THERMAGE INC
Form 10-K
March 30, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For fiscal year ended December 31, 2006

Commission File Number: 001-33123

THERMAGE, INC.

(Exact name of registrant as specified in its charter)

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

25881 Industrial Boulevard,

Hayward, California 94545

(510) 782-2286

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	**The NASDAQ Stock Market, Inc.**

Securities Registered Pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

* The Registrant has not been subject to the filing requirements for the past 90 days as it commenced trading following its initial public offering on November 9, 2006, but has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 since such time.

The number of shares of Registrant s common stock issued and outstanding as of February 28, 2007 was 23,011,374.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant s definitive proxy statement for the 2007 Annual Meeting of Shareholders.

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THERMAGE, INC.

ANNUAL REPORT ON FORM 10-K

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PART I

Item 1. ***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 dermis and subcutaneous tissue while simultaneously cooling and protecting the surface of the skin. The heating and shrinking of the collagen can cause a healing process to begin, which may further tighten the skin and reduce wrinkles over the next two to six months. The Thermage procedure is normally performed in a medical office setting as a single treatment that takes from 20 minutes to two hours, depending on the treatment area. The Thermage procedure provides patients seeking wrinkle reduction as 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 77 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 December 31, 2006, we had an installed base of over 2,000 ThermaCool RF generators and had sold over 350,000 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 the formation of rhytids, or 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

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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 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 2006, total expenditures for aesthetic procedures were approximately $12.2 billion. From 2000 to 2006 the total number of aesthetic procedures increased from approximately 5.7 million to over 11.5 million procedures, representing a 12% compounded annual growth rate. Non-invasive aesthetic procedures were primarily responsible for the overall increase, rising from approximately 4.3 million to approximately 9.5 million procedures over the same period, representing a 14% 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 2006, there were approximately 17,000 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 71,000 family practitioners, 41,000 obstetricians and gynecologists, and 41,000 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 2006 the total number of laser skin resurfacing procedures increased from approximately 117,000 to 577,000 procedures, representing a 30% compounded annual growth rate, and the total number of Botox injection procedures increased from 1.1 million to 3.2 million injections over the same period, representing a 19% 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 210,000 eyelid procedures, 172,000 tummy tucks and 138,000 facelifts were performed in the United States in 2006, 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 3.2 million Botox and 1.9 million soft tissue filler injections were administered in 2006, 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 577,000 laser skin resurfacing procedures performed in 2006 and 93% 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 ThermaCool system consists of an RF generator with cooling capability through the delivery of a coolant to protect the outer layer of the skin from over-heating and a handpiece that, in conjunction with a single-use ThermaTip, regulates epidermis cooling and monitors treatment data. Our system also includes a variety of single-use ThermaTips 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 procedures, 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. 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. Our own clinical experience demonstrates, and published independent, along with affiliated,

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scientific data corroborates, the Thermage procedure s tissue-tightening effect. This body of data provides potential physician 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 ThermaCool 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 ThermaTips to address new applications without requiring additional equipment purchase.

Ease of Use. The ThermaCool 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 ThermaCool 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 ThermaTip Capacitive Coupling Mechanism of Action for Collagen Heating. The single-use ThermaTip 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

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dielectric. Capacitive coupling is the use of the dielectric to create an electric field in the area where our ThermaTip touches the body. The electric field induces a current within the surrounding tissue, resulting in volumetric 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 dermis 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 in 2002, we have monitored and revised our procedure guidelines to safely and effectively deliver RF energy and cryogen cooling to the treatment site with minimal discomfort to the patient. 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 new procedure guidelines that we believe improved 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. Cooling is achieved in conjunction with the generator to deliver a coolant that cools and helps to protect the epidermal surface during a Thermage procedure. As of December 31, 2006, we had an installed base of over 2,000 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.

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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 cm^2, 1.0 cm^2, 1.5 cm^2 and 3.0 cm^2. Each ThermaTip contains a proprietary internal EPROM, or programmable memory chip, which stores treatment parameters and safety limits in order to optimize 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 December 31, 2006, we had sold over 350,000 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 system houses a canister of coolant that can be used for an average of three 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.

In February 2007, we introduced and began shipment of the ThermaCool® NXT, our next generation system. The ThermaCool NXT has been redesigned to save time, reduce procedure cost, simplify the treatment experience and improve clinician comfort. Advances to the technology include a streamlined operating system which speeds treatment times; a lighter, more ergonomic handpiece with remote controls; and a sleek new design with a smaller footprint that takes up 50 percent less floor space than its predecessor.

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 cm^2 tip, designed for the treatment of large areas;

Eyes by Thermage, which involves the use of a small, 0.25 cm^2 tip, designed for the treatment of eyelids;

Face by Thermage, which involves the use of 3.0 cm^2, 1.5 cm^2 or 1.0 cm^2 tip sizes, designed for the treatment of the face and neck;

Tummy by Thermage, which involves the use of 3.0 cm^2 tip size, designed for the treatment of the abdomen; and

Hands by Thermage, which involves the use of 1.5 cm^2 tip size, designed for the treatment of the hands.

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.

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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 cold and heat 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 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 duration and the extent of 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 ThermaTip.

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.

Our 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. When comparing results of a single treatment with results of multiple treatments over time, we have not found a material difference between the two. Our studies typically follow patients over six months, though we have studied patients for up to a year. Generally, results have found improvement in the effect of the treatment increasing up to six months following treatment. Our study results going out one year indicate that if a patient has improvement at six months, the patient will likely have lasting improvement at 12 months. There are no published peer reviewed studies regarding the safety or effectiveness of our new 3.0 cm^2 ThermaTip, which has essentially replaced our 1.0 cm^2 and 1.5 cm^2 ThermaTips, 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 have demonstrated that the Thermage procedure using our new ThermaTips 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

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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 ThermaTip 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 existing customers. 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 ThermaTip Usage. Unlike the capital equipment model of the traditional laser business, because of the disposable nature of our ThermaTips, we maintain an active, continuous relationship with our customer base. We work collaboratively with our customer base to increase ThermaTip 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 customers and ThermaTip 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 ThermaTips for additional applications and conditions. We recently received FDA clearance to market the TherMassager, an accessory to our ThermaCool system, for the temporary improvement in the appearance of cellulite and for therapeutic massage, which we currently intend to commercially launch in 2007. We 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 December 31, 2006, we had 28 issued U.S. patents primarily covering our ThermaCool system and methods of use, the earliest of which will not expire until 2015, 13 pending U.S. patent applications, 15 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

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and building global brand-recognition. In 2006, approximately 48% 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 ThermaCool system to physicians in the United States through a direct sales force of trained sales consultants. As of December 31, 2006, we had a 31-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 ThermaCool system to physicians in 77 countries through 31 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;

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 actively seek opportunities to obtain positive media exposure, have engaged in direct-to-consumer marketing, 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 ThermaCool 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 ThermaCool systems have pursued and met the

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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 search engines 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 ThermaCool 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 and following our DTC efforts.

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 December 31, 2006, we had an international sales team of 12 employees supporting 31 independent distributors who market our ThermaCool system in 77 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 48%, 44% and 28% in fiscal 2006, 2005 and 2004, 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 marketing efforts into select international markets.

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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.

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;
- 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
- developing a new cooling system that integrates a substitute for hydroflurocarbon, to maintain compliance with changes in international environmental regulations.

As of December 31, 2006, we had a staff of 12 technical professionals focused on product development projects and a research staff of two. 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 2006, 2005 and 2004 were $9.6 million, $8.9 million and $8.5 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 December 31, 2006, we had 28 issued U.S. patents primarily covering our ThermaCool TC system and methods of use, the earliest of which expire in 2015; 13 pending U.S. patent applications, 15 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.

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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.

As a result of a settlement of litigation 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. We excluded from this license any rights to utilize monopolar RF technologies and capacitive electrical coupling, which we 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 December 31, 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 December 31, 2006, we have 56 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

Our clinical studies of the Thermage procedure have been performed primarily on the face, using a single treatment, to demonstrate safety and effectiveness. We have conducted a split face study that demonstrated the comparability of our 3.0 cm^2 and 1.5 cm^2 treatment tips. Our study results have shown the Thermage procedure to have a low incidence of injury. The most frequent of these injuries consists of temporary burns related to overheating the skin. Generally, study results of effectiveness demonstrate that the majority of patients are satisfied with their treatment results. Our studies typically follow patients over six months, though we have studied patients for up to a year. Generally, results have found improvement in the effect of the treatment increasing up to six months following treatment. Our study results going out one year indicate that results of the procedure are not temporary. If a patient has improvement at six months, the patient will likely have lasting improvement at 12 months. Additionally, when comparing results of a single treatment with results of multiple treatments over time, we have not found a material difference between the two.

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Our studies consistently include patients that experience a range in effect from no improvement to significant improvement. We believe that our study results generally demonstrate that most patients will obtain modest wrinkle reduction from a single treatment. We typically use multiple approaches to assessing improvement in a patient. The most common approaches are subjective before and after evaluations by the treated patient and by the treating physician. We have also used instruments such as the BTC-2000, which is a device that measures the physical properties of the skin by means of vacuum pressure that pulls an area of skin into a chamber, where lasers are used to measure how far the skin is pulled in, at what rate, and how quickly the skin snaps back. We have also used a widely accepted method known as the Fitzpatrick s Wrinkle Assessment Scale to measure improvement.

As of December 31, 2006, our clinical research department had a 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 December 31, 2006, there were 40 published peer-reviewed scientific journal articles and 24 medical conference abstracts that discuss the tissue-tightening effect of our non-invasive monopolar RF technology, authored both by physicians affiliated with our company as clinical and scientific advisors and by unaffiliated, independent, physicians.

Manufacturing

Our manufacturing strategy involves the combined utilization of our internal manufacturing resources and expertise, approved suppliers and contract manufacturers. Our internal manufacturing activities include the assembly, testing and packaging of ThermaTips and handpieces, as well as the final integration, system testing and packaging of our ThermaCool NXT system. 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.

We 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

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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 13485:2003 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.

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 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 first generation ThermaCool system, at a contract manufacturer s facility. All ThermaCool systems and components are serialized or lot tracked, 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

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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 device we wish to commercially distribute in the United States will require either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting clearance to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring premarket approval. All of our current products are class II devices.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications, or PMA. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial

equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device, or the particular use, into class III.

Radiofrequency devices used for aesthetic procedures, such as wrinkle reduction, have generally qualified for clearance under 510(k) procedures. We received FDA clearance to market our ThermaCool system

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for the treatment of periorbital wrinkles and rhytids in November 2002 and for treatment of facial wrinkles and rhytids in June 2004. In December 2005, we received FDA clearance to market our ThermaCool system for full body treatment of wrinkles. In October 2006, we received FDA clearance to market the TherMassager, an accessory to our ThermaCool system, for the relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local circulation (i.e., blood circulation) and temporary improvement in the appearance of cellulite. We have a pending application for FDA clearance to market our ThermaCool system specifically for the treatment of eyelids, though eyelids are not contraindicated in our clearance. We cannot predict when or if such clearance will be obtained.

Premarket Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device.

No device that we have developed has required premarket approval, nor do we currently expect that any future device or indication will require premarket approval.

Product Modifications

We have modified aspects of our ThermaCool system and accessories since receiving regulatory clearance, and we have made additional 510(k) filings when we deem it necessary. Decisions and rationale not to file a 510(k) for device modifications are documented. After a device receives 510(k) clearance any modification that could affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any decision and disagree with a manufacturer s determination not to file a new 510(k) or PMA. If the FDA disagrees with our determination the FDA may retroactively require us to seek 510(k) clearance or premarket approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Clinical Trials

Clinical trials are almost always required to support an FDA premarket application and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain patients informed consent that complies with both FDA requirements and state and federal privacy regulations. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain clearance or approval of the product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies with high-risk devices, by the Ministry of Health in the applicable country.

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Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- Quality System regulations, or QSRs, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, or CDHS, to determine compliance with the QSR and other regulations. In the past, our facility has been inspected, and observations were noted. The FDA and CDHS have accepted our responses to these observations, and we believe that we are in substantial compliance with the QSR.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, 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 products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products or new intended uses;
- withdrawing 510(k) clearance or premarket approvals that are already granted; and
- criminal prosecution.

If any of these events were to occur, they could have a material adverse effect on our business.

We are also subject to a wide range of federal, state and local laws and regulations, including those related to the environment, health and safety, land use and quality assurance. We believe that compliance with these laws and regulations as currently in effect will not have a material adverse effect on our capital expenditures, earnings and competitive and financial position.

International

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country

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may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. Some countries, such as Japan, have their own governmental approval process through which clinical trial data and other information are submitted to a regulatory authority. In other countries, a medical device may be commercialized if the product has been approved in the United States or in Europe.

The primary regulatory environment in Europe is that of the European Union. The European Union has adopted numerous directives and European Standardization Committees have promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union. The method of assessing conformity varies, depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body, an independent and neutral institution appointed by a country to conduct an assessment of compliance with applicable directives. This third-party assessment may consist of an audit of the manufacturer s quality system, standards, and specific testing of the manufacturer s device. An assessment by a Notified Body is required in order for a manufacturer to commercially distribute a product throughout the participating countries. Our products are CE Marked and in conformance with applicable medical device directives and can be commercially sold throughout the European Union, as well as in other countries that recognize products bearing the CE Mark. Our facility has been awarded the ISO 9001:2000 and the CAN/CSA ISO 13485:2003 certifications.

Employees

As of December 31, 2006, we had 154 employees, with 64 employees in sales and marketing, four employees in technical services, 31 employees in manufacturing operations, 30 employees in research and development including clinical, regulatory and certain quality functions, and 25 employees in general and administrative. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union, and we believe our employee relations are good.

Available Information

You may find on our website at http://www.thermage.com electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. Our most recent charter for our Audit and Compensation Committees and our Code of Ethics are available on our website as well. In the event that we grant a waiver under our Code of Ethics to any of our officers or directors we will publish it on our website.

You can read our SEC filings over the Internet at the SEC s web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at (202) 551-8090 or (800) 732-0330 for further information on the operation of the public reference facilities.

Item 1A. ***Risk Factors***

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

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

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

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

Most published studies of our ThermaCool system have investigated the tissue-tightening effect of our monopolar RF technology in procedures on the face, using a single treatment with our first generation 1.0 cm^2 ThermaTip and our prior procedure protocol, which involved the use of fewer energy pulses at a higher power than our current procedure protocol. There are no published, peer-reviewed studies regarding the effectiveness of our latest generation 0.25 cm^2 and 3.0 cm^2 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 results from treatment with our ThermaCool system to surgery or treatment with other aesthetic devices. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase our ThermaCool system. If we decide to pursue additional studies in the future, they could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians expectations, our ThermaCool system may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

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

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

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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 $3.9 million in 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.

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

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decision to undergo a Thermage procedure is thus driven by consumer demand, which may be influenced by a number of factors, such as:

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

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

Negative publicity regarding our Thermage procedure could harm demand, which would adversely affect sales and our financial performance.

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

Our reputation and competitive position may be harmed not only by negative media exposure, but also by other publicly-available information suggesting that our Thermage procedure is not safe. For example, we file adverse event reports with the FDA that are publicly available on the FDA s website if our product may have caused or contributed to a serious injury or malfunctioned in a way that would likely cause or contribute to a serious injury if it were to recur. There are under 200 such medical device reports, excluding duplicate reports, on the FDA s website related to the Thermage procedure. Based upon an estimated 350,000 Thermage procedures performed to date, the rate of such reports is under 0.1%, with over 99.9% of procedures performed without an adverse event reported. Despite this safety record, competitors may attempt to harm our reputation by pointing to isolated injuries that have been reported or publicized, or by claiming that their product is superior because they have not filed as many adverse event reports with the FDA. Such negative publicity and competitor behavior could harm our reputation and our future sales.

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

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Thermage procedures to others. In order to generate repeat and referral business, we also believe that patients must be satisfied with the effectiveness of the Thermage procedure. Results obtained from a Thermage procedure are subjective and may be subtle. A Thermage treatment may produce results that may not meet patients expectations. If patients are not satisfied with the procedure or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

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

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

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

We rely on a direct sales force to sell our ThermaCool system in the United States. In order to meet our anticipated sales objectives, we expect to grow our domestic sales organization significantly over the next several years. There are significant risks involved in building and managing our sales organization, including risks related to our ability to:

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

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

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

International sales accounted 48% of our revenue for the year ended December 31, 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;

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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;

regulation of the sale of the hydroflurocarbon used with our ThermaCool system;

fluctuating foreign currency exchange rates;

foreign certification and regulatory clearance or approval requirements;

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

customs clearance and shipping delays;

political and economic instability; and

preference for locally produced products.

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

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

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

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

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

Competing in the aesthetics market could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. Our ability to compete effectively depends upon our ability to distinguish our company

and our ThermaCool system from our competitors and their products, and on such factors as:

safety and effectiveness;

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product pricing;

success of our marketing initiatives;

compelling clinical data;

intellectual property protection;

quality of customer support; and

development of successful distribution channels, both domestically and internationally.

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

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

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

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

We may not be successful in commercializing a product for cellulite.

We recently received FDA clearance to market the TherMassager, an accessory to our ThermaCool system, for the temporary improvement in the appearance of cellulite and for therapeutic massage, which we currently intend to commercially launch in 2007. We have not previously marketed our ThermaCool system to reduce the appearance of cellulite, and our anticipated marketing and training efforts may not be successful in encouraging physicians and patients to adopt this new procedure in commercially meaningful numbers. We expect to face significant competition in the area of cellulite products, in some cases from companies that are

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more established, market more widely known products and have greater resources than we do. We may not be able to differentiate our cellulite product sufficiently from our competitors products to achieve significant market penetration. In addition, integrating a new accessory into our existing ThermaCool system will require additional physician training as well as manufacturing and technical support. As a result of these factors, we may incur significant marketing and development expenses relating to this new product opportunity without achieving commercial success, which could harm our business and our competitive position.

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

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

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

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

- interruption of supply resulting from modifications to or discontinuation of a supplier s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier s variation in a component;
- 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.

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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 manufacturing processes internally at our principal facility, and we outsource the manufacture of components, subassemblies and certain finished products to a limited number of third parties. For financial or operational purposes, we have in the past elected, and may in the future elect, to perform additional component or system manufacturing functions internally. Implementing complex or specialized manufacturing processes could lead to difficulties in producing sufficient quantities of manufactured items that meet our quality standards and that comply with applicable regulatory requirements in a timely and cost-effective manner. In addition, if we experience internal manufacturing difficulties, it may be expensive and time consuming to engage subcontractor or supplier to fulfill our replacement manufacturing needs. The occurrence of any of these events could harm our business.

If the ThermaCool System malfunctions or if we discover a manufacturing defect that could lead to a malfunction, we may have to initiate a product recall, which could adversely impact our business.

Problems in our manufacturing processes, or those of our manufacturing subcontractors, that lead to an actual or possible malfunction in the ThermaCool system, may require us to recall product from customers and could disrupt our operations. For example, in December 2002, we initiated our only recall to date following a change we had made in the seal around the edge of the treatment tip. We discovered that the newly-designed seal could fail to hold, resulting in leakage of cryogen and the possibility of skin damage. Burns, including one classified as third degree, were reported in five patients and we filed Medical Device Reports, or MDRs, with the FDA for each of these injuries. The problem was resolved within two weeks and did not have a significant impact on our ability to supply products to our customers or, more generally, on our results of operations. However, our results of operations, our reputation and market acceptance of our products could be harmed if we encounter difficulties in manufacturing that result in a more significant recall or significant patient injury, and delays in our ability to fill customer orders.

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

The cooling capability of our first generation and ThermaCool NXT RF generators relies upon a hydroflurocarbon, or HFC, called R134a, to protect the outer layer of the skin from over-heating while our device delivers RF energy to the subcutaneous tissue. New environmental regulations phasing out certain HFCs over the next decade have been adopted or are under consideration in a number of countries, and recent European Union directives require the phase-out of certain HFCs and place certain restrictions on the import of R134a, and new products that utilize R134a beginning July 4, 2007. If we are unable to develop an alternative cooling system for our device which is not dependent on R134a in a timely or cost-effective manner, our ThermaCool system may not be in compliance with environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

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

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

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

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

While we only sell our ThermaCool system to licensed physicians who have met our training requirements, Federal regulations allow us to sell our ThermaCool system to licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our ThermaCool system may be operated by licensed practitioners with varying levels of training, and in many states by non-physicians, including physician assistants, registered nurses and nurse practitioners. Thus, in some states, the definition of licensed practitioner may result in the legal use of our ThermaCool system by non-physicians. Outside the United States, our independent distributors sell in many jurisdictions that do not require specific qualifications or training for purchasers or operators of our ThermaCool system. We do not supervise the procedures performed with our ThermaCool system, nor can we be assured that direct physician supervision of our equipment occurs according to our recommendations. We, and our distributors, require purchasers of our ThermaCool system to undergo an initial training session as a condition of purchase, but do not require ongoing training. In addition, we prohibit the sale of our system to companies that rent our system to third parties, but cannot prevent an otherwise qualified physician from contracting with a rental company in violation of their purchase agreement with us. The use of our ThermaCool system by non-physicians, as well as noncompliance with the operating guidelines set forth in our training programs, may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

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

If our ThermaCool system is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our ThermaCool system or failing to adhere to operating guidelines could cause significant skin damage and underlying tissue damage. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. We have been and may, in the future, be involved in litigation related to the use of our ThermaCool system. Product liability claims could divert management s attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all future claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and reducing our operating results.

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

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

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

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

Our success largely depends on the skills, experience and efforts of our officers and other key employees. We do not have employment contracts with any of our officers or other key employees. Any of our officers and other key employees may terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use and benefits of our ThermaCool system. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

Risks Related to Our Intellectual Property

Intellectual property rights may not provide adequate protection for our ThermaCool system, which may permit third parties to compete against us more effectively.

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and ThermaCool system. As of December 31, 2006, we had 28 issued U.S. patents and 15 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

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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.

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.

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Risks Related to Regulatory Matters

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

Our ThermaCool system is a medical device that is subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or premarketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. The FDA s 510(k) clearance process usually takes from three to 12 months, but it can last significantly longer. The process of obtaining premarketing approval is much more costly and uncertain than the 510(k) clearance process, and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the non-invasive treatment of wrinkles and rhytids. However, our clearances can be revoked if safety or effectiveness problems develop. We also are subject to Medical Device Reporting regulations, which require us to report to the FDA if our product causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. Our ThermaCool system is also subject to state regulations which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations allow our ThermaCool system to be sold to, or on the order of, licensed practitioners, as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase and operate our ThermaCool system. However, a state could change its regulations at any time, disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

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

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

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

operating restrictions or partial suspension or total shutdown of production;

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

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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 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;

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inappropriate management override of procedures; and

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

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

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

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

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

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert management s time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies or products. If we decide to expand our product offerings beyond radiofrequency technologies, we may spend time and money on projects that do not increase our revenue. Any cash acquisition we pursue would diminish funds available to us for other uses, and any stock acquisition would dilute our stockholders ownership. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any acquisitions or collaborative projects.

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Risks Related to Our Common Stock

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

We intend to provide guidance to the investing community regarding our anticipated future operating performance. Our business typically has a short sales cycle, so that we do not have significant backlog of orders at the start of a quarter, and our ability to sell our ThermaCool system successfully is subject to many uncertainties, as discussed in this prospectus. In light of these factors, it is difficult for us to estimate with accuracy our future results. Our expectations regarding these results will be subject to numerous risks and uncertainties that could make actual results differ materially from those anticipated. If our actual results do not meet our public guidance or our guidance or actual results do not meet the expectations of third-party financial analysts, our stock price could decline significantly.

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

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

volume and timing of sales of our ThermaCool system;

the introduction of new products or product enhancements by us or our competitors;

disputes or other developments with respect to our intellectual property rights or the intellectual property rights of others;

our ability to develop, obtain regulatory clearance or approval for and market new and enhanced products on a timely basis;

product liability claims or other litigation;

quarterly variations in our or our competitors results of operations;

sales of large blocks of our common stock, including sales by our executive officers and directors;

developments in our industry;

media exposure of our ThermaCool system or products of our competitors;

changes in governmental regulations or in the status of our regulatory approvals or applications;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

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

If our stockholders sell substantial amounts of our common stock in the public market, for example, upon the expiration of lock-up agreements approximately 180 days following our initial public offering,

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

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

Our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control approximately 55% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

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

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

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

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

Our certificate of incorporation provides for 100,000,000 shares of authorized common stock, of which 77.1 million shares will be available for future issuance, and 10,000,000 shares of preferred stock, all of which will be available for future issuance. The issuance of additional shares of common stock may have a dilutive effect on earnings per share and relative voting power. We could use the shares of common stock that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

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

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

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

Item 1B. ***Unresolved Staff Comments***
Not applicable

Item 2. ***Properties***
We occupy an 88,000 square foot facility in Hayward, California, under a lease that ends in September 2010, with an option to extend for an additional three-year term.

Item 3. ***Legal Proceedings***
We are not a party to any material pending or threatened litigation.

Item 4. ***Submission of Matters to a Vote of Security Holders***
Not applicable

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PART II

Item 5. ***Market for the Registrant s Common Stock and Related Shareholder Matters***

Stock Exchange Listing

Our common stock has traded on the Nasdaq Global Market under the symbol THRM since our initial public offering on November 9, 2006. Prior to that time, there was no public market for our stock. On February 28, 2007, the closing sale price of our common stock was $8.70 per share.

Common Stockholders

As of February 28, 2007, there were approximately 139 stockholders of record of our common stock.

Stock Prices

The following table sets forth quarterly high and low closing sales prices of our common stock for the indicated periods.

Year Ended December 31, 2006	High	Low
Fourth Quarter	$ 8.15	$ 6.40

Dividend Policy

We have never paid a cash dividend and have no present intention to pay cash dividends in the foreseeable future. The Board of Directors currently intends to retain any future earnings for use in our business.

Use of Proceeds

In November 9, 2006, a registration statement (Registration No. 333-136501) relating to our initial public offering of our common stock was declared effective by the Securities and Exchange Commission. Under this registration statement, we registered 6,000,000 shares of our common stock, and another 900,000 shares subject to the underwriters over-allotment option. The 6,000,000 shares of common stock registered under the registration statement, as well as 150,000 shares covered by the over-allotment option, were sold at a price to the public of $7.00 per share. The offering closed on November 15, 2006. The managing underwriters were Merrill Lynch, Pierce, Fenner & Smith Incorporated, Thomas Weisel Partners LLC, Wachovia Capital Markets, LLC, C.E. Unterberg, Towbin, LLC and Maxim Group LLC.

Proceeds from the offering after deducting underwriting discounts and commissions of $3.0 million, but before expenses were $40.0 million. Of the $40.0 million in net proceeds, through December 31, 2006, we have spent approximately, $3.1 million for sales and marketing initiatives, $1.3 million for research and development activities and $1.3 million for operating and general corporate purposes. We also used $5.0 million to pay off our working capital line with GE Capital. In addition, we invested the remaining proceeds from the offering in money market funds.

We did not sell any unregistered securities during the period covered by this Annual Report on Form 10-K.

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Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Stock Performance Graph

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Medical Equipment Index for the period beginning on November 10, 2006, our first day of trading after our initial public offering, and ending on December 31, 2006.

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* The graph assumes that $100 was invested on November 10, 2006 in our common stock, or on October 31, 2006 in the Nasdaq Composite Index and the Nasdaq Medical Equipment Index, and that all dividends were reinvested. No dividends have been declared or paid on our common stock. Stock performance shown in the above chart for the common stock is historical and should not be considered indicative of future price performance. This graph was prepared by Research Data Group, Inc.

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Item 6. ***Selected Financial Data***

The following table presents certain financial data for each of the last five fiscal years. 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 in this Form 10-K.

Statement of Operations Data

(in thousands of dollars, except share and per share data)	Years Ended December 31,				
	2006	2005	2004	2003	2002
Net revenue	$ 54,320	$ 40,655	$ 50,384	$ 24,910	$ 1,704
Cost of revenue	15,259	12,309	12,452	12,566	1,807
Gross margin	39,061	28,346	37,932	12,344	(103)
Operating expenses					
Sales and marketing	24,071	19,997	15,596	8,945	2,694
Research and development	9,639	8,908	8,490	6,569	7,316
General and administrative	9,973	7,414	8,873	3,612	1,541
Litigation settlement gain		(1,646)			
Total operating expenses	43,683	34,673	32,959	19,126	11,551
Income (loss) from operations	(4,622)	(6,327)	4,973	(6,782)	(11,654)
Interest and other income	768	340	177	205	253
Interest and other expense	(55)	(1,549)	(14)	(7)	(8)
Income (loss) before income taxes and cumulative effect of change in accounting principle	(3,909)	(7,536)	5,136	(6,584)	(11,409)
Provision for income taxes			(103)		
Net income (loss) before cumulative effect of change in accounting principle	(3,909)	(7,536)	5,033	(6,584)	(11,409)
Cumulative effect of change in accounting principle		(697)			
Net income (loss)	$ (3,909)	$ (8,233)	$ 5,033	$ (6,584)	$ (11,409)
Net income (loss) allocable to common stockholders	$ (3,909)	$ (8,233)	$ 313	$ (6,584)	$ (11,409)
Net income (loss) per share basic and diluted:					
Before cumulative effect of change in accounting principle		$ (2.06)			
Cumulative effect of change in accounting principle		(0.19)			
Net income (loss) per share basic	$ (0.60)	$ (2.25)	$ 0.10	$ (2.85)	$ (6.10)
Net income (loss) per share diluted	$ (0.60)	$ (2.25)	$ 0.06	$ (2.85)	$ (6.10)
Weighted average shares outstanding used in calculating net income (loss) per common share:					
Basic	6,561,648	3,664,990	3,023,225	2,307,238	1,868,232
Diluted	1,824,386	3,664,990	5,319,754	2,307,238	1,868,232

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	As of December 31,				
	2006	2005	2004	2003	2002
			(in thousands)		
Balance Sheet Data					
Cash and cash equivalents	$ 45,915	$ 10,121	$ 11,706	$ 12,383	$ 15,588
Working capital	46,153	10,947	12,110	9,435	15,317
Total assets	59,875	24,032	26,202	17,667	19,399
Borrowings, less current portion		4,040	13	18	5
Preferred stock warrant liability		3,937			
Redeemable convertible preferred stock		45,169	45,169	45,167	45,013
Total stockholders equity (deficit)	$ 49,121	$ (38,733)	$ (29,440)	$ (35,189)	$ (28,826)

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion should be read in conjunction with the attached financial statements and notes thereto. This Annual report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning our expectations that ThermaTip sales will continue to increase as a percentage of revenue versus generator sales, while generator sales increase in absolute terms; development and commercialization of new procedures and treatment tips; continued expansion of our customer base; identifying growth opportunities via complementary products, technologies or businesses; sales organization growth; growth in international sales and expansion into new international markets; and our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Risk Factors section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance of these forward-looking statements, which reflect management s analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.

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 December 31, 2006, we had an installed base of over 2,000 ThermaCool RF generators and had sold over 350,000 ThermaTips.

Significant Business Trends

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

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We derive revenue primarily from the sale of ThermaTips and other consumables and sales of our ThermaCool RF generator. For 2004, 2005 and 2006 we derived 60%, 66% and 73% respectively, of our revenue from ThermaTip and other consumable sales, and 39%, 31% and 24% respectively, of our revenue from ThermaCool RF generator sales. As the installed base of ThermaCool RF generators has grown, so too have grown the number of physicians performing our Thermage procedure, and, consequently, sales of disposable ThermaTips have increased as a percentage of revenue versus generator sales. We expect this trend to continue, and we expect to derive a greater percentage of our revenue from sales of ThermaTips and other consumables in the future. During 2004 and 2005, sales of RF generators have declined, not only on a percentage basis, but also on an absolute basis. This reflects our decision to prioritize our limited resources towards servicing existing customers demands, rather than seeking new customers, because we believe we maximize operating results by emphasizing repeat ThermaTip sales over one time RF generator sales. With growth in our sales organization, we believe that the sale of RF generators will grow in absolute terms, but continue to decline as a percentage of revenue. 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 31 distributors in 78 countries. In 2004, 2005 and 2006, we derived 72%, 56% and 52%, respectively, of our revenue from sales of our products and services within the United States. For 2004, 2005 and 2006, we derived 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,		
	2006	2005	2004
United States	52%	56%	72%
Asia Pacific	24%	23%	16%
Europe/Middle East	13%	11%	3%
Rest of the world	11%	10%	9%
Total net revenue	100%	100%	100%

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, when both physicians and prospective patients take summer vacations.

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Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. We have in the past noticed brief increases both in demand for our products and in demand for our Thermage procedure, as well as in traffic to our website, following positive national media coverage, such as when Thermage was featured on *Oprah* in 2003 and on subsequent rebroadcasts. However, we believe that, conversely, negative media exposure has adversely impacted potential sales. We experience frequent positive, negative and neutral media coverage throughout a fiscal quarter. Our sales are also impacted by other factors outside of our control, such as prior patient and practicing physician recommendations. Consequently, while we believe that media exposure and other factors outside of our direct control play a role in our long-term success, to date we have not been able to quantify the impact of particular media exposure or media exposure, in general, and have not observed any material effect, positive or negative, on our quarterly financial results of operations. A detailed discussion of these and other factors that impact our business is provided in the Risk Factors section in this Annual Report on Form 10-K.

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 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

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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 2006, we had deferred revenue balances of $0.3 million and $0.2 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 $29,000 and $31,000 at December 31, 2005 and 2006, respectively. Doubtful account write-offs have been insignificant during the years ended December 31, 2004, 2005 and 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 and $0.3 million at December 31, 2005 and 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 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, 2005 and 2006 were $1.0 million and $0.4 million, respectively.

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Litigation and Claims