

THERMAGE INC
Form S-1
August 10, 2006
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As filed with the Securities and Exchange Commission on August 10, 2006

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

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

Hayward, California 94545

(510) 782-2286

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

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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.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1) (2)	Amount of Registration Fee
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Common Stock \$0.001 par value	\$ 86,250,000	\$ 9,229
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- (1) In accordance with Rule 457(o) under the Securities Act, the number of shares being registered and the proposed maximum offering price per share are not included in this table.
- (2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457 under the Securities Act.

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 August 10, 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

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 is not complete and 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 epidermis 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 surgical procedures that cost thousands of dollars and 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.

We received U.S. Food and Drug Administration, or FDA, clearance and commercially launched our ThermaCool system in 2002. 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 through clinically-proven technology;

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 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, such as cellulite. 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**Six Months Ended**

<i>(in thousands of dollars, except share and per share data)</i>	Years Ended December 31,			June 30,	
	2003	2004	2005	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)	\$ 1,233	\$ (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)		
Net income (loss) per share basic	\$ (2.85)	\$ 0.41	\$ (2.25)	\$ (0.02)	\$ (0.91)

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Net income (loss) per share	diluted			\$	(2.85)	\$	0.30	\$	(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		16,549,946		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

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The following presents our summary balance sheet data as of June 30, 2006, on an actual basis and on a pro forma as adjusted basis to give effect to the conversion of all outstanding shares of our preferred stock into shares of common stock, the reclassification of convertible preferred stock warrants from liabilities to stockholders' equity (deficit) and our receipt of net proceeds from our sale of _____ shares of common stock at an assumed initial public offering price of \$ _____ per share, the mid-point of the range on the 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 as Adjusted
	(in thousands)	
Balance Sheet Data		
Cash and cash equivalents	\$ 10,175	\$
Working capital	11,176	
Total assets	23,947	
Borrowings, less current portion	3,814	
Preferred stock warrant liability	5,177	
Redeemable convertible preferred stock	45,169	
Total stockholders' equity (deficit)	(40,190)	

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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 involved 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 to use in the non-invasive treatment of wrinkles and rhytids, and 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. This clearance restricts 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. In the past, we have only sought and obtained FDA clearances for the treatment of wrinkles and rhytids. Future indications, such as cellulite, 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. In addition, we have in the past experienced and expect that in the future we will experience negative media exposure. Media exposure of our ThermaCool system, the Thermage procedure, products of our competitors and our industry in general is often out of our control and could materially impact demand for the Thermage procedure and, consequently, our sales.

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

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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.

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;

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fluctuating foreign currency exchange rates;

foreign certification and regulatory clearance or approval requirements;

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

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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;

quality of customer support; and

development of successful distribution channels, both domestically and internationally.

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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 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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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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 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.

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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.

Properties of the dielectric material in our ThermaTips may cause it to undergo changes during the operation of our device, which may result in damage to the skin. Our research and development staff is working to implement strategies to mitigate the risks associated with dielectric materials. 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 enable 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 such adulterated and counterfeit products reach the market, we would not be able to control their safety profile, quality or clinical efficacy. Accordingly, 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

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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, 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.

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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 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;

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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.

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

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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 expanded disclosures and accelerated reporting requirements and more complex accounting rules. 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 Section 404 of 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 Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our first Annual Report on Form 10-K for which compliance is required, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Securities Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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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.

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;

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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.

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."

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.

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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.

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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects and plans and objectives of management are forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

the implementation of our business model and strategic plans for our business, product and technology;

the scope of protection we are able to establish and maintain for intellectual property rights covering our ThermaCool system and technology;

our ability to operate our business without infringing the intellectual property rights of others;

estimates of our expenses, future revenue, capital requirements and our needs for additional financing;

the timing or likelihood of regulatory filings and approvals;

our use of proceeds from this offering;

our financial performance; and

competitive companies and technologies and our industry.

The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the section entitled Risk Factors, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the _____ shares of our common stock that we are selling in this offering will be approximately \$ _____ million, based on an initial public offering price of \$ _____ per share, 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. If the underwriters overallotment option is exercised in full, we estimate that we will receive net proceeds of approximately \$ _____ million.

Of the net proceeds that we will receive from this offering, we expect to use approximately:

\$ _____ million for sales and marketing initiatives to support the ongoing commercialization of our ThermaCool system;

\$ _____ million for research and development activities, including support of product development, regulatory and clinical study initiatives; and

\$5.0 million for repayment of our working capital line with GE Capital.

We intend to use the remainder of our net proceeds for general corporate purposes. We may use a portion of our net proceeds to acquire complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction and are not involved in negotiations to do so. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, we intend to invest our net proceeds from this offering primarily in investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business. Our board of directors will determine the timing and amount of any such future dividends.

Table of Contents**CAPITALIZATION**

The following table sets forth our capitalization 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.

You should read this table together with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes thereto appearing elsewhere in this prospectus.

	As of June 30, 2006		
	Actual (in thousands, except share and per share data)	Pro Forma	Pro Forma as Adjusted
Borrowings, net of current portion	\$ 3,814	\$ 3,814	\$
Preferred stock warrants liability	5,177		
Redeemable convertible preferred stock, \$0.001 par value; 26,360,000 shares authorized, 12,042,274 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma as adjusted	45,169		
Stockholders' equity:			
Preferred stock \$0.001 par value; no shares authorized actual and 10,000,000 shares authorized pro forma and pro forma as adjusted; and no shares outstanding actual, pro forma or pro forma as adjusted			
Common stock, \$0.001 par value; 29,100,000 shares authorized, 4,328,176 shares issued and outstanding, actual; 16,370,450 shares issued and outstanding, pro forma; _____ shares issued and outstanding, pro forma as adjusted	4	16	
Additional paid-in capital	4,407	54,741	
Deferred stock-based compensation	(7)	(7)	
Notes receivable from stockholders	(562)	(562)	
Accumulated deficit	(44,032)	(44,032)	
Total stockholders' equity (deficit)	(40,190)	10,156	
Total capitalization	\$ 13,970	\$ 13,970	\$

The above table excludes:

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617,607 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2006 at an exercise price of \$4.50 per share;

3,145,579 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2006 under our 1997 Stock Option Plan at a weighted-average exercise price of \$1.70 per share;

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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 reserved for issuance under our 2006 Equity Incentive Plan; and

250,000 shares of common stock reserved for issuance under our 2006 Employee Stock Purchase Plan.

The table should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

Table of Contents**DILUTION**

Our historical net tangible book value (deficit) as of June 30, 2006 was approximately \$(40.2) million, or \$(9.29) per share, based on 4,328,176 shares of common stock outstanding. Historical net tangible book value (deficit) per share is determined by dividing our total tangible assets less total liabilities and shares of redeemable preferred stock by the actual number of our outstanding shares of common stock. Our pro forma net tangible book value as of June 30, 2006 was approximately \$10.2 million, or \$0.62 per share, based on 16,370,450 shares of common stock outstanding after giving effect to the conversion of all outstanding shares of preferred stock into 12,042,274 shares of common stock. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the pro forma number of shares of common stock outstanding before giving effect to this offering.

After giving effect to the issuance and sale of _____ shares of common stock in this offering at an initial public offering price of \$ _____ per share, the mid-point of the range on the front cover of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses, our pro forma net tangible book value as of June 30, 2006 would have been \$ _____ million or \$ _____ per share. This represents an immediate increase in pro forma net tangible book value to existing stockholders of \$ _____ per share and an immediate dilution in pro forma net tangible book value of \$ _____ per share to new investors purchasing our common stock in the offering at an initial public offering price of \$ _____ per share, the mid-point of the range on the front cover of this prospectus. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. The following table illustrates the per share dilution without giving effect to the overallotment option granted to the underwriters:

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of June 30, 2006	\$ (9.29)
Increase per share due to assumed conversion of all shares of preferred stock	9.91
Pro forma net tangible book value per share as of June 30, 2006	0.62
Increase per share attributable to new investors in this offering	
Pro forma net tangible book value per share after the offering	
Dilution of net tangible book value per share to new investors	\$

The following table sets forth, as of June 30, 2006, on the pro forma basis discussed above, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid to us by existing stockholders and to be paid by new investors purchasing shares of common stock in this offering. The table reflects an initial public offering price of \$ _____ per share, the mid-point of the range on the front cover of this prospectus before deducting estimated underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average Price
	Number	Percent (in thousands, except share and per share data)	Amount	Percent	Per Share
Existing stockholders	16,370,450	%	\$ 48,733	%	\$ 2.98
New investors					
Total		100.0%	\$	100.0%	\$

The above discussion and tables exclude:

617,607 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2006 at an exercise price of \$4.50 per share;

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3,145,579 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2006 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 reserved for issuance under our 2006 Equity Incentive Plan; and

250,000 shares of common stock reserved for issuance under our 2006 Employee Stock Purchase Plan.

If the underwriters exercise their overallotment option in full to purchase additional shares of common stock in this offering, the pro forma net tangible book value per share after the offering would be \$ per share, the increase in pro forma net tangible book value per share to existing stockholders would be \$ per share and the dilution to new investors purchasing shares in this offering would be \$ per share.

Table of Contents**SELECTED FINANCIAL DATA**

The following table presents selected historical financial data. We derived the selected statements of operations data for the years ended December 31, 2003, 2004 and 2005 and balance sheet data as of December 31, 2004 and 2005 from our audited financial statements and notes thereto that are included elsewhere in this prospectus. We derived the selected statements of operations data for the years ended December 31, 2001 and 2002 and the balance sheet data as of December 31, 2001, 2002 and 2003 from our audited financial statements that do not appear in this prospectus. We derived the statements of operations data for the six months ended June 30, 2005 and 2006 and the balance sheet data as of June 30, 2006 from our unaudited financial statements that are 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 periods ended June 30, 2005 and 2006 and our financial condition as of June 30, 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 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.

Statement of Operations Data

<i>(in thousands of dollars, except share and per share data)</i>	Years Ended December 31,					Six Months Ended	
	2001	2002	2003	2004	2005	2005	2006
Net revenue	\$	\$	\$	\$	\$	\$	\$
Cost of revenue							
Gross margin							
Operating expenses							
Sales and marketing							
Research and development							
General and administrative							
Litigation settlement gain							
Total operating expenses							
Income (loss) from operations							
Interest and other income							
Interest and other expense							
Income (loss) before income taxes and cumulative effect of change in accounting principle							
Provision for income taxes							
Net income (loss) before cumulative effect of change in accounting principle							
Cumulative effect of change in accounting principle							
Net income (loss)	\$	\$	\$	\$	\$	\$	\$
Net income (loss) allocable to common stockholders	\$	\$	\$	\$	\$	\$	\$

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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)								
Net income (loss) per share	basic	\$	(5.73)	\$	(6.10)	\$	(2.85)	\$	0.41	\$	(2.25)	\$	(0.02)	\$	(0.91)
Net income (loss) per share	diluted	\$	(5.73)	\$	(6.10)	\$	(2.85)	\$	0.30	\$	(2.25)	\$	(0.02)	\$	(0.91)
Weighted average shares outstanding used in calculating net income (loss) per common share:															
Basic															
		1,824,386	1,868,232	2,307,238	3,023,225	3,664,990	3,562,659	4,132,187							
Diluted															
		1,824,386	1,868,232	2,307,238	16,549,946	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				

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	As of December 31,				As of June 30,	
	2001	2002	2003	2004	2005	2006
	(in thousands)					
Balance Sheet Data						
Cash and cash equivalents	\$ 2,616	\$ 15,588	\$ 12,383	\$ 11,706	\$ 10,121	\$ 10,175
Working capital	697	15,317	9,435	12,110	10,947	11,176
Total assets	3,230	19,399	17,667	26,202	24,032	23,947
Borrowings, less current portion	61	5	18	13	4,040	3,814
Preferred stock warrant liability					3,937	5,177
Redeemable convertible preferred stock	20,225	45,013	45,167	45,169	45,169	45,169
Total stockholders deficit	\$ (19,076)	\$ (28,826)	\$ (35,189)	\$ (29,440)	\$ (38,733)	\$ (40,190)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Risk Factors and elsewhere in this prospectus.

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 June 30, 2006, we had an installed base of over 1,800 ThermaCool RF generators and had sold over 275,000 ThermaTips.

Significant Business Trends

We derive revenue primarily from the sale of ThermaTips and other consumables and sales of our ThermaCool RF generator. For 2003, 2004 and 2005, we derived 29%, 60% and 66%, respectively, of our revenue from ThermaTip and other consumable sales, and 70%, 39% and 31%, respectively, of our revenue from ThermaCool RF generator sales. We expect to generate a greater percentage of our revenue from sales of ThermaTips and other consumables in the future. 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.

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 29 distributors in 70 countries. In 2003, 2004 and 2005 and the six months ended June 30, 2006, we derived 79%, 72%, 56% and 52%, respectively, of our revenue from sales of our products and services within the United States. For 2003, 2004, 2005 and the six months ended June 30, 2006, we derived 21%, 28%, 44% and 48%, 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:

	Years Ended December 31,			Six Months Ended June 30,	
	2003	2004	2005	2005	2006
United States	79%	72%	56%	59%	52%
Asia Pacific	12%	16%	23%	21%	23%
Europe/Middle East	0%	3%	11%	11%	14%
Rest of World	9%	9%	10%	9%	11%
Total	100%	100%	100%	100%	100%

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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. We also expect additional stock-based compensation expense in future periods due to our adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, beginning January 1, 2006.

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. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other factors that impact our business is provided in the **Risk Factors** section in this prospectus.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories and warranty reserve. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe that the following critical accounting policies are affected by our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104. Product revenue is recognized when title and risk of ownership have been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable, remaining obligations are insignificant and collectibility is reasonably assured. Transfer of title and risk of ownership occur when the product is shipped to the customer. Revenue is recorded net of customer and distributor discounts. Revenue from the sale of extended service contracts for products beyond their warranty term is recognized on a straight-line basis over the period of the applicable extended contract. We also earn service revenue from customers outside of their warranty term or extended service contracts. Such service revenue is recognized as the services are provided.

Our ThermaCool RF generator sales in the United States typically have post-sale obligations of installation and training. These obligations are fulfilled after product shipment, and in these cases, we recognize revenue in accordance with the multiple element accounting guidance set forth in Emerging Issues Task Force No. 00-21, *Revenue Arrangements with Multiple Deliverables*. When we have objective and reliable evidence of fair value of the undelivered elements, we defer revenue attributable to the post-shipment obligations and

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recognize such revenue when the obligation is fulfilled. Otherwise, we will defer all revenue until all elements are delivered.

We sell to end-users in the United States and to distributors outside of the United States. Sales to distributors do not include return rights. We typically recognize revenues upon shipment for sales to our independent third party distributors as we have no continuing obligations subsequent to shipment, other than replacement parts warranty coverage. The distributors are responsible for all marketing, sales, installation, training and warranty services for our products. We do not provide price protection or stock rotation rights to any of our distributors. In addition, our distributor agreements do not allow the distributor to return or exchange products and the distributor is obligated to pay us for the sale regardless of whether the distributor is able to resell the product. In the quarter ended December 31, 2005, we changed our standard distributor payment terms from upfront payments to payments due within 30 days of shipment. For sales transactions with non-standard extended payment terms or when collectibility is not reasonably assured, we recognize revenue upon receipt of cash payment. At December 31, 2005 and June 30, 2006, we had deferred revenue balances of \$0.3 million and \$0.1 million, respectively, related to sales transactions with extended payment terms.

Certain of our physician customers in the United States who purchased systems prior to August 2003 had the general right to return unused consumable products. Prior to 2004, we lacked sufficient historical experience to reliably estimate sales returns and therefore deferred recognition of revenue and cost of revenues related to such transactions until there was sufficient evidence that the products had been consumed. Since 2004, we have had a sufficient historical basis to estimate return rates and have recorded revenue on such transactions upon shipment, provided that all other revenue recognition criteria are met. Deferred revenues and deferred cost of revenues related to return rights at December 31, 2003 of \$0.6 million and \$0.1 million, respectively, were recognized in 2004.

Accounts Receivable

Accounts receivable are typically unsecured and derived from revenues earned from customers. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We estimate appropriate allowances based upon any specific customer collection issues that we have identified. Our assessment of the ability of our customers to pay generally includes direct contact with the customer, a review of their financial status, as well as consideration of their payment history with us. Allowance for doubtful accounts was \$0 and \$29,000 at December 31, 2004 and 2005, respectively. Doubtful account write-offs have been insignificant during the years ended December 31, 2003, 2004, 2005 and the six month period ended June 30, 2006.

Warranty Reserve

We provide for the estimated cost of product warranties at the time revenue is recognized. As we sell new products to our customers, we must exercise considerable judgment in estimating the expected failure rates. Should actual product failure rates, material usage or service delivery costs differ from our estimates, revisions to the estimated warranty liability would be required. Our estimated warranty liability was \$0.3 million, \$0.3 million and \$0.3 million at December 31, 2004 and 2005 and June 30, 2006, respectively. We offer a three year warranty for systems sold in the United States and a one year replacement parts warranty for systems sold to distributors. We also provide a warranty for our consumable products.

Inventory

We state our inventories at the lower of cost or market value, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis) and market value being determined as the lower of replacement cost or net realizable value. Standard costs are monitored on a monthly basis and updated at least annually and as necessary to reflect changes in raw material costs and labor and overhead rates. Inventory

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reserves are established when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Inventory reserves are charged to cost of revenue and establish a lower cost basis for the inventory. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins. Our inventory reserves as of December 31, 2004 and 2005 and June 30, 2006 were \$0.7 million, \$1.0 million and \$0.9 million, respectively.

Litigation and Claims

We routinely assess the likelihood of any adverse judgments or outcomes related to legal matters and claims, as well as ranges of probable losses. A determination of the amount of the reserves required, if any, for these contingencies is made after thoughtful analysis of each known issue and an analysis of historical experience in accordance with Statement of Financial Accounting Standards No. 5, Accounting for Contingencies, or SFAS No. 5, and related pronouncements. Also in accordance with SFAS No. 5, we do not record gain contingencies.

Income Taxes

We account for income taxes under the liability method. Under this method, we determine deferred tax assets and liabilities at the balance sheet date based upon the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The tax consequences of most events recognized in the current year's financial statements are included in determining income taxes currently payable. However, because tax laws and financial accounting standards differ in their recognition and measurement of assets, liabilities, equity, revenues, expenses and gains and losses, differences arise between the amount of taxable income and pretax financial income for a year and between the tax bases of assets or liabilities and their reported amounts in our financial statements. Because it is assumed that the reported amounts of assets and liabilities will be recovered and settled, respectively, a difference between the tax basis of an asset or a liability and its reported amount on the balance sheet will result in a taxable or a deductible amount in some future years when the related liabilities are settled or the reported amounts of the assets are recovered. We then assess the likelihood that our deferred tax assets will be recovered from future taxable income and unless we believe that recovery is more likely than not, we must establish a valuation allowance to reduce the deferred tax assets to the amounts expected to be realized. As part of the process of preparing our financial statements, we are required to estimate our income taxes. This process involves estimating our current tax liability, together with assessing temporary differences that may result in deferred tax assets.

Based on the available objective evidence, we believe it is more likely than not that the net deferred tax assets will not be fully realized. Accordingly, we have provided a full valuation allowance on those assets and no benefit has been recognized for our net operating loss and other deferred tax assets. Accordingly, deferred tax valuation allowances have been established as of December 31, 2003, 2004 and 2005 and June 30, 2006 to reflect these uncertainties. If we are able to demonstrate consistent profitability in the future, and we are able to establish that recovery is more likely than not, we would reduce the valuation allowance at a future date. As of December 31, 2005, we had federal and state net operating loss carryforwards of approximately \$34.0 million and \$20.0 million, respectively, available to reduce future taxable income, if any, for federal and state income taxes, respectively. The net operating loss carryforwards begin to expire in 2011 and 2010 for federal and state income tax purposes, respectively. Utilization of the net operating loss carryforwards may be subject to an annual limitations due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss carryforwards before utilization.

Table of Contents***Stock-Based Compensation Expense***

Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB No. 25, and its interpretations and complied with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of our stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options. SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity investment.

During the year ended December 31, 2005 and the six-month period ended June 30, 2006, we issued stock options to certain employees with exercise prices below the fair market value of our common stock at the date of grant, determined with hindsight. The fair value of the common stock for options granted during January 1, 2005 through June 30, 2006 was originally estimated by our board of directors, with input from management. We did not obtain contemporaneous valuations by an unrelated valuation specialist. Subsequently, we reassessed the valuations of common stock relating to grants of options during the 18 months ended June 30, 2006. As disclosed more fully in Note 9 of the notes to our financial statements, we granted stock options with exercise prices ranging from \$1.90 to \$4.00 during the 18 months ended June 30, 2006. We retrospectively estimated the fair value of our common stock based upon several factors, including our operating and financial performance, progress and milestones attained in our business, past sales of convertible preferred stock, and the expected valuation that we would obtain in an initial public offering. We have reviewed these key factors and events between each date and have determined that the combination of these factors and events reflect a true measurement of our relative fair value over an extended period of time and believe that the fair value of our common stock is appropriately reflected using a linear progression from \$4.00 per share of common stock at January 1, 2005, to \$11.93 at June 30, 2006. Although it is reasonable to expect that the completion of our initial public offering may add value to the shares as a result of increased liquidity and marketability, the amount of additional value cannot be measured with precision or certainty. In accordance with the requirements of APB No. 25, we have recorded deferred stock-based compensation for the difference between the exercise price of the stock options granted during the year ended December 31, 2005 and the fair market value of our stock at the date of grant, determined with hindsight. The aggregate intrinsic value of the outstanding options vested and expected to vest at June 30, 2006 was \$29.8 million, based upon an estimated fair value of common stock at June 30, 2006 of \$11.93 per share.

Effective January 1, 2006, we adopted the fair value provisions of Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, or SFAS No. 123R, which supersedes previous accounting under APB No. 25. SFAS No. 123R requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. We adopted SFAS No. 123R using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, SFAS No. 123R shall be applied to option awards granted, modified, repurchased or cancelled after the required effective date. For options granted prior to the SFAS No. 123R effective date, which the requisite service period has not been performed as of January 1, 2006, we will continue to recognize compensation expense on the remaining unvested awards under the intrinsic-value method of APB No. 25. For options accounted for under APB No. 25 that were granted prior to January 1, 2006 and then modified after January 1, 2006, we will apply SFAS No. 123R to these option grants upon the date of modification. All option grants valued after January 1, 2006 will be expensed on a straight-line basis.

Under SFAS No. 123R, we calculated the fair value of the stock option grants using the Black-Scholes option-pricing model. For the six months ended June 30, 2006, the fair value was based on the following weighted average assumptions: the expected term of 4.25 years; the expected volatility of 55%, the risk free

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interest rate of 4.77% and 0.0% for the dividend yield. Estimated volatility for the six months ended June 30, 2006 reflects the application of SAB 107 interpretive guidance and, accordingly, due to a lack of historical information regarding the volatility of our stock price, incorporates historical and implied volatility of similar public entities in the aesthetics market. The expected term has been computed based upon the vesting term, cancellation history, historical exercises and contractual term of the options. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions.

We account for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period, on a straight-line basis.

Results of Operations***Six Months Ended June 30, 2005 and June 30, 2006***

Net Revenue. Revenue is derived from the sale of single-use ThermoTips and other consumables, ThermoCool RF generator sales, and service and other revenue. Net revenue increased \$4.3 million, or 19%, from \$22.8 million to \$27.1 million for the six months ended June 30, 2005 and 2006, respectively. Sales of ThermoTips and other consumables increased \$4.3 million, or 28%, from \$15.3 million to \$19.6 million for the six months ended June 30, 2005 and 2006, respectively. Sales of ThermoCool RF generator decreased \$0.3 million, or 4%, from \$6.9 million to \$6.7 million for the six months ended June 30, 2005 and 2006, respectively. Product unit volume of ThermoTips was 45,848 units and 65,964 units for the six month ended June 30, 2005 and 2006, respectively. Product unit volume of our ThermoCool RF generator was 215 units for each of the six months ended June 30, 2005 and 2006, respectively. International sales to distributors accounted for 41% and 48% of revenue for the six months ended June 30, 2005 and 2006, respectively. The increase in revenue was driven by increased adoption of our 3.0 cm² ThermoTip, the introduction of our new 0.25 cm² ThermoTip and expansion into new international markets, partially offset by lower average selling prices beginning in April 2005.

Cost of Revenue. Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. Cost of revenue increased \$1.4 million, or 22%, from \$6.3 million to \$7.7 million for the six months ended June 30, 2005 and 2006, respectively. The increase was primarily due to the increased volume of ThermoTips and other consumables sold. Gross margin was 72% and 72% for the six months ended June 30, 2005 and 2006, respectively.

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 \$2.0 million, or 20%, from \$10.1 million to \$12.1 million for the six months ended June 30, 2005 and 2006, respectively. The increase was primarily attributable to an increase of \$0.8 million in personnel and commission costs and \$0.3 million in related travel expenses associated with the expansion of our international sales force and marketing staff, as well as an increase of \$0.2 million in promotional costs primarily due to an increased number of customer workshops, trade shows and promotional efforts and an increase in stock-based compensation charges of \$0.7 million.

Research and Development. Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, material costs and regulatory and quality assurance costs not directly related to the manufacturing of our products. Research and development expenses increased \$0.6 million, or 15%, from \$4.3 million to \$4.9 million for the six months ended June 30, 2005 and 2006, respectively. The increase was primarily

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related to increased clinical studies costs of \$0.1 million, development of a new proprietary generator platform and research into new applications of \$0.3 million and increased stock-based compensation charges of \$0.2 million.

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 \$0.7 million, or 18%, from \$4.0 to \$4.7 million for the six months ended June 30, 2005 and 2006, respectively. The increase was primarily attributable to \$0.7 million in increased stock-based compensation charges during the six months ended June 30, 2006.

Litigation Settlement. In June 2005, we reached an agreement with Syneron that settled patent-related claims of the parties against each other. Under this agreement, the parties granted each other non-exclusive paid-up licenses under the patents in the suit and related patents. We received a one-time payment of \$1.8 million, recorded net of certain legal expenses as \$1.6 million. The license granted to Syneron excludes the right to utilize our monopolar RF and capacitive electrical coupling and the license granted to us excludes the right to utilize Syneron's Electro-Optical Synergy technology.

Interest and Other Income. Interest and other income consists primarily of interest income generated from our cash and cash equivalent balances. Interest and other income increased \$97,000, or 68%, from \$143,000 to \$240,000 for the six months ended June 30, 2005 and 2006, respectively due to higher average cash balances resulting from the proceeds of our GE Capital borrowings.

Interest and Other Expense. Interest and other other expense of \$1.6 million for the six months ended June 30, 2006 consists primarily of approximately \$1.2 million of expense related to changes in the fair value of our convertible preferred stock warrants under FSP 150-5 and approximately \$0.4 million of interest expense on our GE Capital borrowings. Interest and other other expense for the comparable time period in 2005 was \$13,000 and consisted primarily of interest expense on borrowings. We drew \$5.0 million from GE Capital in the fourth quarter of 2005.

Years Ended December 31, 2004 and December 31, 2005

Net Revenue. Net revenue decreased \$9.7 million, or 19%, from \$50.4 million in 2004 to \$40.7 million in 2005. Sales of ThermaTips and other consumables decreased \$3.1 million, or 10%, from \$30.1 million in 2004 to \$27.0 million in 2005. Sales of ThermaCool RF generator decreased \$7.1 million, or 36%, from \$19.7 million in 2004 to \$12.6 million in 2005. Product unit volume of ThermaTips was 94,099 units and 83,662 units for 2004 and 2005, respectively. Product unit volume of ThermaCool RF generator was 612 units and 408 units for 2004 and 2005, respectively. International sales to distributors accounted for 28% and 44% of revenue for 2004 and 2005, respectively. The decrease in revenue was primarily attributable to a decline in unit volume sales resulting from the reorganization of our U.S. sales force in 2005, which led to the replacement of over 50% of our sales personnel, as well as a reduction in pricing of ThermaCool RF generator and most ThermaTips of 10% to 15%, partially offset by expansion into new international markets.

Cost of Revenue. Cost of revenue decreased \$0.2 million, or 1%, from \$12.5 million in 2004 to \$12.3 million in 2005. The decrease was primarily due to the decrease in sales. Gross margin decreased from 75% in 2004 to 70% in 2005, primarily as a result of a reduction in product pricing.

Sales and Marketing. Sales and marketing expenses increased \$4.4 million, or 28%, from \$15.6 million in 2004 to \$20.0 million in 2005. The increase was primarily attributable to an increase of \$1.8 million in personnel costs and \$0.5 million in related travel expenses associated with the expansion of our international sales force and marketing staff, as well as an increase of \$1.4 million in promotional costs primarily due to an increased number of customer workshops, trade shows and promotional efforts. Stock-based compensation charges accounted for \$0.1 million of the year-over-year increase in expenses.

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Research and Development. Research and development expenses increased \$0.4 million, or 5%, from \$8.5 million in 2004 to \$8.9 million in 2005. The increase was primarily related to the development of our 3.0 cm² ThermaTip, which was commercially launched in the fourth quarter of 2005, our 0.25 cm² ThermaTip, which was commercially launched in the first quarter of 2006, development of a new proprietary generator platform, additional expenditures on research into new applications.

General and Administrative. General and administrative expenses decreased \$1.5 million, or 16%, from \$8.9 million in 2004 to \$7.4 million in 2005. The decrease was primarily attributable to a \$1.0 million decrease in patent litigation costs regarding an infringement suit we initiated against Syneron that was settled in June 2005. Stock-based compensation charges accounted for \$0.1 million of expense in 2005, compared to \$0.2 million of expense in 2004.

Litigation Settlement. In June 2005, we reached an agreement with Syneron that settled patent-related claims of the parties against each other. Under this agreement, the parties granted each other non-exclusive paid-up licenses under the patents in the suit and related patents under the parties' control. We received a one-time payment of \$1.8 million, recorded net of certain legal expenses as \$1.6 million. The license granted to Syneron excludes the right to utilize our monopolar RF and capacitive electrical coupling and the license granted to us excludes the right to utilize Syneron's Electro-Optical Synergy technology.

Interest and Other Income. Interest and other income increased \$163,000, or 92%, from \$177,000 in 2004 to \$340,000 in 2005 primarily due to higher market rates of interest on our cash balances.

Interest and Other Expense. Interest and other expense of \$1.5 million for 2005 consists primarily of approximately \$1.4 million of expense related to changes in the fair value of our convertible preferred stock warrants under FSP 150-5 and approximately \$90,000 of interest expense associated with our borrowings. Interest and other expense for the comparable time period in 2004 was \$14,000 and consisted primarily of interest expense. We drew \$5.0 million from GE Capital in the fourth quarter of 2005. Total outstanding debt balances were \$18,000 and \$5.0 million as of the December 31, 2004 and December 31, 2005, respectively.

Change in Accounting Principles. Freestanding warrants related to our redeemable convertible preferred stock are accounted for in accordance with FSP 150-5 which requires that the warrants be classified as liabilities and recorded at fair value at the end of each reporting period. FSP 150-5 was adopted during the year ended December 31, 2005. A charge of \$0.7 million was recorded in 2005 in connection with the change in accounting principle upon the adoption of FSP 150-5. We will continue to recognize any changes to the fair value of the warrants until the earlier of the exercise or expiration of the preferred stock warrants or the completion of a liquidation event.

Income Taxes. The provision for income taxes for 2004 of \$103,000 consisted of \$80,000 for federal taxes and \$23,000 for state taxes. The provision for income taxes primarily reflects U.S. alternative minimum taxes as well as U.S. state taxes.

Years Ended December 31, 2003 and December 31, 2004

Net Revenue. Net revenue increased \$25.5 million, or 102%, from \$24.9 million in 2003 to \$50.4 million in 2004. Sales of ThermaTips and other consumables increased \$23.0 million, or 322%, from \$7.1 million in 2003 to \$30.1 million in 2004. Sales of our ThermaCool RF generator increased \$2.2 million, or 12%, from \$17.5 million in 2003 to \$19.7 million in 2004. Product unit volume of ThermaTips was 40,233 units and 94,099 units for 2003 and 2004, respectively. Product unit volume of ThermaCool RF generator was 587 units and 612 units for 2003 and 2004, respectively. International sales to distributors accounted for 21% and 28% of net revenue for 2003 and 2004, respectively. Revenue increased as a result of a price increase on the ThermaCool RF generator, higher product unit volumes resulting from international expansion, increased awareness of our product and the successful introduction of new higher-priced ThermaTips.

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Cost of Revenue. Cost of revenue decreased \$0.1 million, or 1%, from \$12.6 million in 2003 to \$12.5 million in 2004. Gross margin increased from 50% in 2003 to 75% in 2004, primarily as a result of economies of scale from higher product unit volume and higher average selling prices on products.

Sales and Marketing. Sales and marketing expenses increased \$6.7 million, or 74%, from \$8.9 million in 2003 to \$15.6 million in 2004. The increase was primarily attributable to an increase of \$4.0 million in personnel costs and \$0.6 million in related travel expenses primarily associated with the expansion of our U.S. and international sales force. Promotional costs increased \$1.1 million primarily due to an increased number of customer workshops, trade shows and promotional efforts.

Research and Development. Research and development expenses increased \$1.9 million, or 29%, from \$6.6 million in 2003 to \$8.5 million in 2004. The increase was primarily related to \$0.4 million on expanded clinical studies and \$1.5 million related to the development of our 1.5 cm² ThermaTip, which was commercially launched in the third quarter of 2004, development of a new proprietary generator platform and research into new applications and products.

General and Administrative. General and administrative expenses increased \$5.3 million, or 146%, from \$3.6 million in 2003 to \$8.9 million in 2004. The increase was primarily attributable to \$2.4 million in personnel costs, \$0.9 million in increased patent litigation costs regarding an infringement suit we initiated against Syneron that was settled in June 2005, costs related to product liability and business insurance of \$0.7 million, outside services of \$0.3 million related to preparation for Sarbanes Oxley compliance and outside services to support and expand information technology of \$0.5 million.

Interest and Other Income. Interest and other income stayed relatively flat at \$205,000 in 2003 and \$177,000 in 2004. Interest and other income consists primarily of interest income related to our cash and cash equivalents.

Interest and Other Expense. Interest and other expense was \$7,000 and \$14,000 for 2003 and 2004, respectively, and relates primarily to interest on borrowings.

Table of Contents**Quarterly Results of Operations**

The following table sets forth our operating results for each of the six quarters indicated below. This data has been derived from unaudited financial data that, in the opinion of our management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of this information when read in conjunction with our annual audited financial statements and the related notes. The amount and timing of our operating expenses may fluctuate significantly in the future as a result of a variety of factors. These operating results are not necessarily indicative of results for any future period.

	Quarters Ended					
	Mar. 31, 2005	Jun. 30, 2005	Sep. 30, 2005	Dec. 31, 2005	Mar. 31, 2006	Jun. 30, 2006
	(in thousands)					
Net revenue	\$ 11,094	\$ 11,723	\$ 8,500	\$ 9,338	\$ 12,431	\$ 14,631
Cost of revenue	2,927	3,359	2,571	3,452	3,778	3,901
Gross margin	8,167	8,364	5,929	5,886	8,653	10,730
Operating expenses:						
Sales and marketing	4,976	5,142	4,952	4,927	5,849	6,301
Research and development	2,125	2,162	2,256	2,365	2,377	2,563
General and administrative	2,085	1,877	1,539	1,913	2,264	2,393
Litigation settlement gain		(1,646)				
Net operating expenses	9,186	7,535	8,747	9,205	10,490	11,257
Income (loss) from operations	\$ (1,019)	\$ 829	\$ (2,818)	\$ (3,319)	\$ (1,837)	\$ (527)

Stock-Based Compensation

For the years ended December 31, 2003, 2004 and 2005 and the six month periods ended June 30, 2005 and 2006, employee and non-employee stock-based compensation expense has been allocated as follows:

	December 31,			Six Months Ended June 30,	
	2003	2004	2005	2005	2006
	(in thousands)				
Cost of revenue	\$	\$ 41	\$ 4	\$ 1	\$ 42
Sales and marketing	138	126	216	63	758
Research and development		77	124	64	289
General and administrative		219	112	68	794
Total stock-based compensation expense	\$ 138	\$ 463	\$ 456	\$ 196	\$ 1,883

At December 31, 2005, we had deferred stock-based compensation under APB No. 25 as shown in the statement of stockholders deficit of approximately \$3.5 million. As of December 31, 2005, deferred stock-based compensation of \$1.0 million is expected to be amortized in 2006, \$1.0 million in 2007, \$0.9 million in 2008 and \$0.6 million in 2009.

We recorded employee stock-based compensation expense of \$1,792 million in the six months ended June 30, 2006. For the six months ended June 30, 2006, the total compensation cost related to stock-based awards granted or modified under SFAS 123R to employees and directors but

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not yet recognized was approximately \$6,487 million, net of estimated forfeitures. We will amortize this cost on a straight-line basis over a weighted average period of approximately 3.4 years.

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During March 2006, we repriced stock option awards held by 116 of our employees. Under the terms of this repricing, we repriced certain employee stock options having an exercise price of \$2.00 or above to an exercise price of \$1.90. Other than the exercise price, all other terms of the repriced options, such as vesting and contractual life, remained the same. In consideration for the repricing of eligible stock option awards, employees who were previously granted stock option awards on February 2, 2005 were also required to return these awards for cancellation. As a result of this repricing, we repriced 447,565 vested options and 1,523,035 unvested options having a weighted average original exercise price of \$4.18 and \$4.10, respectively. Such options were repriced at a new exercise price of \$1.90 per share. As a result of this repricing, we also cancelled 35,216 outstanding employee options with an original exercise price of \$4.00 that were granted on February 2, 2005. We have accounted for the repricing and cancellation transactions as a modification under SFAS No. 123R and recorded any net incremental fair value related to vested awards as compensation expense on the date of modification. In accordance with SFAS No. 123R, we will record the incremental fair value related to the unvested awards, together with unamortized stock-based compensation expense associated with the unvested awards, over the remaining requisite service period of the option holders. In connection with the repricing, we recorded stock-based compensation expense of \$1.2 million in the six months ended June 30, 2006.

In connection with the repricing of stock options during the six months ended June 30, 2006, we followed the provisions of SFAS No. 123R and eliminated deferred stock-based compensation amounts of approximately \$3.3 million related to the repriced stock options. Stock compensation charges for the repriced options will be recorded in accordance with SFAS No. 123R.

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 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 \$0, \$110,000, \$132,000, \$104,000 and \$92,000 for the years ended December 31, 2003, 2004 and 2005 and the six month periods ended June 30, 2005 and 2006.

Liquidity and Capital Resources

We have not achieved sustained profitability since the introduction of our ThermaCool system in 2002. As of June 30, 2006, we had an accumulated deficit of approximately \$44.0 million. We have funded our operations principally from the issuance of our preferred stock that resulted in aggregate net proceeds of \$45.2 million. All of our preferred stock will convert automatically by its terms into common stock upon the closing of this offering. 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. Each of these outstanding borrowings has a term of 36 months and is secured by a first priority security interest in substantially all of our assets, including our intellectual property, and any future borrowings under this working capital line are subject to approval by the lender.

On June 30, 2006, we had working capital of \$11.2 million, and our primary source of liquidity was \$10.2 million in cash and cash equivalents.

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The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2005, excluding the convertible preferred stock to be converted into common stock upon completion of this offering and the liability associated with preferred stock warrants:

	Total	Payments Due by Period		
		Less than 1 year (in thousands)	1-3 years	3-5 years
Operating leases	\$ 1,400	\$ 792	\$ 608	\$
Capital leases	13	5	8	
Notes payable	5,000	900	4,006	94
Total contractual obligations	\$ 6,413	\$ 1,697	\$ 4,622	\$ 94

Upon the completion of this offering, all of our warrants to purchase shares of preferred stock will be either exercised or converted into warrants to purchase common stock and, accordingly, the liability will be reclassified as common stock and additional paid-in capital.

Six Months Ended June 30, 2005 and June 30, 2006

Net Cash Provided by (Used in) Operating Activities. Net cash provided by operating activities was \$0.2 million for the six months ended June 30, 2005 and net cash used in operating activities was \$0.2 million for the six months ended June 30, 2006. During 2006, net cash used by operating activities primarily resulted from \$3.8 million of net loss and an increase in accounts receivables of \$1.2 million, offset by non-cash amortization of stock-based compensation of \$1.9 million, charges related to preferred stock warrant liability of \$1.2 million, non-cash depreciation and amortization of \$1.0 million, and a decrease in inventory and prepaid assets of \$0.6 million. The increase in accounts receivable was the result of increased revenues.

Net Cash Used in Investing Activities. Net cash used in investing activities was \$1.7 million and \$0.2 million for the six months ended June 30, 2005 and 2006, respectively. Our investing activities in the 2005 and 2006 periods consisted principally of property and equipment purchases of \$1.7 million in 2005 and \$0.3 million in 2006. Expenditures were higher in the first six months of 2005 as a result of outfitting our new corporate and manufacturing facility that we moved into at the end of 2004.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was \$21,000 and \$0.4 million for the six months ended June 30, 2005 and 2006, respectively. Cash provided by financing activities was attributable to proceeds from the exercise of stock options.

Years Ended December 31, 2004 and December 31, 2005

Net Cash Provided by (Used in) Operating Activities. Net cash provided by operating activities was \$2.2 million in 2004 and net cash used in operating activities was \$4.3 million in 2005. During 2005, net cash used by operating activities primarily resulted from \$8.2 million of net loss, an increase in accounts receivables of \$1.7 million, a decrease in payables and accrued liabilities of \$0.2 million, and an increase in prepaid expenses of \$0.4 million, offset by charges related to a preferred stock warrant liability of \$2.1 million, non-cash depreciation and amortization of \$2.0 million, a decline in inventories of \$1.6 million, and \$0.5 million of non-cash amortization of stock-based compensation. The increase in accounts receivable was the result of changing our distributor standard payment terms from upfront payment to payment within 30 days of shipment. The decrease in payables and accrued liabilities was due to decreased levels of accrued state sales tax and inventory as a result of lower revenue. The decline in inventories was a result of aligning inventory levels with changes in forecasted customer demand.

Net Cash Provided by (Used in) Investing Activities. Net cash provided by investing activities was \$0.6 million in 2004 and net cash used in investing activities was \$2.3 million in 2005. Our investing activities in

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2004 consisted principally of the purchase and maturity of marketable securities for \$3.8 million offset by \$3.2 million in purchases of property and equipment. Our investing activities in 2005 consisted primarily of \$2.2 million for acquisition of property and equipment in connection with our move to a larger corporate and manufacturing facility in the fourth quarter of 2004 that involved leasehold improvements plus additional infrastructure and equipment expenditures.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was \$0.3 million and \$5.0 million for 2004 and 2005, respectively. In 2004, the increase in cash provided by financing activities was attributable to proceeds from the exercise of stock options. In 2005, the increase in cash provided by financing was primarily attributable to \$5.0 million drawn on a working capital line with GE Capital.

Years Ended December 31, 2003 and 2004

Net Cash Provided by (Used in) Operating Activities. Net cash used in operating activities was \$2.6 million in 2003 and net cash provided by operating activities was \$2.2 million in 2004. During 2004, net cash provided by operating activities primarily resulted from \$5.0 million of net income, non-cash depreciation and amortization of \$1.0 million, an increase in payables and other liabilities of \$1.4 million, and \$0.5 million of non-cash amortization of stock-based compensation, offset by an increase in inventories of \$5.7 million. The increase in inventory levels was the result of increased safety stock driven by higher revenue and additional product catalog numbers. The increase in payables and accrued liabilities was due to higher operating expense and inventory levels, state sales taxes on increased revenue and product liability claims.

Net Cash Used in Investing Activities. Net cash used in investing activities was \$0.6 million for 2003 and net cash provided by investing activities was \$0.6 million for 2004. Our investing activities in 2003 consisted of the purchase and maturity of marketable securities for net cash provided of \$0.2 million offset by \$0.8 million in purchases of property and equipment. Our investing activities in 2004 consisted principally proceeds from the sale of marketable securities for \$3.8 million offset by \$3.2 million in purchases of property and equipment in connection with our move to a larger corporate and manufacturing facility in the fourth quarter of 2004 that involved leasehold improvements plus additional infrastructure and equipment expenditures.

Net Cash Provided by (Used in) Financing Activities. Net cash provided by financing activities was \$0.2 million and \$0.3 million for 2003 and 2004, respectively. In 2003, the increase in cash provided by financing activities was attributable to proceeds from the issuance of preferred stock and warrants, as well as exercise of stock options. In 2004, the increase in cash provided by financing activities was attributable to proceeds from the exercise of stock options.

Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, and continued progress of our research and development of new products.

We expect to increase capital expenditures consistent with our anticipated growth in manufacturing, infrastructure and personnel. We also may increase our capital expenditures as we expand our product lines or invest to address new markets.

We believe that the net proceeds from this offering, together with our current cash and investment balances and cash generated 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 an additional 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

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would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development 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.

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.

Recent Accounting Pronouncements

In November 2004, the FASB issued *SFAS No. 151, Inventory Costs*, an amendment of Accounting Research Bulletins, or ARB No. 43, Chapter 4. SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, handling costs and wasted material (spoilage). Among other provisions, the new rule requires that such items be recognized as current-period charges, regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. SFAS No. 151 was adopted as of January 1, 2006, and did not have a material effect on our financial statements.

In May 2005, the FASB issued *SFAS No. 154, Accounting Changes and Error Corrections*, which replaces Accounting Principles Board Opinion, or APB, No. 20, *Accounting Changes*, and *SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements*. This statement requires retrospective application, unless impracticable, for changes in accounting principles in the absence of transition requirements specific to newly adopted accounting principles. The provisions of SFAS No. 154 will be effective for us beginning on September 1, 2006. We do not expect that the adoption of this standard will have an impact on its financial statements.

In November 2005, the FASB issued *FSP SFAS 115-1* and *SFAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, which clarifies when an investment is considered impaired, whether the impairment is other than temporary, and the measurement of an impairment loss. It also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain related disclosures. FSP 115-1 and 124-1 will be effective for all reporting periods beginning after December 15, 2005. The adoption of these standards did not have a material impact on our financial statements.

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In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109, or FIN 48, which clarifies the accounting uncertainty in tax positions. This Interpretation requires that we recognize in our financial statements, the impact of a tax provision, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on the financial statements.

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BUSINESS

Overview

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 epidermis 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 surgical procedures that cost up to tens of thousands of dollars and 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.

We received FDA clearance and commercially launched our ThermaCool system in 2002. 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 Structure of Skin and Connective Tissue

The skin is comprised of the epidermis, dermis and the hypodermis, or subcutaneous fat layer. The top two layers of skin, the epidermis and dermis, together are known as the cutis and on most areas of the body are approximately two to three millimeters thick. The dermis contains blood vessels, hair follicles and other skin components. The deepest layer of the skin, the hypodermis, contains 50% of the body's fat cells. The hypodermis also contains collagen strands, or fibrous septae, that connect the dermis to the underlying bone and muscle. Collagen has been shown to be a very flexible and stretchable protein with high tensile strength. With advancing age and exposure to damaging environmental factors, collagen deteriorates and loses its elasticity, resulting in a wrinkling of the epidermis. The following diagram illustrates the basic anatomy of the skin:

Electromagnetic radiation, specifically light and heat, applied to the different layers of the skin can have an effect on the skin's appearance. Epidermis exposure to sunlight can tan the skin, while overexposure can lead to burns or blisters. Devices, such as aesthetic lasers, have been designed to generate light waves to deliver heat through the epidermis, into the dermis, for removal of hair, vein treatment and other aesthetic applications. Gels, coolants and other means are used to protect the epidermis from burning during this process. Delivery of heat

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below the dermis, into the subcutaneous fat layer, has been accomplished using other forms of energy, including RF energy, for aesthetic effect.

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. We believe there are several factors contributing to the rapid growth of non-invasive aesthetic procedures, including:

Aging of the U.S. Population. The baby boomer demographic segment, defined by the U.S. Census as those Americans born between 1946 and 1964, represented over 26% of the U.S. population during 2005. Baby boomers control approximately \$2 trillion in spending power and 50% of all discretionary income. The size and wealth of this aging segment and its desire to retain a youthful appearance have driven the growth for aesthetic procedures.

Emergence of Non-Traditional Practitioners. The traditional providers of aesthetic procedures include dermatologists and plastic surgeons. In 2005, there were approximately 16,000 physicians within the specialties of dermatology and plastic surgery according to the American Board of Medical Specialties. Manufacturers of aesthetic systems have placed an increasingly important focus on sales to other physician groups including approximately 67,000 family practitioners, 38,000 obstetricians and gynecologists, and 36,000 general surgeons. Additionally, physician directed medi-spas and non-medical day spas have entered the aesthetics market.

Broader Range of and Accessibility to Safe and Effective Treatments. Technological developments have made non-invasive treatment alternatives increasingly safe and effective. These technological developments have also reduced the required treatment and recovery time from invasive surgical procedures, which in turn have led to greater patient demand. These factors, along with the easy-to-use and low-cost nature of these products, have attracted both traditional and non-traditional practitioners to aesthetic procedures.

Market Shift Towards Less Invasive Procedures. Market trends confirm that patients are moving away from invasive procedures towards minimally-invasive or non-invasive treatments. Notably, the American Society for Aesthetic Plastic Surgery reports that from 2000 to 2005 the total number of laser skin resurfacing procedures increased from approximately 117,000 to 476,000 procedures, representing a 32% compounded annual growth rate, and the total number of Botox injection procedures increased from 1.1 million to 3.3 million injections over the same period, representing a 25% compounded annual growth rate. 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 rate over the next five years, according to the Millennium Research Group.

Changing Practitioner Economics. Managed care and government payor reimbursement restrictions in the United States, and similar payment-related constraints outside the United States, are motivating practitioners to establish or expand their elective aesthetic practices with procedures that are paid for directly by patients. We expect this trend to continue as physicians look for ways to expand their practices.

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Increasing Acceptance of Aesthetic Procedures. Mass-market television shows like *Extreme Makeover* and *The Swan* reflect the mainstream acceptance of aesthetic procedures. Additionally, features in many popular television and print media have the effect of widely advertising the aesthetic procedures undertaken by celebrities, enhancing the glamour associated with and demand for self-improving treatments.

Similar market trends also exist outside the United States, where demand for non-invasive aesthetic procedures has also experienced strong growth. Manufacturers of non-invasive aesthetic devices typically derive one-third to one-half of their revenue from international sales.

Aesthetic Procedures for Skin and Their Limitations

Many medical treatments are available to treat wrinkles, rejuvenate the skin and give a patient a more youthful appearance. The most popular treatments include invasive surgical procedures, minimally-invasive needle injections and non-invasive energy-based procedures.

Surgical Procedures

Of the various aesthetic alternatives for reducing wrinkles and rejuvenating appearance, invasive surgical procedures, such as cosmetic eyelid surgery, tummy tucks and facelifts, can create the most pronounced and long-lasting changes in appearance. They are performed by plastic surgeons with the patient under general anesthesia.

Market Data. Approximately 230,000 eyelid procedures, 169,000 tummy tucks and 150,000 facelifts were performed in the United States in 2005, according to the American Society for Aesthetic Plastic Surgery.

Limitations. Compared to alternative treatments, invasive surgical procedures are expensive, costing thousands of dollars, and can involve weeks of post-surgical recovery and time away from work. They carry risk of hematoma, or accumulation of blood under the skin that may require removal, infection and adverse reactions to anesthesia.

Injections

Popular alternatives for temporarily improving appearance and reducing wrinkles include Botox and soft tissue fillers, such as Restylane, that are injected into the skin. These injections are typically administered by dermatologists at a cost of several hundred dollars. In most instances, they involve little or no restricted recovery time for the patients.

Market Data. Approximately 3.3 million Botox and 1.6 million soft tissue filler injections were administered in 2005, according to the American Society for Aesthetic Plastic Surgery.

Limitations. The effects of these procedures are temporary and require repeat treatment, with Botox lasting from three to four months and injectable fillers typically lasting from three to six months.

Laser Treatments

Lasers and other light-based devices are used to perform skin rejuvenation, to temporarily reduce wrinkles and to perform other aesthetic procedures, such as hair removal and vein treatment. Light-based skin

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rejuvenation, or resurfacing, procedures can be either ablative or non-ablative. Ablative treatments, also known as laser peels, intentionally burn away the epidermis to heat the dermis and to stimulate collagen growth. Non-ablative rejuvenation treatments typically use less energy and employ gels or other substances in order to insulate the epidermis from damage during the treatment. Because they are less intense than ablative lasers, non-ablative procedures typically involve little downtime or recovery.

Market Data. According to the American Society for Aesthetic Plastic Surgery, there were over 470,000 laser skin resurfacing procedures performed in 2005. The Windhover/Medtech Insight Report estimates that 69% of these treatments were non-ablative.

Limitations. Ablative treatments, or laser peels, like surgery, are performed under general anesthesia and can involve weeks of post-surgical recovery and time away from work. Non-ablative light-based procedures are often effective in hair removal and other procedures targeting the epidermis. However, the nature of light makes it challenging to reach the depth of the subcutaneous fat layer. Penetration of light, and consequently the ability to produce heat, is physically limited by the wavelength of the light, the light's natural tendency to scatter within tissue and the absorption of this energy by specific chromophores within the body, such as water, blood and pigmentation. Non-ablative wrinkle treatments typically require multiple sessions, from four to six treatments spread two to four weeks apart per treatment.

These 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 effect from a single procedure that involves little or no downtime.

The Thermage Solution

We believe that our Thermage procedure provides a compelling treatment alternative to treat 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 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, trained and 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.

Benefits of the Thermage Solution

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

Controlled Heating of Collagen through Clinically-Proven Technology. Because RF energy delivery depends on tissue resistance and not on optical light absorption, it can penetrate to a much greater depth than conventional lasers. Delivery of heat into the subcutaneous fat layer of the skin shrinks and shortens collagen strands. Over time, new collagen strands may grow and add strength and reduce the prominence of folds, lines and other wrinkles. Our monopolar RF heating approach delivers energy into the subcutaneous fat layer of the skin where an electrical current can travel along the collagen fibrous septae and cause the heating and contraction of these collagen strands in order to reduce wrinkles. Clinical trials and published independent scientific data corroborate the Thermage procedure's tissue-tightening effect. This body of data provides potential physician

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customers with objective evidence that they can evaluate when considering a purchase of our system.

Non-Invasive, Non-Ablative Alternative to Surgery. The Thermage procedure is non-invasive, involving no surgery or injections, and offers an alternative to surgery at a lower price with little or no downtime from patients' normal routines. It is also a non-ablative procedure that causes minimal temporary surface tissue damage. If desired, the Thermage procedure can be used in a complementary fashion in conjunction with invasive therapies such as liposuction, facelift and thread implants, as well as injectable fillers and other minimally-invasive and non-invasive aesthetic procedures.

Single Procedure Treatment. 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. Studies have shown clinical effect from a Thermage procedure that is both immediate and that can improve over a measurement period of six months following treatment. In addition, Thermage procedures have been used effectively on all skin types and tones and on various areas of the body where wrinkle reduction is desired.

Compelling Physician Economics. We believe physicians are compensated more per hour by performing Thermage treatments than other non-invasive aesthetic device treatments. The ThermoCool system currently requires lower capital costs than competing laser and RF systems, while average procedure fees for Thermage treatments generally exceed our competitors. We continue to design new ThermoTips to address new applications without requiring additional equipment purchase.

Ease of Use. The ThermoCool system incorporates a straightforward user interface that allows a trained physician to easily perform procedures across various parts of the body. Different treatment sites may use different tips, each of which is pre-customized by size, pulse counts, pulse durations and heating profile to the intended procedure. The system provides real-time feedback and can be adjusted during the procedure as needed. The handpiece is designed with a small profile for accurate placement during treatment, comfort and ease of use.

Our Technology

Our ThermoCool system uses our patented method of delivering monopolar RF energy for heating collagen.

Monopolar Radiofrequency. Monopolar RF delivery uses two electrodes, with one active electrode being held in the device handpiece by the physician and the second, a passive return electrode, typically attached to the patient's back. Monopolar delivery allows for precise administration of energy because the electrical current is concentrated where the active electrode touches the body and disperses quickly as it travels towards the return electrode. The monopolar RF process is distinct from bipolar RF-based technology, which is superficial, relying on current passing through tissue located between two probes placed close together on the surface of the skin. We believe that monopolar technology delivers energy effectively to a greater tissue depth than bipolar technology.

The ThermoTip Capacitive Coupling Mechanism of Action for Collagen Heating. The single-use ThermoTip device contains our patented technology that uses monopolar RF energy as a controlled tissue heating source through the use of a non-conducting material, known as a dielectric. Capacitive coupling is the use of the dielectric to create an electric field in the area where our ThermoTip touches the body. The electric field induces a current within the surrounding

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tissue, resulting in heating of the tissue due to the tissue's natural resistance to electrical current flow. The heating depth is based upon the size and geometry of the ThermaTip and can be controlled from a few hundred microns to several millimeters in depth, depending upon the particular ThermaTip selected for various treatment areas. Collagen is a more efficient conductor of electricity than fat tissue and therefore acts as a pathway for the electric current. This process results in preferential heating of the fibrous septae, the strands of collagen fibers that permeate the dermis and hypodermis and connect skin to the underlying bone and muscle. Delivery of heat to the fibrous septae located in deeper layers of the skin shrinks and shortens them, resulting in tightening of the epidermis and subcutaneous tissue. Over time, new collagen strands may grow as part of the body's natural healing process. These new strands may add strength and produce additional skin tightening over the next two to six months. This tightening of the skin has the ability to reduce the prominence of folds, lines and other deep wrinkles. To achieve this deep heating with simultaneous surface cooling, the surface of the ThermaTip transmits RF energy to the skin while serving as a dynamic contact cooling membrane for the cryogen spray. The contact membrane continually monitors skin surface temperature to help protect the epidermis.

Comfort and Safety. Since the initial launch of our ThermaCool system, we have monitored and revised our procedure protocol to promote safe and comfortable delivery of RF energy and cryogen cooling to the treatment site. An energy-based aesthetic treatment, if not used according to the manufacturer's protocol, has the potential to cause patient discomfort, irritation or surface tissue burning. We have designed our ThermaCool system to minimize the risk of these types of occurrences through stringent built-in safety precautions in addition to extensive user training. Our system regulates a combination of inputs to precisely and uniformly distribute RF energy over the treatment site, including temperature and pressure sensors at each corner of the ThermaTip and pre-programmed power levels and times for specific treatments. In April 2004, we introduced a new procedure protocol that we believe improves patient comfort.

Our ThermaCool System

Our ThermaCool system includes three major components: the RF generator, the reusable handpiece and a single-use ThermaTip, as well as several consumable accessories. Physicians attach a single-use ThermaTip to the handpiece, which is connected to the ThermaCool RF generator. The ThermaCool generator authenticates the ThermaTip device and programs the ThermaCool system for the desired treatment without physician intervention.

Radiofrequency Generator. The ThermaCool RF generator produces a six-megahertz signal and is simple and efficient to operate. Controls are within easy reach, and important user information is clearly displayed on the built-in display, including energy delivered, tissue impedance, duration and feedback on procedure technique. Our cooling module works in conjunction with the generator to deliver cryogen that cools and helps to protect the epidermal surface during a Thermage procedure. As of June 30, 2006, we had an installed base of over 1,800 ThermaCool RF generators.

Handpiece. The reusable handpiece holds the ThermaTip in place for the treatment and processes information about skin temperature and contact, treatment force against the skin, cooling system function and other important data. A precision control valve within the handpiece meters the delivery of cryogen, which cools and protects the epidermal surface.

ThermaTip. The ThermaTip device is available in four sizes with several configurations of pulse counts, pulse durations and two heating profiles for efficient implementation of treatment guidelines, based on the size and nature of the treatment area. Physicians currently can order pre-sterilized ThermaTips in sizes of 0.25 cm², 1.0 cm², 1.5 cm² and 3.0 cm². Each ThermaTip

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contains a proprietary internal EPROM, or programmable memory chip, that controls the firing profile of the tip in order to enhance performance and safety in the selected treatment. To enhance procedural safety, we have also programmed the EPROM contained in ThermaTips for single-use treatments. Using the same ThermaTip to perform multiple treatments could result in injury, as a result of the eventual breakdown of the ThermaTip's dielectric coating. Therefore, the EPROM ensures that the ThermaTip is not reused following a particular procedure. Since the introduction of our ThermaCool system in 2002 and through June 30, 2006, we had sold over 275,000 ThermaTips, which we estimate represent an approximately equal number of Thermage procedures performed.

Our system also includes other consumable components in addition to ThermaTips. The cooling module houses a canister of cryogen coolant that can be used for an average of five to six procedures, depending on the total skin surface area treated and the ThermaTip device used. Each patient procedure also requires a return pad, which is typically adhered to the patient's lower back to allow a path of travel for the RF current through the body and back to the generator. We also sell proprietary coupling fluid, a viscous liquid that helps ensure electrical and thermal contact with the ThermaTip device.

Our Thermage Procedure

In order to perform our Thermage procedure, the physician selects a single-use ThermaTip 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;

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

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 marks the treatment area with a temporary grid pattern tattoo, corresponding to the size of the ThermaTip, which is easily wiped away post-procedure. The return pad is then adhered to the patient's lower back to allow a path of travel for the RF current back to the generator. After the application of a conductive fluid, each square of the grid is treated.

For each grid square, the physician places the tip against the patient's skin and depresses the handpiece button. The handpiece processes information from the tip about skin temperature and contact, treatment force against the skin, cooling system function and other important data. The information from the handpiece is sent to the console in order to generate the proper RF signal. A precision control valve within the handpiece also regulates the delivery of cryogen, which cools and protects the skin's surface. The ThermaTip device transmits RF energy to the skin while serving as a contact cooling membrane for the cryogen spray. Our system monitors a combination of inputs, such as temperatures, power levels and delivery duration, to precisely and safely control the RF energy and cooling delivery to each treatment site.

Patients feel alternating sensations of heat and cold during the procedure and some physicians elect to use a topical anesthetic or an oral pain medication. 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. Patients may notice immediate improvement in the appearance of wrinkles and are typically able to resume normal activities immediately after having the procedure. Over the subsequent two to six months, patients may experience further

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reduction of wrinkles at the site of the treated skin as new collagen strands grow and reinforce the strands shrunk by the treatment.

As with other non-invasive energy-based devices, the beneficial 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. Burns and blisters may occur either as a result of improper use of the device or as a result of a breakdown in the dielectric material within the ThermoTip.

Prior to April 2004, we trained physicians to follow a procedure protocol, or treatment guidelines, of fewer energy pulses on the skin at higher energy levels. This initial protocol, along with instances of poor operator technique, resulted in reported patient comfort challenges. We modified our procedure protocol in April 2004, and we retrained and recertified our physician customers on the new procedure protocol. The new procedure protocol involves lower energy levels with an increased number of pulses at the treatment site. We believe these modifications have generally increased patient comfort.

Published peer reviewed clinical studies of the Thermage procedure have been performed primarily on the face, using a single treatment. These studies included patients that experienced a range in effect from no improvement to significant improvement. Most experienced modest improvement from a single treatment. There are no published peer reviewed studies regarding the safety or effectiveness of our new 3.0 cm² ThermoTip, which has essentially replaced our 1.0 cm² and 1.5 cm² ThermoTips, our new 0.25 cm² ThermoTip or our current procedure protocol, which involves use of more energy pulses at a lower power. However, based upon our own research and unpublished clinical studies, we believe that the Thermage procedure using our new ThermoTip and protocol are at least as safe and effective.

Our Customers

To date, we have focused on physician customers who have a demonstrated commitment to building a high-volume, non-invasive, aesthetic skin-tightening business within their practice. We have found physicians with an active aesthetics practice tend to perform more Thermage procedures after purchasing our machine than physicians who are new to aesthetic medicine. We encourage our sales force to work closely with our target physician customers to accelerate growth in their aesthetics practices, which, in turn, generates more ThermoTip sales for our company. As a broader group of physicians are adding non-invasive aesthetic procedures to their practices, our target physician base is expanding to include not only plastic surgeons and dermatologists, but also obstetricians, gynecologists and general practitioners. Plastic surgeons and dermatologists currently represent the majority of our market. Many of these physicians are seeking a less expensive alternative to the invasive procedures that they offer in order to augment their customer base and establish a relationship with those patients that do not desire, or cannot afford, an invasive procedure.

Business Strategy

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

Driving Increased ThermoTip Usage. Unlike the capital equipment model of the traditional laser business, because of the disposable nature of our ThermoTips, we maintain an active, continuous relationship with our customer base. 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. We believe that our customers' interests are closely aligned with our own, and we monitor the market to foster continued procedure growth for our

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customers and ThermoTip sales for us. With innovative marketing programs, such as our PatientBuilder.com resource, our sales force works with physician customers to develop a profitable Thermage procedure practice.

Developing New Applications and Treatment Tips. We intend to expand our line of ThermoTips for additional applications and conditions such as cellulite. Our products currently have FDA clearance for the non-invasive treatment of wrinkles and rhytids. 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. We believe that our intellectual property rights protect our position as the exclusive provider of wrinkle treatment using monopolar RF technology in the United States. Because our technology is RF-based and not light-based, we believe we are less exposed to the litigation, licenses and royalties that have been common in the aesthetic laser market. In June 2005, we settled a lawsuit with Syneron, which admitted the validity of six of our patents. As of June 30, 2006, we had 25 issued U.S. patents primarily covering our ThermoCool system and methods of use, the earliest of which will not expire until 2015, 14 pending U.S. patent applications, eight issued foreign patents and 41 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries.

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 believe the size of the international market is comparable to the U.S. market, and we are focused on increasing our market penetration overseas and building global brand-recognition. In 2005, approximately 44% of our revenue originated outside of the United States. We intend to add distributors and sales support staff to increase sales and strengthen physician relationships in international markets.

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 products for the aesthetics market.

Sales and Marketing

We sell our ThermoCool system to physicians in the United States through a direct sales force of trained sales consultants. As of June 30, 2006, we had a 29-person U.S. direct sales force, including three regional sales managers, a vice-president and a practice management specialist. Outside of the United States, we sell our ThermoCool system to physicians in 70 countries through 29 independent distributors.

United States Sales

Our strategy to increase sales in the United States is to:

continue to position the Thermage procedure as an attractive alternative to other aesthetic treatments for wrinkle reduction;

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work closely with our physician customers to increase product usage and enhance the marketing of Thermage procedures in their practices;

leverage direct-to-consumer marketing campaigns; and

selectively expand our sales efforts to reach physicians outside of the traditional specialties for aesthetic procedures. Further, we actively engage in promotional opportunities through participation in industry tradeshows, clinical workshops and company-sponsored conferences with expert panelists, as well as through trade journals, brochures and our website. We have an active media presence, and have been highlighted on such national broadcasts as *Oprah*, *Good Morning America*, and *E! Live from the Red Carpet*, as well as numerous local news programs.

Consultative Sales Process. Through our consultative sales process, we form strong relationships with our customers through frequent interactions. Beyond performing initial system installation and on-site training and certification, which can occur within two weeks of a physician's purchase decision, our sales consultants provide consultation to physicians on how to integrate our system into their practices and market procedures to their patients. Our sales consultants' compensation structure emphasizes treatment tip sales and customer service over capital equipment sales, although our sales force also has incentives to generate new accounts through system sales. We require our sales consultants to invest substantial time in training and servicing our physician customers, and therefore we discourage sales to physicians who do not show the potential to drive aesthetic procedure volume.

Physician Training and Certification. We provide comprehensive training and education to each physician before we deliver the ThermoCool system. We require this initial training to assist physicians in safely and effectively performing the Thermage procedure. The majority of physicians operating our installed base of ThermoCool systems have pursued and met the advanced training criteria that we establish. To signify their achievement, we award a Certificate of Training to these physicians and identify them within the physician locator on our website with a small certificate icon next to their names. We do not identify physicians within our physician locator unless they have met these training requirements.

PatientBuilder.com. To enhance the consultative sales process, we provide access to easily implemented marketing tools and materials through an exclusive arrangement with PatientBuilder.com. Accessed through our website, PatientBuilder.com enables physicians to create professional marketing campaigns for their own Thermage services, while protecting our brand. Using PatientBuilder.com, physicians can create direct mail pieces and a selective mailing list based on targeted patient demographics in their local areas, print ads for magazines and newspapers, printed brochures and an individually tailored website. We have also produced television commercials that physicians can use in the event that they would like to purchase local airtime.

Direct-to-Consumer Marketing. In 2005, we launched direct-to-consumer, or DTC, marketing campaigns designed to build brand awareness and recognition, demonstrate our commitment to supporting our physician customers and distributors and increase demand for Thermage procedures. Currently, our DTC marketing efforts are focused primarily on paid Internet search results, through websites such as Google and Yahoo!, and banner ads placed strategically on websites targeting people who may be seeking aesthetic procedures. Also, our website at www.thermage.com has a separate patient area that includes information on our ThermoCool system, the underlying technology and potential treatment outcomes, as well as short films and listings of local physicians who offer Thermage procedures. We have observed our website traffic increase significantly following national television appearances and their periodic re-broadcasts.

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Expansion into Non-Traditional Specialties. The majority of our systems sales to date in the United States have been made to dermatologists and plastic surgeons. These physicians constitute the traditional specialties focused on aesthetic procedures. However, by broadening our direct sales efforts to selectively target non-traditional practitioners within the gynecology, primary care, ophthalmology and ear, nose and throat specialties whose practices may be complemented by our aesthetic procedures we hope to increase sales of our systems and consumable products. Also, we hope to generate additional revenue by increasing our penetration into the growing medi-spa market, which is comprised of physicians offering aesthetic treatments in a spa setting.

International Sales

As of June 30, 2006, we had an international sales team of 11 employees supporting 29 independent distributors who market our ThermaCool system in 70 countries. We require our distributors to provide customer training, to invest in equipment and marketing and to attend certain exhibitions and industry meetings. The percentage of our revenue from customers located outside the United States was approximately 28% and 44% in fiscal 2004 and 2005, respectively.

Our strategy to grow sales outside the United States is to:

increase penetration of our ThermaCool system in international markets in which our ThermaCool system is currently sold;

expand into attractive new international markets by identifying and training qualified distributors; and

expand our DTC marketing campaigns into select international markets.

Competition

Our industry is characterized by intense competition and rapid innovation. For example, laser devices have advanced rapidly over the past decade, with a variety of technologies available for a wide range of applications. Most recently, other types of devices have been developed that are competitive in the area of wrinkle reduction, such as those based upon filtered light, bipolar RF energy and ultrasound. We compete directly against laser and other energy-delivery devices offered by public companies, including Candela, Cutera, Cynosure, Lumenis, Palomar Medical Technologies and Syneron, as well as by many private companies. Our ThermaCool system also competes with other wrinkle reduction solutions, including Botox and collagen injections, soft tissue fillers, chemical peels, microdermabrasion and liposuction, as well as cosmetic surgical procedures such as face lifts, blepharoplasty and abdominoplasty. Additionally, less invasive surgical solutions, such as implanted sutures, have been developed that may offer a compelling alternative to facelifts.

Competition among providers of medical devices and other treatments for the aesthetics market is characterized by extensive research efforts and rapid technological progress. 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 would compete directly with ours. In addition, we have encountered and expect to continue to encounter physicians who, due to relationships with our competitors or the nature of their practice, will not purchase our ThermaCool system.

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Research and Development

Our research and development efforts currently focus on:

designing new treatment tips optimally designed for new clinical applications, such as cellulite, as well as specific areas of the body, such as arms, the abdomen and hands;

developing a new proprietary generator platform with greater power to enable larger treatment tips and expanded applications and improved ease of use;

identifying and incorporating new or modified dielectric materials and processes to mitigate the risk of dielectric breakdown;

increasing security against the use of devices designed to enable re-use of treatment tips, resulting in procedure efficacy and safety concerns; and

modifying our cooling system as necessary to maintain compliance with changes in environmental regulations.

As of June 30, 2006, we had a staff of 12 technical professionals focused on product development projects and a research staff of three. We have also formed strategic relationships with outside contractors for assistance on specialized projects, and we work closely with experts in the medical community to supplement our internal research and development resources. Research and development expenses for 2003, 2004 and 2005 were \$6.6 million, \$8.5 million and \$8.9 million, respectively. In the future, we expect to pursue further research and development initiatives to improve and extend our technological capabilities and to foster an environment of innovation and quality.

Patents and Proprietary Technology

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of June 30, 2006, we had 25 issued U.S. patents primarily covering our ThermoCool TC system and methods of use, the earliest of which expire in 2015; 14 pending U.S. patent applications, eight issued foreign patents and 41 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries. We intend to file for additional patents to strengthen our intellectual property rights.

In addition to the use of RF-based energy, our patent portfolio covers use of other non-ablative energy modalities, including, but not limited to, microwaves, ultrasound and optical wavelengths. Our patent applications may not result in issued patents, and we cannot assure you that any patents that issue will protect our intellectual property rights. Third parties may challenge any patents issued to us as invalid, may independently develop similar or competing technology or may design around any of our patents. We cannot be certain that the steps we have taken will prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights in these foreign countries as fully as in the United States.

In July 2004, we filed a lawsuit against Syneron in the United States District Court, Northern District of California. In that lawsuit, we sought damages and injunctive relief for infringement of six of our patents that we alleged were infringed by Syneron's systems for non-invasively treating skin. Syneron subsequently filed a patent infringement counterclaim against us. As a result of a settlement reached in June 2005, Syneron and we have granted each other a non-exclusive paid-up license under the patents asserted in the lawsuit and related patents under the parties' control. In addition, Syneron paid us a one-time sum of \$1.8 million. We excluded from this license any rights to utilize monopolar RF technologies and capacitive electrical coupling, which we

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believe in combination allow the Thermage procedure to create a reverse thermal gradient and deep, near uniform, volumetric heating to achieve tissue tightening effects. Syneron excluded from its license any patents related to its proprietary Electro-Optical Synergy technology. Both parties admitted the validity of all patents in the litigation, but neither admitted any wrongdoing or liability.

In addition, 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. Patent litigation is very expensive and could divert management's attention from our core business. We have in the past and may in the future offer certain of our intellectual property rights for license to our competitors. As of June 30, 2006, we have not entered into any such licenses with our competitors other than our license with Syneron. We granted Edward Knowlton, one of our founders and inventor of our original patents, an exclusive license under those original patents and related patents for certain non-cosmetic applications.

Thermage, ThermaCool and ThermaCool TC are registered trademarks in the United States and several foreign countries. As of June 30, 2006, we have 54 pending and registered trademark filings worldwide, some of which apply to multiple countries, providing coverage in 48 countries. We intend to file for additional trademarks to strengthen our trademark rights, but we cannot be certain that our trademark applications will issue or that our trademarks will be enforceable.

All employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived or made in connection with the employment or consulting relationship. We cannot provide any assurance that employees and consultants will abide by the confidentiality or invention assignment terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary.

Clinical Research

As of June 30, 2006, our clinical research department had staff of eight that included clinical research associates and imaging specialists. This department compliments our product development efforts by conducting in-house bench and animal testing for the development and evaluation of products and by providing support to scientific and clinical studies conducted by investigators and institutions studying the use of our technologies. The department also is able to assist outside investigators who seek our help in writing protocols, collecting data, site monitoring and performing research.

As part of our clinical research, we have studied and continue to study the interaction of RF energy and tissue, both to understand the mechanism of action of the Thermage procedure and to guide our efforts to develop new products and treatments. We have used transmission electron microscopy on biopsied tissue samples to corroborate that our products induce the denaturing of collagen that leads to immediate tissue tightening. We have developed histology techniques to investigate the depth of heat in tissue and a wound healing process that we believe is responsible for long-term improvement and tightening of tissue. We have also created three-dimensional computer models to study tissue heating with our products. Determining the effectiveness of an aesthetic treatment is inherently a subjective evaluation. When performing our clinical research and studies, we attempt to utilize the most compelling measures we can in order to provide compelling evidence of efficacy.

As of June 30, 2006, there were 23 peer-reviewed scientific journal articles discussing the effects of our RF technology, and both physicians affiliated with our company as clinical and scientific advisors and unaffiliated physicians had presented 18 abstracts at medical conferences.

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Manufacturing

Our manufacturing strategy involves the combined utilization of our internal manufacturing resources and expertise, approved suppliers and contract manufacturers. We perform certain value-added and proprietary manufacturing processes at our facility in Hayward, California. In addition, we outsource the manufacture of components, subassemblies and certain finished products that are produced to our specifications and shipped to our facility for final assembly or inspection, testing and certification. Finished product is stored at and distributed primarily from our Hayward facility. Quality control, risk management, efficiency and the ability to respond quickly to changing requirements are the primary goals of our manufacturing operations.

We have arrangements with our suppliers that allow us to adjust the delivery quantities of components, subassemblies and finished products, as well as delivery schedules, to match our changing requirements. The forecasts we use are based on historical trends, current utilization patterns and sales forecasts of future demand. Lead times for components, subassemblies and finished products may vary significantly depending on the size of the order, specific supplier requirements and current market demand for the components and subassemblies. Most of our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, the components used in our devices.

Our current generation RF generator and cooling module are manufactured for us exclusively by Stellartech, a medical device manufacturer in California. We do not believe that we could replace this supplier without significant effort and delay in production. We also obtain programmable memory chips for our treatment tips and the coolant valve for our handpiece from single suppliers, for which we attempt to mitigate risks through inventory management and utilization of 12- to 18-month purchase orders, and sterilization services from a single vendor, for which we attempt to mitigate risks by using two sterilization chambers at each of two locations. Other products and components come from single suppliers, but alternate suppliers have been qualified or, we believe, can be readily identified and qualified. In addition, the availability of cryogen for our cooling module, which we can source from multiple suppliers, may fluctuate due to changes in the global supply of this material. To date, we have not experienced material delays in obtaining any of our components, subassemblies or finished products, nor has the ready supply of finished product to our customers been adversely affected.

We are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR. The QSR covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. We maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. These certifications include EN ISO 9001:2000 and CAN/CSA ISO 13485:1998/ISO 13485:1996 and are also required to maintain our product registration in a number of other foreign markets such as Canada.

We use small quantities of common cleaning products in our manufacturing operations, which are lawfully disposed of through a normal waste management program. We do not forecast any material costs due to compliance with environmental laws or regulations. In addition, we are working to develop an alternative cooling system for our ThermaCool system which is not dependent upon hydrofluorocarbons, a class of substances which is being phased out by new international environmental regulations.

Services and Support

We strive to provide highly responsive service and support for both our ThermaCool RF generator and our single-use ThermaTip products.

Our ThermaTips are shipped from finished goods inventory typically on the day of the order. All ThermaTips are identified with lot numbers and date codes that indicate the expiration date of the product and are

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fully warranted until the date of expiration. We maintain a staff of customer service personnel in our Hayward, California facility that is available by phone to our customers to answer questions regarding the use of our ThermaCool system. In addition, in the United States our direct sales force provides on-site support and training to our customers in the use of our ThermaCool system.

In the United States, our ThermaCool RF generator and accessory products are shipped to a customer's site for initial installation and training by one of our direct sales consultants. Our direct sales force, our customer service personnel and our product service staff provide post-installation support and service. In the event of a failure of a ThermaCool RF generator, our customer service department arranges for the immediate shipment of loaner equipment to the customer for its use during the time that the equipment is being repaired. Our goal is to minimize the disruption caused by a service event, and our customers typically receive loaner equipment within one day after notifying us of a problem. In addition, we arrange for the customer's equipment to be returned to our Hayward facility where we confirm and diagnose the problem. Any necessary repairs are performed either at our facility or, in the case of the ThermaCool RF generator or cooling module, at our contract manufacturer's facility. All ThermaCool RF generators are serialized, and device history records are maintained that track service history and configuration. In markets outside of the United States, our ThermaCool system is serviced and supported through our independent distributors.

Government Regulation

Our ThermaCool system is a medical device subject to extensive and rigorous regulation by the FDA, as well as other regulatory bodies. FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design and development;

product testing;

product manufacturing;

product safety;

product labeling;

product storage;

recordkeeping;

premarket clearance or approval;

advertising and promotion;

production; and

product sales and distribution.

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical de