, we may elect to perform additional component or system manufacturing functions internally. In that event, we would face a number of challenges beyond those that we currently address in our internal assembly, inspection, testing and certification activities. Our limited experience with potentially more complex and 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

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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.

Our cooling module 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 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 HFCs and prohibit the introduction of new products incorporating HFCs beginning in mid 2007. If we are unable to develop an alternative cooling system for our device which is not dependent on HFCs 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 have reduced their current 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 manufacture our ThermaCool system and adversely affect our results of operations.

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

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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, 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.

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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 Our Intellectual Property

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 June 30, 2006, we had 25 issued U.S. patents and eight 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.

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

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,

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import or export our ThermaCool system. We may also initiate litigation against third parties to protect our own intellectual property. For example, in July 2004 we filed a lawsuit in federal court against Syneron, and during the course of the litigation we asserted infringement of six Thermage patents. This lawsuit was expensive and protracted, and was not resolved until a settlement was reached in June 2005. We believe that there are companies that are marketing or may, in the future, market products for competing purposes in a direct challenge to our intellectual property position, and we may be required to initiate litigation in order to stop them. We have notified certain competitors of our belief that they may be infringing or may need a license under one or more of our issued patents. These notices may result in litigation in the future in the United States or abroad. 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.

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our ThermaCool system in one or more countries.

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

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

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the order of, licensed practitioners, as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase and operate our ThermaCool system. However, a state could change its regulations at any time, disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

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

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our product;

operating restrictions or partial suspension or total shutdown of production;

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

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

criminal prosecution.

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

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

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing product in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. We have made modifications to our device in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified device, which could harm our operating results and require us to redesign our product.

If we or our 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.

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

Sales of our ThermaCool system outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We 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.

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:

faulty human judgment and simple errors, omissions or mistakes;

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

inappropriate management override of procedures; and

the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we 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

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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 restated our financial statements included in this prospectus 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 herein. 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 the proceeds from this offering 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 This Offering

There has been no prior public market for our common stock and an active trading market may not develop.

Prior to this offering, there has been no public market for our common stock. An active trading market may not develop following completion of this offering or, if developed, may not be sustained. The lack of an active market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies, products or technologies by using our shares as consideration.

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

We anticipate that as a public company we will 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.

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We expect that the price of our common stock will fluctuate substantially and you may not be able to sell the shares you purchase in this offering at or above the offering price.

The initial public offering price for the shares of our common stock sold in this offering is determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. In addition, 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.

New investors in our common stock will experience immediate and substantial dilution after this offering.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in pro forma net tangible book value. If the holders of outstanding options exercise those options, you will incur further dilution. See Dilution.

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

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If our stockholders sell substantial amounts of our common stock in the public market after this 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. See [Shares Eligible for Future Sale](#).

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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.

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively will control approximately % of our outstanding common stock, without giving effect to the purchase of shares by any such persons in this offering. 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.

We have broad discretion in the use of proceeds of this offering for working capital and general corporate purposes.

The net proceeds of this offering will be allocated to sales and marketing initiatives to support the ongoing commercialization of our ThermaCool system, research and development activities, repayment of our working capital line with GE Capital and general corporate purposes, as well as potential acquisitions of complementary products, technologies or businesses. Our management will have broad discretion over the use and investment of the net proceeds of this offering within those categories, and accordingly investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management's specific intentions. See Use of Proceeds.

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

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

a classified board of directors;

advance notice requirements to stockholders for matters to be brought at stockholder meetings;

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

limitations on stockholder actions by written consent; and

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

These provisions 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. See Description of Capital Stock.

