

THERMAGE INC
Form 10-K
March 30, 2007
Table of Contents

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
(State or other jurisdiction of
incorporation or organization)

25881 Industrial Boulevard,

Hayward, California 94545

(510) 782-2286

68-0373593
(I.R.S. Employer

Identification No.)

(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:

Edgar Filing: THERMAGE INC - Form 10-K

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	

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

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

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

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

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

* 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.

Table of Contents

THERMAGE, INC.

ANNUAL REPORT ON FORM 10-K

INDEX

	Page
<u>PART I</u>	
ITEM 1. <u>Business</u>	1
ITEM 1A. <u>Risk Factors</u>	19
ITEM 1B. <u>Unresolved Staff Comments</u>	36
ITEM 2. <u>Properties</u>	36
ITEM 3. <u>Legal Proceedings</u>	36
ITEM 4. <u>Submission of Matters to a Vote of Security Holders</u>	36
<u>PART II</u>	
ITEM 5. <u>Market for the Registrant's Common Stock and Related Shareholder Matters</u>	37
ITEM 6. <u>Selected Financial Data</u>	39
ITEM 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	41
ITEM 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	53
ITEM 8. <u>Financial Statements and Supplementary Data</u>	54
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	84
ITEM 9A. <u>Controls and Procedures</u>	84
ITEM 9B. <u>Other Information</u>	84
<u>PART III</u>	
ITEM 10. <u>Directors, Executive Officers and Corporate Governance</u>	85
ITEM 11. <u>Executive Compensation</u>	85
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters</u>	85
ITEM 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	85
ITEM 14. <u>Principal Accountant Fees and Services</u>	85
<u>PART IV</u>	
ITEM 15. <u>Exhibits and Financial Statement Schedules</u>	86

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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,

Table of Contents

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 ThermoCool system currently requires lower capital costs than competing laser and RF systems, while average procedure fees for Thermage treatments generally exceed our competitors. We continue to design new ThermoTips to address new applications without requiring additional equipment purchase.

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

Our Technology

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

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

The ThermoTip Capacitive Coupling Mechanism of Action for Collagen Heating. The single-use ThermoTip device contains our patented technology that uses monopolar RF energy as a controlled tissue heating source through the use of a non-conducting material, known as a

Table of Contents

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.

Table of Contents

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

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

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

Tummy by Thermage, which involves the use of 3.0 cm² tip size, designed for the treatment of the abdomen; and

Hands by Thermage, which involves the use of 1.5 cm² 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.

Table of Contents

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 ThermoTip 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 ThermoTip.

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

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 cm² ThermoTip, which has essentially replaced our 1.0 cm² and 1.5 cm² ThermoTips, 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 ThermoTips 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

Table of Contents

physicians who are new to aesthetic medicine. We encourage our sales force to work closely with our target physician customers to accelerate growth in their aesthetics practices, which, in turn, generates more ThermoTip sales for our company. As a broader group of physicians are adding non-invasive aesthetic procedures to their practices, our target physician base is expanding to include not only plastic surgeons and dermatologists, but also obstetricians, gynecologists and general practitioners. Plastic surgeons and dermatologists currently represent the majority of our 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 ThermoTip Usage. Unlike the capital equipment model of the traditional laser business, because of the disposable nature of our ThermoTips, we maintain an active, continuous relationship with our customer base. We work collaboratively with our customer base to increase ThermoTip usage by expanding clinical applications and augmenting and facilitating the marketing efforts of our physician customers. We believe that our customers' interests are closely aligned with our own, and we monitor the market to foster continued procedure growth for our customers and ThermoTip sales for us. With innovative marketing programs, such as our PatientBuilder.com resource, our sales force works with physician customers to develop a profitable ThermoTip procedure practice.

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

Investing in Intellectual Property and Patent Protection. We will continue to invest in expanding our intellectual property portfolio in the aesthetics market, and we intend to file for additional patents to strengthen our intellectual property rights. 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 ThermoCool 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

Table of Contents

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 ThermoCool 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 ThermoCool 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 ThermoCool system. We require this initial training to assist physicians in safely and effectively performing the Thermage procedure. The majority of physicians operating our installed base of ThermoCool systems have pursued and met the

Table of Contents

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.

Table of Contents

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 hydrofluorocarbon, 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.

Table of Contents

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 cm² and 1.5 cm² 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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Edgar Filing: THERMAGE INC - Form 10-K

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 ThermoCool system

Table of Contents

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.

Table of Contents

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

Edgar Filing: THERMAGE INC - Form 10-K

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

Table of Contents

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

Table of Contents

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

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

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

Most published studies of our ThermaCool system have investigated the tissue-tightening effect of our monopolar RF technology in procedures on the face, using a single treatment with our first generation 1.0 cm² ThermaTip and our prior procedure protocol, which involved the use of fewer energy pulses at a higher power than our current procedure protocol. There are no published, peer-reviewed studies regarding the effectiveness of our latest generation 0.25 cm² and 3.0 cm² ThermaTips or our current procedure protocol, which have essentially replaced our first generation tip and procedure protocol, or for procedures on other parts of the body. Additionally, we have not conducted any head-to-head clinical studies that compare 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.

Table of Contents

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

Table of Contents

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

Our future success depends upon patients having a positive experience with the Thermage procedure in order to increase physician demand for our products, as a result of both individual patients' repeat business and as a result of word-of-mouth referrals. We believe that patients may be dissatisfied with the Thermage procedure if they find it to be too painful. Furthermore, Thermage patients may experience temporary swelling or reddening of the skin as a procedure side effect. In rare instances patients may receive burns, blisters, skin discoloration or skin depressions. Experiencing excessive pain, any of these side effects or adverse events could discourage a patient from having a Thermage procedure or discourage a patient from having additional procedures or referring

Table of Contents

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;

Table of Contents

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

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

export restrictions, trade regulations and foreign tax laws;

regulation of the sale of the hydrofluorocarbon 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;

Table of Contents

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

Table of Contents

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.

Table of Contents

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

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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;

Table of Contents

inappropriate management override of procedures; and

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

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

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

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

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

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

Table of Contents

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.

Edgar Filing: THERMAGE INC - Form 10-K

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,

Table of Contents

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.

Table of Contents

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

Table of Contents**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.

Table of Contents

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.

* 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.

Table of Contents**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

Table of Contents

	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)

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

Table of Contents

Litigation and Claims

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

Income Taxes

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

Based on the available objective evidence, we believe it is more likely than not that the net deferred tax assets will not be fully realized. Accordingly, we have provided a full valuation allowance on those assets and no benefit has been recognized for our net operating loss and other deferred tax assets. Accordingly, deferred tax valuation allowances have been established as of December 31, 2004 and 2005 and 2006 to reflect these uncertainties. If we are able to demonstrate consistent profitability in the future, and we are able to establish that recovery is more likely than not, we would reduce the valuation allowance at a future date. As of December 31, 2006, we had federal and state net operating loss carryforwards of approximately \$34.0 million and \$22.0 million, respectively, available to reduce future taxable income, if any, for federal and state income taxes, respectively. The net operating loss carryforwards begin to expire in 2011 and 2010 for federal and state income tax purposes, respectively. Utilization of the net operating loss carryforwards may be subject to an annual limitations due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss carryforwards before utilization.

Stock-Based Compensation Expense

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

Table of Contents

SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity investment.

During the years ended December 31, 2005 and 2006, we issued stock options to certain employees with exercise prices below the fair market value of our common stock at the date of grant, determined with hindsight. In accordance with the requirements of APB No. 25, we have recorded deferred stock-based compensation for the difference between the exercise price of the stock options granted and the fair market value of our stock at the date of grant, determined with hindsight. During the year ended December 31, 2005, we recorded deferred stock-based compensation related to these options of \$3.9 million. This deferred stock based compensation is amortized to expense on a straight-line basis over the period during which the options vest, generally four years. Amortization of deferred stock-based compensation was \$0.3 millions and \$0.2 million during the year ended December 31, 2005 and 2006, respectively.

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

Under SFAS No. 123R, we calculated the fair value of the stock option grants using the Black-Scholes option-pricing model. For the year ended December 31, 2006, the fair value was based on the following weighted average assumptions: the expected term of 4.25 years; the expected volatility of 55%, the risk free interest rate of 4.77% and 0.0% for the dividend yield. Estimated volatility for the year ended December 31, 2006 reflects the application of SAB 107 interpretive guidance and, accordingly, due to a lack of historical information regarding the volatility of our stock price, incorporates historical and volatility of similar public entities in the aesthetics market. The expected term has been computed based upon the vesting term, cancellation history, historical exercises and contractual term of the options. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions. The aggregate intrinsic value of the outstanding options vested and expected to vest at December 31, 2006 was \$16.1 million, based upon the fair market value of common stock at December 31, 2006 of \$6.99 per share.

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

Table of Contents**Results of Operations*****Year Ended December 31, 2005 and December 31, 2006***

Net Revenue. Revenue is derived from the sale of single-use ThermaTips and other consumables, ThermaCool RF generator sales, and service and other revenue. Net revenue increased \$13.6 million, or 34%, from \$40.7 million to \$54.3 million for the year ended December 31, 2005 and 2006, respectively. Sales of ThermaTips and other consumables increased \$12.4 million, or 46%, from \$27.0 million to \$39.4 million for the year ended December 31, 2005 and 2006, respectively. Sales of ThermaCool RF generator increased \$0.7 million, or 6%, from \$12.6 million to \$13.3 million for the year ended December 31, 2005 and 2006, respectively. Product unit volume of ThermaTips was 83,660 units and 130,690 units for the year ended December 31, 2005 and 2006, respectively. Product unit volume of our ThermaCool RF generator was 408 units and 437 units for the year ended December 31, 2005 and 2006, respectively. International sales to distributors accounted for 44% and 48% of revenue for the year ended December 31, 2005 and 2006, respectively. The increase in revenue was driven by increased adoption of our 3.0 cm² ThermaTip, the introduction of our new 0.25 cm² ThermaTip and expansion into new international markets, partially offset by lower average selling prices beginning in April 2005.

Cost of Revenue. Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. Cost of revenue increased \$3.0 million, or 24%, from \$12.3 million to \$15.3 million for the year ended December 31, 2005 and 2006, respectively. The increase was primarily due to the increased volume of ThermaTips and other consumables sold. Gross margin was 70% and 72% for the year ended December 31, 2005 and 2006, respectively.

Sales and Marketing. Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops and trade shows, marketing, customer service and business development. Sales and marketing expenses increased \$4.1 million, or 20%, from \$20.0 million to \$24.1 million for the year ended December 31, 2005 and 2006, respectively. The increase was primarily attributable to an increase of \$2.8 million in personnel and commission costs and related travel expenses associated with the expansion of our international sales force and marketing staff, as well as an increase of \$0.2 million in promotional costs primarily due to an increased number of customer workshops, trade shows and promotional efforts and an increase in stock-based compensation charges of \$1.1 million.

Research and Development. Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, material costs and regulatory and quality assurance costs not directly related to the manufacturing of our products. Research and development expenses increased \$0.7 million, or 8%, from \$8.9 million to \$9.6 million for the year ended December 31, 2005 and 2006, respectively. The increase was primarily related to increased stock-based compensation charges of \$0.5 million, higher personnel costs of \$0.4 million, partially offset by lower clinical studies costs and other research and development discretionary spending of \$0.2 million.

General and Administrative. General and administrative expenses consist primarily of personnel costs, legal and accounting fees, information technology costs, human resources costs and other general operating expenses. General and administrative expenses increased \$2.6 million, or 35%, from \$7.4 million to \$10.0 million for the year ended December 31, 2005 and 2006, respectively. The increase was primarily attributable to expenses incurred in connection with the November 2006 initial public offering of \$0.9 million, an increase in stock-based compensation charges of \$1.4 million and higher employee related and other expenses of \$0.3million.

Litigation Settlement. In June 2005, we reached an agreement with Syneron that settled patent-related claims of the parties against each other. Under this agreement, the parties granted each other non-exclusive paid-up licenses under the patents in the suit and related patents. We received a one-time payment of \$1.8

Table of Contents

million, recorded net of certain legal expenses as \$1.6 million. The license granted to Syneron excludes the right to utilize our monopolar RF and capacitive electrical coupling and the license granted to us excludes the right to utilize Syneron's Electro-Optical Synergy technology.

Interest and Other Income. Interest and other income consists primarily of interest income generated from our cash and cash equivalent balances. Interest and other income increased \$0.5 million, or 126%, from \$0.3 million to \$0.8 million for the year ended December 31, 2005 and 2006, respectively due to higher average cash balances resulting from the proceeds of our initial public offering and GE Capital borrowings.

Interest and Other Expense. Interest and other expense consists primarily of interest expense on our borrowings and changes in the fair value of our convertible preferred stock warrants under FSP 150-5. Interest and other expense decreased \$1.4 million from \$1.5 million to \$55,000 for the year ended December 31, 2005 and 2006, respectively. The decrease was primarily attributable to \$2.3 million decrease in the fair value of the convertible preferred stock warrants, partially offset by increase in interest expense of \$0.8 million.

Years Ended December 31, 2004 and December 31, 2005

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

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

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

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

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

Table of Contents

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

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

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

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

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

Stock-Based Compensation

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

	December 31,		
	2006	2005	2004
Cost of revenue	\$ 73	\$ 4	\$ 41
Sales and marketing	1,306	216	126
Research and development	666	124	77
General and administrative	1,472	112	219
Total stock-based compensation expense	\$ 3,517	\$ 456	\$ 463

We recorded stock-based compensation expense of \$3.5 million in the year ended December 31, 2006. At December 31, 2006, the total compensation cost related to stock-based awards granted or modified under SFAS 123R to employees and directors but not yet recognized was approximately \$6.2 million, net of estimated forfeitures. We will amortize this cost on a straight-line basis over a weighted average period of approximately 3.0 years.

During March 2006, we repriced stock option awards held by 116 of our employees. Under the terms of this repricing, we repriced certain employee stock options having an exercise price of \$2.00 or above to an exercise price of \$1.90. Other than the exercise price, all other terms of the repriced options, such as vesting and

Table of Contents

contractual life, remained the same. In consideration for the repricing of eligible stock option awards, employees who were previously granted stock option awards on February 2, 2005 were also required to return these awards for cancellation. As a result of this repricing, we repriced 447,565 vested options and 1,523,035 unvested options having a weighted average original exercise price of \$4.18 and \$4.10, respectively. Such options were repriced at a new exercise price of \$1.90 per share. As a result of this repricing, we also cancelled 35,216 outstanding employee options with an original exercise price of \$4.00 that were granted on February 2, 2005. We have accounted for the repricing and cancellation transactions as a modification under SFAS No. 123R and recorded any net incremental fair value related to vested awards as compensation expense on the date of modification. In accordance with SFAS No. 123R, we will record the incremental fair value related to the unvested awards, together with unamortized stock-based compensation expense associated with the unvested awards, over the remaining requisite service period of the option holders. In connection with the repricing, we recorded stock-based compensation expense of \$2.0 million in the year ended December 31, 2006.

In connection with the repricing of stock options during the year ended December 31, 2006, we followed the provisions of SFAS No. 123R and eliminated deferred stock-based compensation amounts of approximately \$3.3 million related to the repriced stock options. Stock compensation charges for the repriced options will be recorded in accordance with SFAS No. 123R.

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line basis. The options generally vest ratably over four years. The values attributable to these options are amortized over the service period and the unvested portion of these options are remeasured as the services are provided and the options are earned. The stock-based compensation expense will fluctuate as the deemed fair value of the common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of \$110,000, \$132,000 and \$200,000 for the years ended December 31, 2004 and 2005 and 2006.

Liquidity and Capital Resources

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

On December 31, 2006, we had working capital of \$46.2 million, which consists primarily of \$45.9 million in cash and cash equivalents.

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2006:

	Total	Payments Due by Period	
		Less than 1 year (in thousands)	1-3 years
Operating leases	\$ 3,710	\$ 820	\$ 2,890
Deferred rent	55	55	
Total contractual obligations	\$ 3,765	\$ 875	\$ 2,890

Table of Contents**Year Ended December 31, 2005 and December 31, 2006**

Net Cash Provided by (Used in) Operating Activities. Net cash used in operating activities was \$4.3 million for the years ended December 31, 2005 and net cash provided by operating activities was \$1.2 million for the year ended December 31, 2006. During 2006, net cash provided by operating activities primarily resulted from \$3.9 million of net loss, changes in preferred stock warrant liability of \$0.8 million, non-cash decrease in reserve for excess and obsolete inventory of \$0.6 million, increase in accounts receivable of \$0.4 million and decrease in accounts payable of \$0.6 million, offset by non-cash amortization of stock-based compensation of \$3.5 million, non-cash depreciation and amortization of \$2.1 million, and an increase in accrued and other liabilities of \$2.1 million. The decrease in preferred stock liability was the result of the decrease in fair market value and the exercise of the preferred stock warrants upon the completion of our initial public offering. The increase in accrued and other liabilities was primarily due to increased levels of bonus and payroll related expenses and inventory purchases to support higher revenue.

Net Cash Used in Investing Activities. Net cash used in investing activities was \$2.3 million and \$0.8 million for the years ended December 31, 2005 and 2006, respectively. Our investing activities in the 2005 and 2006 periods consisted principally of property and equipment purchases of \$2.2 million in 2005 and \$0.9 million in 2006. Expenditures were higher in 2005 as a result of outfitting our new corporate and manufacturing facility that we moved into at the end of 2004.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was \$5.0 million and \$35.3 million for the years ended December 31, 2005 and 2006, respectively. In 2005, the increase in cash provided by financing was primarily attributable to \$5.0 million drawn on a working capital line with GE Capital. In 2006, the increase in cash provided by financing was primarily from proceeds from our initial public offering, proceeds from exercise of stock options and preferred stock warrants, collection of a note receivable from stockholder, partially offset by repayment of \$5.0 million of the working capital line with GE Capital.

Years Ended December 31, 2004 and December 31, 2005

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

Net Cash Provided by (Used in) Investing Activities. Net cash provided by investing activities was \$0.6 million in 2004 and net cash used in investing activities was \$2.3 million in 2005. Our investing activities in 2004 consisted principally of the purchase and maturity of marketable securities for \$3.8 million offset by \$3.2 million in purchases of property and equipment. Our investing activities in 2005 consisted primarily of \$2.2 million for acquisition of property and equipment in connection with our move to a larger corporate and manufacturing facility in the fourth quarter of 2004 that involved leasehold improvements plus additional infrastructure and equipment expenditures.

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

Table of Contents

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

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

We believe that our current cash and investment balances and cash generated from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If existing cash and cash generated from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not have any undisclosed borrowings or debt, and we have not entered into any synthetic leases. We are, therefore, not materially exposed to any financing, liquidity, market or credit risk that could arise if we engaged in such relationships.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting uncertainty in tax positions. This Interpretation requires that we recognize in our financial statements, the impact of a tax provision, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of January 1, 2007, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. We do not expect the adoption of FIN 48 to have a material impact on our financial statements.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB108). SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year s financial statements are materially misstated. SAB 108 became effective for the year ending December 31, 2006. The adoption of SAB 108 did not have any impact on our financial statements.

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FAS115* (SFAS No.159). SFAS No. 159 allows companies

Table of Contents

to chose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on our financial statements.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

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

Although, currently, all of our sales and purchases are denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

Table of Contents

Item 8. *Financial Statements and Supplementary Data*

THERMAGE, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	55
<u>Balance Sheets</u>	56
<u>Statements of Operations</u>	57
<u>Statements of Stockholders' Equity (Deficit)</u>	58
<u>Statements of Cash Flows</u>	59
<u>Notes to Financial Statements</u>	60

The following Financial Statement Schedule of the Registrant for the years ended December 31, 2006, 2005 and 2004 is filed as part of this Report as required to be included in Item 8 and should be read in conjunction with the Financial Statements of the Registrant:

	Page
<u>Schedule II Valuation and Qualifying Accounts</u>	83

All other required schedules are omitted because of the absence of conditions under which they are required or because the required information is given in the Financials Statements or the Notes thereto.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Thermage, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Thermage, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule appearing under Item 8 on page 83 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for share-based compensation for the year ended December 31, 2006.

As discussed in Note 3 to the financial statements, the Company adopted FASB Staff Position 150-5 (FSP 150-5), *Issuers Accounting under FASB Statement No. 150 for Free-standing Warrants and Other Instruments on Shares that are Redeemable*, during the year ended December 31, 2005.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 30, 2007

Table of Contents**Thermage, Inc.****BALANCE SHEETS**

<i>(in thousands of dollars, except share and per share data)</i>	December 31,	
	2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 45,915	\$ 10,121
Accounts receivable, net of allowance for doubtful accounts in 2006 and 2005 of \$31 and \$29, respectively	3,285	2,857
Inventories, net	5,219	5,411
Prepaid expenses and other current assets	1,717	1,350
Total current assets	56,136	19,739
Restricted cash		107
Property and equipment, net	3,638	4,073
Other assets	101	113
Total assets	\$ 59,875	\$ 24,032
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Liabilities:		
Accounts payable	\$ 1,398	\$ 1,977
Accrued liabilities	7,372	4,774
Current portion of deferred revenue	1,151	1,188
Customer deposits	62	45
Current portion of borrowings		808
Total current liabilities	9,983	8,792
Deferred rent, net of current portion	55	110
Other long-term liabilities		107
Deferred revenue, net of current portion	716	610
Borrowings, net of current portion		4,040
Preferred stock warrants liability		3,937
Total liabilities	10,754	17,596
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, \$0.001 par value:		
Authorized: 10,000,000 and 26,360,000 shares at December 31, 2006 and 2005, respectively		
Issued and outstanding: none and 12,042,274 shares at December 31, 2006 and 2005, respectively		45,169
Stockholders' equity (deficit):		
Common stock, \$0.001 par value:		
Authorized: 100,000,000 and 29,100,000 shares at December 31, 2006 and 2005, respectively		
Issued and outstanding: 22,906,851 and 4,037,774 shares at December 31, 2006 and 2005, respectively	23	4
Additional paid-in capital	93,418	5,682
Deferred stock-based compensation	(6)	(3,541)
Notes receivable from stockholders	(125)	(598)
Accumulated deficit	(44,189)	(40,280)
Total stockholders' equity (deficit)	49,121	(38,733)
Total liabilities and stockholders' equity (deficit)	\$ 59,875	\$ 24,032

Edgar Filing: THERMAGE INC - Form 10-K

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

Table of Contents**Thermage, Inc.****STATEMENTS OF OPERATIONS**

<i>(in thousands of dollars, except share and per share data)</i>	Years Ended December 31,		
	2006	2005	2004
Net revenue	\$ 54,320	\$ 40,655	\$ 50,384
Cost of revenue	15,259	12,309	12,452
Gross margin	39,061	28,346	37,932
Operating expenses			
Sales and marketing	24,071	19,997	15,596
Research and development	9,639	8,908	8,490
General and administrative	9,973	7,414	8,873
Litigation settlement gain		(1,646)	
Total operating expenses	43,683	34,673	32,959
Income (loss) from operations	(4,622)	(6,327)	4,973
Interest and other income	768	340	177
Interest and other expense	(55)	(1,549)	(14)
Income (loss) before income taxes and cumulative effect of change in accounting principle	(3,909)	(7,536)	5,136
Provision for income taxes			(103)
Net income (loss) before cumulative effect of change in accounting principle	(3,909)	(7,536)	5,033
Cumulative effect of change in accounting principle (Note 3)		(697)	
Net income (loss)	\$ (3,909)	\$ (8,233)	\$ 5,033
Net income (loss) allocable to common stockholders	\$ (3,909)	\$ (8,233)	\$ 313
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 (Note 3)		(0.19)	
Net income (loss) per share basic	\$ (0.60)	\$ (2.25)	\$ 0.10
Net income (loss) per share diluted	\$ (0.60)	\$ (2.25)	\$ 0.06
Weighted average shares outstanding used in calculating net income (loss) per common share:			
Basic	6,561,648	3,664,990	3,023,225
Diluted	6,561,648	3,664,990	5,319,754

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

Table of Contents

Thermage, Inc.

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

<i>(in thousands of dollars, except share amounts)</i>	Common Stock		Additional Capital	Deferred Compensation	Notes Receivable from Stockholders	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount					
Balances, December 31, 2003	3,596,520	\$ 4	\$ 2,491	\$ (604)	\$ (37,080)	\$ (35,189)	
Exercise of stock options	489,808		273				273
Interest receivable on notes for exercise of stock options					(20)		(20)
Nonemployee stock compensation expense			110				110
Employee stock compensation expense			353				353
Net income						5,033	5,033
Balances, December 31, 2004	4,086,328	4	3,227	(624)	(32,047)	(29,440)	
Exercise of stock options	51,446		47				47
Issuance of stock options in connection with 2004 employee bonus accrual			73				73
Interest receivable on notes for exercise of stock options					(20)		(20)
Deferred stock-based employee compensation			3,865	(3,865)			
Amortization of deferred stock-based employee compensation				324			324
Nonemployee stock compensation expense			132				132
Reduction of notes receivable upon common stock repurchase	(100,000)		(46)		46		
Reclassification of preferred stock warrants upon adoption of FSP No. 150-5			(1,616)				(1,616)
Net loss						(8,233)	(8,233)
Balances, December 31, 2005	4,037,774	4	5,682	(3,541)	(598)	(40,280)	(38,733)
Issuance of common stock from initial public offering, net of issuance costs	6,150,000	6	38,328				38,334
Conversion of redeemable convertible preferred stock to common stock at initial public offering	12,406,134	12	48,918				48,930
Conversion of warrants from warrants for preferred stock to warrants for common stock			95				95
Exercise of stock options	415,027	1	459				460
Amortization of deferred stock-based employee compensation				191			191
Interest receivable on notes for exercise of stock options					(4)		(4)
Elimination of deferred stock-based compensation due to modification of options under SFAS No. 123R			(3,344)	3,344			
Employee stock-based compensation expense recognized under SFAS No. 123R, net of estimated forfeitures			3,126				3,126
Reduction of notes receivable upon common stock repurchase	(102,084)		(46)		46		
Collection of notes and interest receivable					431		431
Nonemployee stock compensation expense			200				200
Net loss						(3,909)	(3,909)
Balances, December 31, 2006	22,906,851	\$ 23	\$ 93,418	\$ (6)	\$ (125)	\$ (44,189)	\$ 49,121

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

Table of Contents**Thermage, Inc.****STATEMENTS OF CASH FLOWS**

<i>(in thousands of dollars)</i>	Years Ended December 31,		
	2006	2005	2004
Cash flows from operating activities			
Net income (loss)	\$ (3,909)	\$ (8,233)	\$ 5,033
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,079	1,995	1,047
Interest receivable on stockholder notes	44	(20)	(20)
Amortization of warrants on notes payable	165	20	
Changes in preferred stock warrant liability	(836)	2,136	
Loss on disposal on property, plant and equipment	18	4	40
Stock-based compensation	3,517	456	463
Allowance for doubtful accounts	2	29	
Reserve for excess and obsolete inventory	(608)	256	600
Change in assets and liabilities			
Accounts receivable	(430)	(1,700)	(490)
Inventories	28	1,557	(5,729)
Prepaid expenses and other current assets	(367)	(413)	(181)
Other non-current assets	12	10	(124)
Accounts payable	(585)	(190)	532
Accrued and other liabilities	2,078	(14)	899
Deferred revenue	69	(126)	367
Customer deposits	17	(51)	(338)
Deferred rent	(55)	(32)	141
Net cash provided by (used in) operating activities	1,239	(4,316)	2,240
Cash flows from investing activities			
Acquisition of property and equipment	(899)	(2,247)	(3,156)
Change in restricted cash	107	(64)	(43)
Proceeds from maturities of marketable securities			3,792
Proceeds from sale of property and equipment	12		14
Net cash provided by (used in) investing activities	(780)	(2,311)	607
Cash flows from financing activities			
Repayment of equipment leases	(13)	(5)	(6)
Repayment of notes payable	(5,000)		
Collection of notes receivable from stockholders	384		
Proceeds from exercise of stock options	460	47	273
Proceeds from exercise of preferred stock warrants	755		1
Proceeds from notes payable		5,000	
Proceeds from IPO, net of capitalized IPO related costs (1)	38,749		
Net cash provided by financing activities	35,335	5,042	268
Net increase (decrease) in cash and cash equivalents	35,794	(1,585)	3,115
Cash and cash equivalents at beginning of year	10,121	11,706	8,591
Cash and cash equivalents at end of year	\$ 45,915	\$ 10,121	\$ 11,706

Edgar Filing: THERMAGE INC - Form 10-K

Supplemental disclosure of cash flow information

Cash paid for interest	\$ 607	\$ 82	\$ 14
Cash paid for taxes		158	1

Supplemental disclosure of significant non-cash investing and financing activities

Reduction of note receivable issued for common stock	(46)	(46)	
Reclassification of preferred stock warrants upon adoption of FSP 150-5		1,616	
Issuance of preferred stock upon net exercise of preferred stock warrants	882		
Conversion of redeemable convertible preferred stock to common stock at initial public offering	48,930		

(1) The difference between \$38.7 million and \$38.3 million in Note 1 is \$0.4 million offering costs accrued and not yet paid at December 31, 2006

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

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS

(In thousands of dollars, except share and per share amounts)

NOTE 1 THE COMPANY

Background

Thermage, Inc. (the Company) develops, manufactures, and markets radiofrequency-based equipment and disposable products for non-invasive treatment of wrinkles. The Company was incorporated in California on January 11, 1996 and reincorporated in Delaware on September 10, 2001. The Company commercially launched its first products in October 2002.

Initial Public Offering

On November 9, 2006, the Company completed an initial public offering (IPO) of 6,000,000 shares of its common stock at \$7.00 per share. Additionally, on December 4, 2006, the underwriters partially exercised their over-allotment option and purchased 150,000 shares at \$7.00 per share. The Company raised approximately \$38.3 million, net of underwriting discounts, commissions and other offering costs. Upon the closing of the offering, all the Company's outstanding shares of redeemable convertible preferred stock converted on a one-to-one basis into 12,406,134 shares of common stock.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the accompanying financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash equivalents or short-term financial investments that are readily convertible to cash are stated at cost, which approximates market value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents.

Restricted Cash

At December 31, 2005, cash balances of \$107 were restricted from withdrawal and held by a brokerage firm in the form of a trust. Corresponding amounts were also included in liabilities at December 31, 2005. This trust is associated with a deferred compensation plan, which is available to certain members of management. The plan allows participants to defer a portion of his or her compensation. The principal of the trust and any earnings are held separate and apart from other funds of the Company and shall be used exclusively for the uses and the purposes of the plan participants and beneficiaries. The sole participant left the Company's employment during 2006 upon which time the restricted cash and liabilities were released.

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

Fair Value of Financial Instruments

Carrying amounts of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate their fair values due to their short maturities. Based on the borrowing rates available to the Company for loans with similar terms, the carrying value of the borrowings approximates their fair value. The carrying amounts of restricted cash, other liabilities and other assets approximate their fair values based upon their nature and size. The carrying amount of the preferred stock warrants liability represents its fair value (see note 3).

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash and cash equivalents and accounts receivable. The Company's cash and cash equivalents are primarily invested in deposits, certificates of deposit and money market accounts with a major bank in the United States. Deposits in this bank may exceed the amount of insurance provided on such deposits, if any. Management believes that this financial institution is financially sound and, accordingly, minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company is subject to risks common to companies in the medical device industry including, but not limited to, new technological innovations, dependence on key personnel, dependence on key suppliers, protection of proprietary technology, product liability and compliance with government regulations. To achieve and sustain profitable operations, the Company must successfully design, develop, manufacture and market its products. There can be no assurance that current products will continue to be accepted in the marketplace. Nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all. These factors could have a material adverse effect on the Company's future financial results, financial position and cash flows.

Future products developed by the Company may require clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's products will continue to meet the necessary regulatory requirements. If the Company was denied such clearances or such clearances were delayed, it may have a materially adverse impact on the Company.

Accounts Receivable

Accounts receivable are typically unsecured and are derived from revenues earned from customers. The Company performs ongoing credit evaluations of its customers and maintains reserves for potential credit losses. Allowance for doubtful accounts was \$31 and \$29, respectively, at December 31, 2006 and 2005. Doubtful account write-offs have been insignificant during the years ended December 31, 2006 and 2005.

Segment Information

The Company operates in one business segment, which encompasses the developing, manufacturing and marketing of radiofrequency based equipment for the aesthetics market. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

The following table summarizes net revenue by product:

	Years Ended December 31,		
	2006	2005	2004
RF generators	\$ 13,262	\$ 12,556	\$ 19,682
ThermaTips and other consumables	39,436	27,010	30,112
Net revenue from products	52,698	39,566	49,794
Services and other	1,622	1,089	590
Total net revenue	\$ 54,320	\$ 40,655	\$ 50,384

The following table summarizes net revenue by geographic region:

	Years Ended December 31,		
	2006	2005	2004
United States	\$ 28,305	\$ 22,751	\$ 36,285
Asia Pacific	12,858	9,188	7,867
Europe/Middle East	6,976	4,513	1,799
Rest of the world	6,181	4,203	4,433
Total net revenue	\$ 54,320	\$ 40,655	\$ 50,384

Inventories

Inventory is stated at the lower of cost or market, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis) and market being determined as the lower of replacement cost or net realizable value. Lower of cost or market is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which is five years for furniture and fixtures, three to five years for machinery and equipment, and three years for software and computers and equipment. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, typically five years. Upon sale or retirement of assets, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

In accordance with the provisions of Statement of Financial Accounting Standards Board (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets*, the Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under SFAS No. 144, an

Edgar Filing: THERMAGE INC - Form 10-K

impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

by which the carrying amount of a long-lived asset exceeds its fair value. Through December 31, 2006, there have been no such impairments.

Freestanding Preferred Stock Warrants

Freestanding warrants and other similar instruments related to shares that are redeemable are accounted for in accordance with SFAS No. 150. Under SFAS No. 150, the outstanding freestanding warrants that are related to the Company's convertible preferred stock are classified as liabilities on the balance sheet (see Note 3). The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income or other expense. During the year ended December 31, 2006, warrants to purchase 590,329 shares of preferred stock were net exercised into 364,360 shares of convertible preferred stock and then converted into 364,360 shares of common stock in connection with the Company's initial public offering in November 2006. Additional preferred stock warrants for 27,778 shares of preferred stock were not exercised upon the Company's initial public offering and were converted into warrants for common stock. At December 31, 2006, there were no outstanding warrants to purchase shares of the Company's convertible preferred stock.

Revenue Recognition

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104. Product revenue is recognized when title and risk of ownership has 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 occurs when the product is shipped to the customer. Revenue is recorded net of customer and distributor discounts. For sales transactions with non-standard extended payment terms, or when collectibility is not reasonably assured, the Company recognizes revenue upon receipt of cash payment.

The Company's system 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, the Company recognizes 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 the Company has objective and reliable evidence of fair value of the undelivered elements, it defers revenue attributable to the post-shipment obligations and recognizes such revenue when the obligation is fulfilled. Otherwise, the Company will defer all revenue until all elements are delivered.

The Company sells to end-users in the United States and to distributors outside of the United States. Sales to distributors do not include return rights. The Company typically recognizes revenues upon shipment for sales through independent, third party distributors as the Company has 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 the Company's products. The Company does not provide price protection or stock rotation rights to any of its distributors. In addition, the Company's distributor agreements do not allow the distributor to return or exchange products and the distributor is obligated to pay the Company for the sale regardless of whether the distributor is able to resell the product.

Certain of the Company's customers in the United States who purchased systems prior to August 2003 had the general right to return unused consumable products. Prior to 2004, the Company lacked sufficient

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

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, the Company has had a sufficient historical basis to estimate return rates and has 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 \$648 and \$97, respectively, were recognized in 2004.

The Company offers a three year warranty for systems sold in the United States and a one year replacement parts warranty for systems sold to distributors. The Company also provides a warranty for its consumable products. The Company provides for the estimated cost to repair or replace products under warranty at the time of sale. The Company also offers customers extended warranty service contracts. Revenue from the sale of extended service contracts is recognized on a straight-line basis over the period of the applicable extended contract. The Company also earns service revenue from customers outside of their warranty term or extended service contracts. Such service revenue is recognized as the services are provided.

Shipping and Handling Costs

Shipping and handling costs charged to customers are included in net revenue and the associated expense is included in cost of revenue in the statements of operations

Research and Development Expenditures

Costs related to research, design and development of products are charged to research and development expense as incurred.

Advertising Costs

Advertising costs are included in sales and marketing expenses and are expensed as incurred. Advertising costs were \$929 for the year ended December 31, 2006 and were insignificant for the years ended December 31, 2005 and 2004.

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* and its interpretations and complied with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options. SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity investment. The Company used the minimum value method in connection with the disclosure provisions of SFAS No. 123. The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

the measurement date and are subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period, on a straight-line basis.

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

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and tax basis of assets and liabilities, measured at tax rates that will be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Comprehensive Income

Comprehensive income is defined as the change in equity from transactions and other events and circumstances other than those resulting from investments by owners and distributions to owners. For the years ended December 31, 2006, 2005 and 2004, the Company did not have any significant components of comprehensive income other than net income (loss). Therefore, no separate statement of comprehensive income has been presented.

Net Income (Loss) Per Share

Basic net income (loss) per share attributed to common shares is computed by dividing the net income (loss) attributable to common shares for the period by the weighted average number of common shares outstanding during the period as reduced by the weighted average unvested common shares subject to repurchase by the Company. Net income (loss) available to common stockholders is calculated using the two class method as the net income less amounts allocated to preferred stock to reflect the nondiscretionary contractual participation rights of the preferred stock to share in current earnings as if all of the earnings for the period had been distributed.

Diluted net income (loss) per share attributed to common shares is computed by dividing the net income (loss) attributable to common shares for the period by the weighted average number of common and potential common shares outstanding during the period, if the effect of each class of potential common shares is dilutive.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

Potential common shares include common stock subject to repurchase rights and incremental shares of common stock issuable upon the exercise of stock options and warrants and upon conversion of preferred stock.

	Years Ended December 31,		
	2006	2005	2004
Historical net income (loss) per share:			
Numerator			
Net income (loss)	\$ (3,909)	\$ (8,233)	\$ 5,033
Income allocable to preferred stockholders			4,720
Net income (loss) allocable to common stockholders	\$ (3,909)	\$ (8,233)	\$ 313
Denominator			
Weighted-average common shares outstanding	6,587,976	4,038,302	3,905,830
Less: weighted-average unvested common shares subject to repurchase	(26,328)	(373,312)	(882,605)
Denominator for basic net income (loss) per share	6,561,648	3,664,990	3,023,225
Dilutive effect of stock options			1,413,924
Dilutive effect of common stock subject to repurchase			882,605
Denominator for diluted net income (loss) per share	6,561,648	3,664,990	5,319,754
Basic net income (loss) per share	\$ (0.60)	\$ (2.25)	\$ 0.10
Diluted net income (loss) per share	\$ (0.60)	\$ (2.25)	\$ 0.06

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

	Years Ended December 31,		
	2006	2005	2004
Options to purchase common stock	3,272,144	3,347,541	
Common stock subject to repurchase	6,250	203,959	
Convertible preferred stock		12,042,274	12,042,274
Convertible preferred stock warrants		628,718	600,940
Employee stock purchase plan	92,039		

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting uncertainty in tax positions. This Interpretation requires that the Company recognizes in its financial statements, the impact of a tax provision, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of January 1, 2007, with the

Edgar Filing: THERMAGE INC - Form 10-K

cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company does not expect the adoption of FIN 48 to have a material impact on its financial statements.

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB108). SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year s financial statements are materially misstated. SAB 108 becomes effective for the year ended December 31, 2006. The adoption of SAB 108 did not have any impact on the Company s financial statements.

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115* (SFAS No.159). SFAS No. 159 allows companies to chose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and will be applied prospectively. The Company is currently evaluating the impact of adopting SFAS No. 159 on its financial statements.

NOTE 3 CHANGE IN ACCOUNTING POLICY

On June 29, 2005, the FASB issued Staff Position 150-5, *Issuer s Accounting under FASB Statement No. 150 (SFAS 150) for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable* (FSP 150-5). FSP 150-5 affirms that such warrants are subject to the requirements in SFAS 150, regardless of the timing of the redemption feature or the redemption price. Therefore, under SFAS 150, the freestanding warrants that are related to the purchase of the Company s convertible preferred stock are liabilities that should be recorded at fair value. The Company previously accounted for freestanding warrants for the purchase of convertible preferred stock under EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18).

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

The Company adopted FSP 150-5 and accounted for the cumulative effect of the change in accounting principle as of July 1, 2005. For the year ended December 31, 2005, the impact of the change in accounting principle was to increase net loss by \$697, or \$0.19 per share. There was \$1,439 of additional expense recorded in other expense to reflect the increase in fair value between July 1, 2005 and December 31, 2005. The pro forma effect of the adoption of FSP 150-5 on the Company's results of operations for 2005 and 2004, if applied retroactively, would be as follows:

	Years Ended December 31,	
	2005	2004
Net income (loss) as reported	\$ (8,233)	\$ 5,033
Net income (loss) assuming retroactive application of accounting principal	\$ (8,574)	\$ 5,159
Net income (loss) allocable to common stockholders as reported	\$ (8,233)	\$ 313
Net income (loss) allocable to common stockholders assuming retroactive application of accounting principle	\$ (8,574)	\$ 344
Basic net income (loss) per share as reported	\$ (2.25)	\$ 0.10
Basic net income (loss) per share assuming retroactive application of accounting principle	\$ (2.34)	\$ 0.11
Diluted net income (loss) per share as reported	\$ (2.25)	\$ 0.06
Diluted net income (loss) per share assuming retroactive application of accounting principle	\$ (2.34)	\$ 0.06

The Company used a Black-Scholes option pricing model to value the convertible preferred stock warrants at each reporting period and upon initial adoption of FSP 150-5. The weighted average assumptions used to value the preferred stock warrants upon adoption of FSP 150-5 and at the end of each subsequent reporting period were as follows:

	December 31,	July 1,
	2005	2005
Risk free interest rate	4.36%	3.74%
Remaining contractual life (in years)	3.42	3.76
Dividend yield		
Expected volatility	54%	55%
Fair value of preferred stock	\$ 9.58	\$ 6.78

During the year ended December 31, 2006, 590,329 shares of preferred stock warrants were net exercised into 364,360 shares of convertible preferred stock and then converted into 364,360 shares of common stock in connection with the Company's initial public offering in November 2006. Additional preferred stock warrants for 27,778 shares of preferred stock were not exercised upon the Company's initial public offering and were converted into warrants for shares of common stock. The Company recorded a credit of \$836 in other expense during the year ended December 31, 2006 to reflect the change in fair value of the preferred stock warrants in 2006.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)****NOTE 4 BALANCE SHEET DETAIL*****Inventories, Net***

Inventories, net consist of the following:

	December 31,	
	2006	2005
Raw materials	\$ 2,134	\$ 1,685
Work-in-process	710	293
Finished goods	2,375	3,433
	\$ 5,219	\$ 5,411

Property and Equipment, Net

Property and equipment, net consists of the following:

	Years Ended December 31,	
	2006	2005
Leasehold improvements	\$ 2,611	\$ 2,326
Furniture and fixtures	712	772
Machinery and equipment	3,403	2,281
Software	684	616
Computers and equipment	1,833	1,714
	9,243	7,709
Less: Accumulated depreciation and amortization	(5,605)	(3,636)
	\$ 3,638	\$ 4,073

Depreciation and amortization expense related to property and equipment was \$2,079, \$1,995 and \$1,047 for the years ended December 31, 2006, 2005 and 2004, respectively.

Machinery and equipment includes \$0 and \$23 of machinery under capital leases at December 31, 2006 and 2005, respectively. Computers and equipment includes \$0 and \$19 of office equipment under capital leases at December 31, 2006 and 2005, respectively. Accumulated amortization of assets under capital leases totaled \$0 and \$27 at December 31, 2006 and 2005, respectively.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)***Accrued Liabilities*

Accrued liabilities consist of the following:

	December 31,	
	2006	2005
Marketing expenses	\$ 226	\$ 136
Travel and entertainment	191	138
Warranty	329	296
Sales and use tax	171	215
Payroll and related expenses	3,947	2,342
Professional fees	269	191
Fixed Assets	283	
IPO expenses	409	
Accrued claims	477	846
Accrued inventory purchases	294	81
Other	776	529
	\$ 7,372	\$ 4,774

NOTE 5 WARRANTY AND SERVICE CONTRACTS*Standard Warranty*

The Company currently accrues for the estimated cost to repair or replace products under warranty at the time of sale. A summary of standard warranty accrual activity is shown below:

	Years Ended December 31,	
	2006	2005
Balance at beginning of period	\$ 296	\$ 345
Accruals for warranties issued during the period	256	276
Accruals related to pre-existing warranties (including changes in estimates)	58	
Settlements made during the period	(281)	(325)
Balance at end of period	\$ 329	\$ 296

Extended Warranty Contracts

The Company sells extended warranty contracts to its customers. At the time of sale, the Company defers the amounts billed for such service contracts. Deferred service contract revenue is recognized on a straight-line basis over the period of the applicable extended warranty contract. A summary of extended warranty contract activity is shown below:

Edgar Filing: THERMAGE INC - Form 10-K

	Years Ended December 31,	
	2006	2005
Balance at beginning of period	\$ 1,442	\$ 1,657
Payments received	1,243	482
Revenue recognized	(1,039)	(697)
Balance at end of period	\$ 1,646	\$ 1,442

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

The Company incurred costs of \$695, \$453 and \$57 under extended warranty contracts during the years ended December 31, 2006, 2005 and 2004, respectively.

NOTE 6 COMMITMENTS AND CONTINGENCIES***Facility Lease******Commitments***

In November 2004, the Company entered into a noncancelable operating lease at its current headquarters facility with an expiration date of September 30, 2007. This lease was renewed in December 2006 for another three years through September 30, 2010. Under the terms of the lease, the Company is responsible for its share of taxes, insurance and common area maintenance costs. Rent expense for the years ended December 31, 2006, 2005 and 2004 was \$737, \$739 and \$774, respectively, net of sublease income of \$0, \$92 and \$0, respectively.

Future minimum lease payments under the noncancelable operating lease at December 31, 2006 are as follows:

Years Ending December 31,	
2007	\$ 820
2008	981
2009	1,074
2010	835
	\$ 3,710

Contingencies

From time to time, the Company is involved in litigation relating to claims arising from the ordinary course of business. Management does not believe the final disposition of these matters will have a material adverse effect on the financial statements of the Company.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representation and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its certificate of incorporation, bylaws and individual indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such a capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amount paid for future claims.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)****NOTE 7 BORROWINGS*****Notes Payable***

In November and December 2005, the Company borrowed amounts of \$2,500 and \$2,500, respectively, under a debt financing agreement. The notes bear interest at 10.19% and 10.64%, respectively, per annum. Under the original terms of the notes, interest was payable in installments over the first six months and both interest and principal were payable in installments over the remaining 30 months. During June 2006, the repayment terms were modified such that interest only payments are due for the first 12 months and both interest and principal are due for the remaining 24 months. In November and December 2006, the Company repaid the outstanding balances on the notes payable. At December 31, 2006 and 2005, the Company had \$0 and \$5,000 outstanding under the notes, respectively.

Equipment Lease

In April 2003, the Company borrowed \$23 under an equipment lease with a leasing company. The note is collateralized by the equipment leased and bears interest at 11.10% per annum with interest and principal due in installments over 60 months. In December 06, the Company repaid the note. At December 31, 2006 and 2005, the Company had \$0 and \$13 outstanding under the lease, respectively.

NOTE 8 REDEEMABLE CONVERTIBLE PREFERRED STOCK

Redeemable convertible preferred stock at December 31, 2005 consists of the following:

	Number Outstanding	Carrying Amount	Liquidation Amount
Series A Convertible Preferred Stock	1,100,000	\$ 1,281	\$ 1,309
Series B Convertible Preferred Stock	1,886,792	4,953	5,000
Series C Convertible Preferred Stock	9,055,482	38,935	40,750
Total	12,042,274	\$ 45,169	\$ 47,059

Upon the completion of the Company's initial public offering, all of the Company's outstanding shares of redeemable convertible preferred stock converted on a one-to-one basis into 12,406,134 shares of common stock.

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue 10,000,000 shares of preferred stock of \$0.001 par value. There were no shares of convertible preferred stock outstanding at December 31, 2006.

Warrants for Convertible Preferred Stock

In connection with an equipment financing line of credit, the Company issued warrants during 2001 to purchase 11,111 shares of Series C Convertible Preferred Stock, with an exercise price of \$4.50 per share. Such warrants were outstanding at December 31, 2005 and expired in May 2006. The value of the warrants was calculated using the Black-Scholes option pricing model and was deemed insignificant.

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

In connection with the issuance of Series C Preferred Stock in 2002, the Company issued warrants to purchase 590,329 shares of Series C Convertible Preferred Stock, with an exercise price of \$4.50 per share. The proceeds from the Series C Preferred Stock financing were allocated between the issuance of preferred stock and the issuance of the warrants based on their relative fair values. The fair value of the warrants was calculated using the Black-Scholes option pricing model. The proceeds of \$1,616 allocated to the warrants was recorded as a credit to additional paid-in capital. During the year-ended December 31, 2004, warrants to purchase 500 shares of preferred stock were exercised. During the year ended December 31, 2006, warrants to purchase 590,329 shares of preferred shares were net exercised into 364,360 shares of convertible preferred stock and then converted into 364,360 shares of common stock in connection with the Company's initial public offering in November 2006.

In connection with a debt financing agreement, the Company issued warrants during 2005 to purchase 27,778 shares of Series C Convertible Preferred Stock, with an exercise price of \$4.50 per share. The warrants to purchase the 27,778 shares were outstanding at December 31, 2005. The warrants expire on the earliest of (a) October through December 2012, (b) the third anniversary of the closing of an initial public offering of the Company's common stock pursuant to a registration statement declared effective under the Securities Act of 1933, as amended, or (c) the closing of a Qualifying Acquisition, defined as any consolidation or merger of the Company with another corporation, or the sale of all or substantially all of its assets to another corporation which is effected such that (i) the Company's stockholders shall be entitled to receive cash or shares of stock that are of a publicly traded company listed on a national market or exchange which may be sold without restrictions after the close of such event, (ii) the Company's stockholders own less than 50% of the voting securities of the surviving entity and (iii) the surviving entity does not assume other options or warrants of the Company. The value of the warrants was calculated using the Black-Scholes option pricing model. The value of \$185 allocated to the warrants was recorded as a credit to preferred stock warrants liability and as a discount to the carrying value of the debt at the time of issuance. The discount on the debt was amortized to interest expense over the life of the debt. The unamortized value of the discount at December 31, 2006 and 2005 was \$0 and \$165, respectively.

As disclosed in Note 3, in 2005 the Company reclassified the freestanding preferred stock warrants as a liability and began adjusting the warrants to fair value at each reporting period. Following the closing of the initial public offering of the Company's common stock in November 2006, these preferred stock warrants became exercisable for 27,778 shares of the Company's common stock at an exercise price of \$4.50 per share. The value of the warrants of \$95, calculated using the Black-Scholes option pricing model, was transferred from preferred stock warrants liability to additional paid-in capital at the date of closing of the initial public offering.

NOTE 9 COMMON STOCK

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of \$0.001 par value common stock. Common stockholders are entitled to dividends as and when declared by the Board of Directors subject to the prior rights of the preferred stockholders.

2006 Employee Stock Purchase Plan

On August 2, 2006, the Board of Directors adopted the 2006 Employee Stock Purchase Plan. A total of 250,000 shares of common stock were reserved for issuance pursuant to the 2006 Employee Stock Purchase Plan.

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

The 2006 Employee Stock Purchase Plan was approved by the Company's stockholders on August 4, 2006. The 2006 Employee Stock Purchase Plan became effective upon the closing of the Company's initial public offering. Under the 2006 Employee Stock Purchase Plan, eligible employees are permitted to purchase common stock through payroll deduction at a price of 85% of the lower market value as of the beginning or the end of the six-month offering period. Shares of common stock will be increased on the first day of each fiscal year, commencing in 2007, by an amount equal to the least of: (i) 900,000 shares; (ii) 2.0% of the outstanding shares of the Company's common stock on the first day of the fiscal year; or (iii) such other amount as may be determined by the Board of Directors. Each offering period starts on the first trading day on or after May 15 and November 15 of each year. The initial offering period commenced on November 9, 2006, the effective date of the Company's initial public offering. No shares have been issued under the plan in 2006. At December 31, 2006, 250,000 shares remained available for future issuance. In addition, on January 1, 2007, the Company added 458,137 shares to the Plan.

Stock Option Plans

In 1997, the Company adopted the 1997 Stock Option Plan. The Plan provides for the granting of stock options to employees and consultants of the Company. Options granted under the Plan may be either incentive stock options or nonqualified stock options. Incentive stock options (ISO) may be granted only to Company employees (including officers and directors who are also employees). Nonqualified stock options (NSO) may be granted to Company employees and consultants. The Company has reserved 5,940,000 shares of common stock for issuance under the Plan.

On August 2, 2006, the Board of Directors adopted the 2006 Equity Incentive Plan. A total of 2,750,000 shares of common stock were reserved for issuance pursuant to the 2006 Equity Incentive Plan. In addition, the shares reserved for issuance under the 2006 Equity Incentive Plan included shares reserved but unissued under the Company's 1997 Stock Option Plan as the result of termination of options or the repurchase of shares. The 2006 Equity Incentive Plan was approved by the Company's stockholders on August 4, 2006.

Shares of common stock approved under the 2006 Equity Incentive Plan will be increased on the first day of each fiscal year, commencing in 2007, by an amount equal to the least of: (i) 1,800,000 shares; (ii) 3.5% of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year; or (iii) such other amount as may be determined by the Board of Directors. On January 1, 2007, the Company added 801,739 shares to the 2006 Equity Incentive Plan.

Options under the 1997 Stock Option Plan and 2006 Equity Incentive Plan may be granted for periods of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors, provided, however, that (i) the exercise price of an ISO and NSO shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant, respectively, and (ii) the exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively. Options granted generally vest over four years.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

Activity under the 1997 Stock Option Plan and 2006 Equity Incentive Plan is summarized as follows:

	Shares Available for Grant	Number of Options	Options Outstanding Weighted Average Exercise Price	Options Outstanding Weighted Average Contractual Terms (Years)	Aggregate Intrinsic Value
Balance, December 31, 2003	125,074	1,836,917	\$ 0.71		
Additional shares reserved	700,000				
Options granted	(700,150)	700,150	4.49		
Options exercised		(489,808)	0.97		
Options repurchased or cancelled	83,022	(83,022)	1.84		
Balance, December 31, 2004	207,946	1,964,237	1.94		
Additional shares reserved	1,200,000				
Options granted	(1,908,049)	1,908,049	4.00		
Options exercised		(51,446)	2.33		
Options repurchased or cancelled	573,299	(473,299)	3.00		
Balance, December 31, 2005	73,196	3,347,541	2.96		
Additional shares reserved	3,000,000				
Options granted	(2,608,386)	2,608,386	2.78		
Options exercised		(415,027)	1.11		
Options repurchased or cancelled	2,370,840	(2,268,756)	4.02		
Balance, December 31, 2006	2,835,650	3,272,144	\$ 2.31	7.96	\$ 16,145
Options vested and expected to vest at December 31, 2006		3,062,406	\$ 2.23	7.79	\$ 15,300
Options vested at December 31, 2006		1,644,382	\$ 1.46	7.12	\$ 9,124

Included in the above table are non-employee stock options granted in December 31, 2006, 2005 and 2004 for 5,000, 5,000 and 0, shares of common stock, respectively. The Company had non-employee stock options outstanding for 72,293, 103,209 and 103,209 shares of common stock, respectively, at December 31, 2006, 2005 and 2004, at weighted average exercise prices of \$0.59, \$0.65 and \$0.48, respectively. The non-employee options outstanding have weighted average remaining contractual term of 6.03 years and an aggregate intrinsic value of \$463 at December 31, 2006.

The options outstanding and currently exercisable by exercise price at December 31, 2006 are as follows:

Options Outstanding			Options Vested and Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Number Exercisable	Weighted Average Exercise Price	
\$0.00	30,000	0.58	30,000	\$0.00	
0.12	2,500	2.21	2,500	0.12	

Edgar Filing: THERMAGE INC - Form 10-K

0.45	265,124	5.68	247,949	0.45
0.70	34,967	6.56	29,082	0.70
1.00	33,688	6.73	24,145	1.00
1.10	471,807	6.89	424,553	1.10
1.90	1,999,169	8.33	850,561	1.90
3.00	200,187	9.34	28,664	3.00
4.00	3,000	8.57	1,062	4.00
8.15	29,752	9.93	0	8.15
11.00	201,950	9.66	5,866	11.00
	3,272,144	7.96	1,644,382	\$1.46

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

The number of outstanding options vested and exercisable at December 31, 2005 was 1,241,540 options with a weighted average exercise price of \$1.699 per share.

Stock Option Repricing

During March 2006, the Company repriced certain stock option awards held by 116 of its employees. Under the terms of this repricing, the Company repriced employee stock options having an exercise price of \$2.00 or above to an exercise price of \$1.90. Other than the exercise price, all other terms of the repriced options, such as vesting and contractual life, remained the same. In consideration for the repricing of eligible stock option awards, the employees who were previously granted certain stock option awards on February 2, 2005 were also required to return these awards for cancellation. As a result of this repricing, the Company repriced 447,565 vested options and 1,523,035 unvested options having a weighted average original exercise price of \$4.18 and \$4.10, respectively. Such options were repriced at a new exercise price of \$1.90 per share. As a result of this repricing, the Company also cancelled 35,216 outstanding employee options with an original exercise price of \$4.00 that were granted on February 2, 2005. The Company has accounted for the repricing and cancellation transactions as a modification under SFAS No. 123R and recorded any net incremental fair value related to vested awards as compensation expense on the date of modification. In accordance with SFAS No. 123R, the Company will record the incremental fair value related to the unvested awards, together with unamortized stock-based compensation expense associated with the unvested awards, over the remaining requisite service period of the option holders. In connection with the repriced options, the Company recorded stock compensation expense of \$2,008 in the year ended December 31, 2006. Incremental compensation cost resulting from the modification was \$1,605 in the year ended December 31, 2006.

Stock-based Compensation under APB No. 25

During the years ended December 31, 2006 and 2005, the Company issued stock options to certain employees with exercise prices below the fair market value of the Company's common stock at the date of grant, determined with hindsight. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options granted and the fair market value of the Company's stock at the date of grant, determined with hindsight. During the year ended December 31, 2005, the Company recorded deferred stock-based compensation related to these options of \$3,865. This deferred stock based compensation is amortized to expense on a straight-line basis over the period during which the Company's options vest, generally four years. Amortization of deferred stock-based compensation was \$191 and \$324 during the years ended December 31, 2006 and 2005, respectively.

The Company granted stock options to employees with exercise prices below estimated fair market value, determined with hindsight, on the date of grant as follows:

	Number of Options Granted	Weighted Average Exercise Price Per Share	Weighted Average Fair Value Per Share	Weighted Average Intrinsic Value Per Share
Grants Made During Quarter Ended				
March 31, 2005	864,849	\$ 4.00	\$ 4.47	\$ 0.47
June 30, 2005	406,850	\$ 4.00	\$ 5.55	\$ 1.55
September 30, 2005	56,500	\$ 4.00	\$ 7.19	\$ 3.19
December 31, 2005	579,850	\$ 4.00	\$ 8.78	\$ 4.78
March 31, 2006	2,139,184	\$ 1.90	\$ 10.64	\$ 8.74
June 30, 2006	237,500	\$ 3.00	\$ 11.48	\$ 8.48
September 30, 2006	139,350	\$ 11.00	\$ 11.93	\$ 0.93
December 31, 2006	92,352	\$ 10.08	\$ 10.71	\$ 0.63

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

During the year ended December 31, 2004, the Company also recorded stock-based compensation expense of \$353 in connection with the issuance of common stock to employees and the modification of certain employee stock options.

In connection with the repricing of stock options during the year ended December 31, 2006, the Company followed the provisions of SFAS No. 123R and eliminated its remaining deferred stock-based compensation amounts of \$3,344 related to modified stock options. Stock compensation charges for the modified options will be recorded in accordance with SFAS No. 123R.

Stock-based Compensation under EITF No. 96-18

During the years ended December 31, 2006 and 2005, the Company issued options to non-employees. The options generally vest ratably over four years. The values attributable to these options are amortized on a straight line basis over the service period and the unvested portion of these options was remeasured at each vesting date. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The value of the stock options granted were revalued at each reporting date using the Black-Scholes option pricing model as prescribed by SFAS No. 123 and SFAS No. 123R using the following assumptions:

	December 31,		
	2006	2005	2004
Risk-free interest rate	4.96%	3.86%	3.46%
Contractual life (in years)	10	10	10
Dividend yield			
Expected volatility	60%	60%	60%

The weighted average estimate grant date fair values of the non-employee stock options were \$3.31 and \$3.31 for the years ended December 31, 2006 and 2005, respectively.

The stock-based compensation expense will fluctuate as the deemed fair value of the common stock fluctuates. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation expense of \$200, \$132 and \$110 for the years ended December 31, 2006, 2005 and 2004, respectively.

Adoption of SFAS No. 123R

The Company adopted SFAS No. 123R on January 1, 2006. Under SFAS No. 123R, the Company estimated the fair value of each option award on the date of grant using the Black-Scholes option-pricing model using the assumptions noted in the following table. Due to a lack of historical information regarding the volatility of the Company's own stock price, expected volatility is based on an average of the historical and implied volatility of a peer group of publicly traded entities in the aesthetics market. The expected term of options gave consideration to historical exercises, the vesting term of the Company's options, the cancellation history of the Company's options and the options' contractual term of ten years. The risk-free rate for the expected term of the option is based on the U.S. Treasury Constant Maturity rate as of the date of grant. The assumptions used to value options granted during the year ended December 31, 2006 were as follows:

	Year Ended December 31, 2006
Dividend yield	0.00%
Annual risk-free return	4.77%
Expected volatility	55%

Expected term (years)

4.25

77

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

The assumptions used to value employee stock purchase plan (ESPP) shares during the year ended December 31, 2006 were as follows:

	Year Ended December 31, 2006
Dividend yield	0.00%
Annual risk-free return	5.16%
Expected volatility	51%
Expected term (years)	0.52
	Year Ended December 31, 2006
Stock-based compensation expense under FAS123R:	
Employee stock-based compensation expense	\$ 3,070
Employee stock purchase plan	56
Total stock-based compensation expense under FAS123R	\$ 3,126

During the year ended December 31, 2006, the Company granted stock options to purchase an aggregate of 2,608,386 shares of common stock with an estimated weighted-average grant-date fair value of \$8.79 per share. These amounts include new grants and the options that were repriced during March 2006. The total fair value of options that vested during the year ended December 31, 2006 was \$3,757. The total intrinsic value of options exercised during the year ended December 31, 2006 was \$3,986. Net cash proceeds from the exercise of stock options were \$460 for the year ended December 31, 2006.

Employee stock-based compensation expense recognized under SFAS No. 123R in the year ended December 31, 2006 was \$3,126 and was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

At December 31, 2006, the Company had \$6,198 of total unrecognized compensation expense under SFAS 123R, net of estimated forfeitures, related to stock option plans that will be recognized over a weighted-average period of 3.0 years.

At December 31, 2006, the unrecognized compensation cost related to ESPP shares was \$142, which will be recognized using the straight-line attribution method over 0.4 years. The weighted average estimated fair values of each stock issuance under the ESPP for the year ended December 31, 2006 was \$2.14 per share.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)**

Stock-based compensation expense recorded under APB No. 25, SFAS No. 123R and EITF No. 96-18 related to options granted to employees and non-employees was allocated to cost of revenue, sales and marketing, research and development and general and administrative expense as follows:

	December 31,		
	2006	2005	2004
Cost of revenue	\$ 73	\$ 4	\$ 41
Sales and marketing	1,306	216	126
Research and development	666	124	77
General and administrative	1,472	112	219
Total stock-based compensation expense	\$ 3,517	\$ 456	\$ 463

NOTE 10 NOTES RECEIVABLE FROM STOCKHOLDERS

In December 2002, the Company's former Chief Executive Officer (who continues to be a member of the Board of Directors) immediately exercised common stock options on the date of grant to purchase 1,055,000 shares of restricted common stock at \$0.45 per share. The total exercise price of \$475 was paid in the form of a full-recourse note bearing interest at 3.31% per annum. In March 2005, the Company repurchased 100,000 unvested shares at the exercise price of \$0.45 for a total amount of \$46. In February 2006, the Company repurchased 102,084 unvested shares at the exercise price of \$0.45 for a total amount of \$46. In July 2006, the note holder repaid the balance of the note in the amount of \$384 plus accrued interest in the amount of \$47.

In September 2003, a director exercised common stock options to purchase 250,000 shares of restricted common stock at \$0.45 per share. The options were originally granted during the year ended December 31, 2002. During 2003, the Company permitted the officer to exercise the option award with a full-recourse note bearing interest at 3.31% per annum. Principal and interest is due on September 22, 2012. In July 2006, the note holder resigned as a director from the Company and the note remained outstanding at December 31, 2006.

NOTE 11 LITIGATION SETTLEMENT GAIN

On July 23, 2004, the Company filed a lawsuit against Syneron Medical LTD (Syneron) in the United States District Court, Northern District of California that sought damages and injunctive relief for infringement of six of the Company's patents that the Company alleged were infringed by Syneron's systems for non-invasively treating skin. Syneron subsequently filed a patent infringement counterclaim against the Company. As a result of a settlement reached in June 2005, the Company and Syneron have granted each other a non-exclusive paid-up license under their patents asserted in the lawsuit and related patents. In addition, Syneron paid the Company a non-returnable one-time amount of approximately \$1,800 in connection with this settlement. External legal fees incurred during the same period in connection with the settlement amounted to \$154. In connection with this settlement, the Company has recorded a net gain of \$1,646 in operating results during the year ended December 31, 2005.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)****NOTE 12 INCOME TAXES**

The components of the provision for income taxes are as follows:

	Year Ended December 31,		
	2006	2005	2004
Current:			
Federal	\$	\$	\$ 80
State			23
Foreign			
Total provision for income taxes	\$	\$	\$ 103

The Company's deferred tax asset consists of the following:

	December 31,	
	2006	2005
Net operating loss carryforward	\$ 12,814	\$ 12,769
Capitalized start-up costs	7	224
Research and development credit	2,010	2,165
Other	1,968	1,432
Total deferred tax assets	16,799	16,590
Less: Valuation allowance	(16,799)	(16,590)
Net deferred tax asset	\$	\$

The differences between the U.S. federal statutory income tax rate and the Company's effective tax rate are as follows:

	Year Ended December 31,		
	2006	2005	2004
Tax at federal statutory rate	(34.00)%	(34.00)%	34.00%
State, net of federal benefit	(5.83)%	(5.83)%	5.83%
Meals and entertainment	2.56%	0.89%	1.21%
Other	1.45%	0.01%	(0.24)%
Benefit for research and development credit	(3.95)%	(5.62)%	(6.00)%
Stock-based compensation	35.84%	2.40%	3.77%
Preferred stock warrant liabilities	(1.42)%	7.58%	
Change in valuation allowance	5.35%	34.57%	(36.47)%
Provision for taxes	0.00%	0.00%	2.10%

Edgar Filing: THERMAGE INC - Form 10-K

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realized. Accordingly, the Company has provided a full valuation allowance against its net deferred tax asset at December 31, 2006. The valuation allowance increased by \$209 and \$2,611 during the years ended December 31, 2006 and 2005, respectively. During the year ended December 31, 2004, the valuation allowance decreased by \$1,783.

As of December 31, 2006, the Company has a net operating loss carryforward of approximately \$34,000 and \$22,000 for federal and state tax purposes, respectively. If not utilized, these carryforwards will begin to expire in 2011 for federal and in 2010 for state purposes.

Table of Contents

Thermage, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

(In thousands of dollars, except share and per share amounts)

The Company has research and development credit carryforwards of approximately \$1,200 and \$1,300 for federal and state income tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2011. The state credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has a change in ownership, utilization of the carryforwards could be restricted.

NOTE 13 EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) defined contribution plan covering all employees. Contributions made by the Company are determined annually by the Board of Directors. The Company made no contributions under this plan for the years ended December 31, 2006, 2005 and 2004.

NOTE 14 RELATED PARTY TRANSACTIONS

During the years ended December 31, 2006, 2005 and 2004, the Company paid \$75 each year to a member of its Board of Directors under the terms of a consulting agreement.

NOTE 15 SUBSEQUENT EVENTS

On February 7, 2007, the Board of Directors approved issuance of 100,377 shares of restricted stock units at the grant price of \$10.65 to all employees. The restricted stock units vest quarterly for four quarters commencing January 1, 2007.

In February 2007, the Company introduced and began shipment of the ThermaCool NXT, the next generation system.

Table of Contents**Thermage, Inc.****NOTES TO FINANCIAL STATEMENTS (Continued)****(In thousands of dollars, except share and per share amounts)****NOTE 16 QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

The following table sets forth our unaudited quarterly financial results:

	Quarters Ended							
	Dec. 31, 2006	Sep. 30, 2006	Jun. 30, 2006	Mar. 31, 2006	Dec. 31, 2005	Sep. 30, 2005	Jun. 30, 2005	Mar. 31, 2005
Net revenue	\$ 14,751	\$ 12,507	\$ 14,631	\$ 12,431	\$ 9,338	\$ 8,500	\$ 11,723	\$ 11,094
Cost of revenue	4,087	3,493	3,901	3,778	3,452	2,571	3,359	2,927
Gross margin	10,664	9,014	10,730	8,653	5,886	5,929	8,364	8,167
Operating expenses:								
Sales and marketing	6,136	5,785	6,301	5,849	4,927	4,952	5,142	4,976
Research and development	2,510	2,189	2,563	2,377	2,365	2,256	2,162	2,125
General and administrative	2,628	2,688	2,393	2,264	1,913	1,539	1,877	2,085
Litigation settlement gain							(1,646)	
Total operating expenses	11,274	10,662	11,257	10,490	9,205	8,747	7,535	9,186
Income (loss) from operations	(610)	(1,648)	(527)	(1,837)	(3,319)	(2,818)	829	(1,019)
Interest and other income	393	135	126	114	89	108	75	68
Interest and other expense	1,606	(33)	(579)	(1,049)	(809)	(727)	(7)	(6)
Income (loss) before cumulative effect of change in accounting principle	1,389	(1,546)	(980)	(2,772)	(4,039)	(3,437)	897	(957)
Cumulative effect of change in accounting principle						(697)		
Net income (loss)	\$ 1,389	\$ (1,546)	\$ (980)	\$ (2,772)	\$ (4,039)	\$ (4,134)	\$ 897	\$ (957)
Basic and diluted earnings per share	\$ 0.00	\$ (0.36)	\$ (0.23)	\$ (0.68)	\$ (1.06)	\$ (1.11)	\$ 0.00	\$ (0.28)

Table of Contents**SCHEDULE II****THERMAGE, INC.****VALUATION AND QUALIFYING ACCOUNTS****(in thousands)****For the years ended December 31, 2006, 2005 and 2004**

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Allowance for doubtful accounts receivable				
Year ended December 31, 2004	\$	\$	\$	\$
Year ended December 31, 2005	\$	\$ 29	\$	\$ 29
Year ended December 31, 2006	\$ 29	\$ 2	\$	\$ 31
Reserve for excess and obsolete inventory				
Year ended December 31, 2004	\$ 125	\$ 738	\$ 138	\$ 725
Year ended December 31, 2005	\$ 725	\$ 548	\$ 292	\$ 981
Year ended December 31, 2006	\$ 981	\$ 139	\$ 747	\$ 373

Table of Contents

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to management as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during our fourth quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. *Other Information*

None

Table of Contents

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our year ended December 31, 2006.

Item 10. *Directors, Executive Officers and Corporate Governance*

The Information required by this item is incorporated herein by reference to the Proxy Statement.

Item 11. *Executive Compensation*

The Information required by this item is incorporated herein by reference to the Proxy Statement.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The Information required by this item is incorporated herein by reference to the Proxy Statement.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The Information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. *Principal Accountant Fees and Services*

The Information required by this item is incorporated herein by reference to the Proxy Statement.

Table of Contents**PART IV****Item 15. Exhibits and Financial Statement Schedules.**

- (a) (1) The financial statements required by Item 15(a) are filed as Item 8 of this annual report
 (2) The financial statement schedules required by Item 15(a) are filed as Item 8 of this annual report
 (3) Exhibits

Exhibit

Number	Description
3.2*	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect.
3.4*	Bylaws of the Registrant as currently in effect.
4.1*	Specimen Common Stock certificate of the Registrant.
4.2*	Amended and Restated Investor Rights Agreement dated March 12, 2002 by and among the Registrant and certain stockholders.
10.1*	Form of Indemnification Agreement for directors and executive officers.
10.2*	1997 Stock Option Plan.
10.3*	2006 Equity Incentive Plan.
10.4*	2006 Employee Stock Purchase Plan.
10.5*	Sublease Agreement dated September 7, 2004 by and between the Registrant and iAnywhere Solutions, Inc. for office space located at 25881 and 25901 Industrial Boulevard, Hayward, California and exhibits thereto.
10.6*	Development and Supply Agreement dated October 1, 1997 by and between the Registrant and Stellartech Research Corporation and the amendments thereto.
10.7*	Service Agreement dated January 14, 2003 by and between the Registrant and Stellartech Research Corporation.
10.8*	Patent License and Settlement Agreement dated June 3, 2005 by and between the Registrant and Syneron.
10.9*	Restated and Amended Consulting Agreement dated July 30, 1998 by and between the Registrant and Edward W. Knowlton, M.D. and the amendments thereto.
10.10*	Restated and Amended Intellectual Property Assignment and License Agreement dated July 30, 1998 by and between the Registrant and Edward W. Knowlton, M.D.
10.11*	Employment Agreement dated January 7, 2005 by and between the Registrant and Stephen J. Fanning.
10.12*	Severance Benefit Plan effective as of February 1, 2005.
10.13*	Severance Agreement and Release dated March 23, 2005 by and between the Registrant and Keith L. Mullowney.
10.14**	Form of Notice of Grant for, and Terms and Conditions of, Restricted Stock Units under the 2006 Equity Incentive Plan.
10.15**	Form of Notice of Grant for, and Terms and Conditions of, Restricted Stock under the 2006 Equity Incentive Plan.
10.16**	Form of Notice of Grant for, and Terms and Conditions of, Stock Options under the 2006 Equity Incentive Plan.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K).
31.1	Certification of Chief Executive Officer under Securities Exchange Act Rule 13a-14(a).
31.2	Certification of Chief Financial Officer under Securities Exchange Act Rule 13a-14(a).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S. C. 1350 and Securities Exchange Act Rule 13a-14(b).

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

** Incorporated by reference from our Current Report on Form 8-K dated February 13, 2007.

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Hayward, State of California, on the 30th day of March 2007.

THERMAGE, INC.

By: /s/ STEPHEN J. FANNING
Stephen J. Fanning

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen J. Fanning and Laureen DeBuono, his attorney-in-fact, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ STEPHEN J. FANNING	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2007
Stephen J. Fanning		
/s/ LAUREEN DeBUONO	Chief Financial Officer (Principal Accounting Officer)	March 30, 2007
Laureen DeBuono		
/s/ ROBERT F. BYRNES	Director	March 30, 2007
Robert F. Byrnes		
/s/ SAMUEL D. COLELLA	Director	March 30, 2007

Edgar Filing: THERMAGE INC - Form 10-K

Samuel D. Colella

/s/ JOSEPH DeVivo

Director

March 30, 2007

Joseph DeVivo

/s/ EDWARD W. KNOWLTON, MD

Director

March 30, 2007

Edward W. Knowlton, MD

/s/ KENNETH LUDLUM

Director

March 30, 2007

Kenneth Ludlum

/s/ MARK M. SIECZKAREK

Director

March 30, 2007

Mark M. Sieczkarek