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