CUTERA INC
Form 10-K
March 16, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

SECURITIES EXCHANGE ACT OF 1934

For fiscal year ended December 31, 2005

Commission file number: 000-50644

CUTERA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0492262**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

3240 Bayshore Blvd.

Brisbane, California 94005

(415) 657-5500

(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: None

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

Common Stock, $0.001 par value per share

(Title of Class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x

The aggregate market value of the registrant s voting and non-voting stock, held by non-affiliates of the registrant as of June 30, 2005 (which is the last business day of registrant s most recently completed second fiscal quarter) based upon the closing price of such stock on the NASDAQ Stock Market on that date, was $186 million. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of Registrant s common stock issued and outstanding as of February 28, 2006 was 12,287,510.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

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PART I

ITEM 1. BUSINESS

Overview

We are a global medical device company specializing in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetics systems to the professional aesthetic market. Our easy-to-use families of products-CoolGlide, Xeo and Solera enable dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners to perform safe, effective and non-invasive aesthetic procedures for their patients. We commercially launched our first CoolGlide product in March 2000 for hair removal, and every year since then we have introduced at least one new product. We introduced our first Xeo product in 2003 combining pulsed light and laser treatments in a single platform. In 2004, we introduced our first Solera product, a compact tabletop system designed to support a single technology platform. The first technology available on the Solera platform was the Titan, a heat lamp used for deep dermal heating to treat wrinkles, which was introduced initially as an upgrade option on the Xeo platform. In 2005, we added the Solera Opus to our Solera family. To date, we have received FDA clearance to market our products for hair removal and the permanent reduction of hair; for the treatment of vascular lesions, including leg and facial veins; for the treatment of wrinkles using laser technology but not using broadband infrared light; for the treatment of benign pigmented lesions; and for deep dermal heating.

Each of our products consists of one or more handpieces and a console that incorporates a universal graphic user interface, a laser or other light-based module, control system software and high voltage electronics. We offer our customers the ability to select the system that best fits their practice. We design our products to allow our customers to cost-effectively upgrade to our multi-application products, which enables them to add applications to their aesthetic practice and provides us with a source of recurring revenue.

We were incorporated in Delaware in August 1998 as Acme Medical, Inc. We changed our name to Altus Medical, Inc. in July 1999 and to Cutera, Inc. in January 2004.

The Structure of Skin and Conditions that Affect Appearance

The skin is the body s largest organ and is comprised of layers called the epidermis and dermis. The epidermis is the outer layer, and serves as a protective barrier for the body. It contains cells that determine pigmentation, or skin color. The underlying layer of skin, the dermis, contains hair follicles and large and small blood vessels that are found at various depths below the epidermis. Collagen, also found within the dermis, provides strength and flexibility to the skin.

Many factors, such as age, sun damage and the human body s diminished ability to repair and renew itself over time, can result in aesthetically unpleasant changes in the appearance of the skin. These changes can include undesirable hair growth. Additionally, blood vessels can enlarge or swell due to circulatory changes and become visible at the skin s surface in the form of unsightly veins. Collagen can deteriorate, thereby weakening the skin, leading to wrinkles and looseness. Long-term sun exposure can result in uneven pigmentation, or sun spots. People with undesirable hair growth or the above mentioned skin conditions often seek aesthetic treatments to improve their appearance.

The Market for Aesthetic Procedures

The market for aesthetic procedures has grown significantly over the past several years. The American Society of Plastic Surgeons estimates that its members treated approximately 3.1 million people in 2004, representing a 230% increase over 1998 and a 8% increase over 2003. We believe there are several factors contributing to the growth of aesthetic procedures, including:

Aging of the U.S. Population. The baby boomer demographic segment, ages 42 to 60 in calendar 2006, represented approximately 28% of the U.S. population in 2003. The size of this aging segment, and its desire to retain a youthful appearance, has driven the growth for aesthetic procedures.

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Broader Range of Safe and Effective Treatments. Technical developments have led to safe, effective, easy-to-use and low-cost treatments with fewer side effects, resulting in broader adoption of aesthetic procedures by practitioners. In addition, technical developments have enabled practitioners to offer a broader range of treatments. Finally, these technical developments have reduced the required treatment and recovery time, which in turn has led to greater patient demand.

Changing Practitioner Economics. Managed care and government payer 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. As a result, in addition to the traditional users such as dermatologists and plastic surgeons, other practitioners, such as gynecologists and primary care physicians, have begun to perform these procedures.

Aesthetic Procedures for Improving the Skin s Appearance and Their Limitations

Many alternative therapies are available for treatment of conditions that affect a person s appearance by treating specific structures within the skin. These procedures utilize injections or abrasive agents to reach different depths of the dermis and the epidermis. In addition, non-invasive treatments have been developed that employ laser and other light-based technologies to achieve similar therapeutic outcomes. Some of these more common therapies and their limitations are described below.

Hair Removal- Techniques for hair removal include waxing, depilatories, tweezing, shaving, electrolysis and laser and other light-based hair removal. The only techniques that provide a long-lasting solution are electrolysis and laser and other light-based hair removal. Electrolysis is usually painful, time-consuming and expensive for large areas, but is the only permanent method for removing light-colored hair. During electrolysis, an electrologist inserts a needle directly into a hair follicle and activates an electric current in the needle. Since electrolysis only treats one hair follicle at a time, the treatment of an area as small as an upper lip may require numerous visits and up to ten hours of treatment. In addition, electrolysis can cause blemishes and infection related to needle use.

Leg and Facial Veins- The current aesthetic treatment methods for leg and facial veins include sclerotherapy and laser-based treatments. With these treatments, patients seek to eliminate visible veins and improve overall skin appearance. Sclerotherapy requires a skilled practitioner to inject a saline or detergent-based solution into the target vein, which breaks down the vessel causing it to collapse and be absorbed into the body. The need to correctly position the needle on the inside of the vein makes it difficult to treat smaller veins, which limits the treatment of facial vessels and small leg veins. The American Society of Plastic Surgeons estimates that its members performed over 544,000 sclerotherapy procedures in 2004.

Skin Rejuvenation- Non-light-based skin rejuvenation treatments include a broad range of popular alternatives, including Botox and collagen injections, chemical peels and microdermabrasions. With these treatments, patients hope to improve overall skin tone and texture, reduce pore size, and remove other signs of aging, including mottled pigmentation, diffuse redness and wrinkles. All of these procedures are temporary solutions and must be repeated within several weeks or months to sustain their effect, thereby increasing the cost and inconvenience to patients. For example, the body absorbs Botox and collagen and patients require supplemental injections every three to six months to maintain the benefits of the treatment.

Other skin rejuvenation treatments, such as chemical peels and microdermabrasions, can have undesirable side effects. Chemical peels use acidic or caustic solutions to peel away the epidermis, and microdermabrasion generally utilizes sand crystals to resurface the skin. These techniques can lead to post-procedure stinging, redness, irritation and scabbing. In addition, more serious complications, such as changes in skin color, can result from deeper chemical peels. Patients that undergo these deep chemical peels are also advised to avoid exposure to the sun for several months following the procedure. The American Society of Plastic Surgeons estimates that in 2004 its members performed over 2.9 million Botox and over 500,000 collagen injection procedures, over 1.0 million chemical peels and over 800,000 microdermabrasion procedures.

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Tissue Tightening and the Treatment of Wrinkles- Techniques for treatment of wrinkles include surgery, radiofrequency and light-based technologies. The most common treatment for lax skin is surgery, which can include a facelift, or rhytidectomy, forehead lift or treatment around the eyes, or blepharoplasty. In this procedure, an incision is made along the hairline from the temples down around the ears and extending to the lower scalp. The surgeon then separates the skin from the fat and muscle below. Excess fat may be removed as part of this procedure to improve the contour of the skin. The surgeon then tightens the underlying muscle and membrane, pulls the skin back, and removes the excess fat, creating a tighter appearance to the skin. Surgical procedures have risk, which can include excess bleeding, nerve damage, or an adverse reaction to anesthesia. Additionally, a facelift can result in an unnatural, overly tightened appearance of the face. According to the American Society of Plastic Surgeons, there were over 114,000 facelifts and over 233,000 blepharoplasties performed in 2004.

A recent alternative to a facelift is radiofrequency tissue tightening. In this approach, radio-frequency energy is applied to heat the dermis of the skin with the goal of shrinking and tightening the collagen fibers. This approach may result in a more subtle, and incremental change to the skin than a facelift. Drawbacks to this approach may include surface irregularities, that can resolve over time, and the risk of burning the treatment area.

Laser and Other Light-Based Aesthetic Treatments

Laser and other light-based aesthetic treatments can achieve therapeutic results by non-invasively affecting structures within the skin. The development of safe and effective aesthetic treatments has created a well-established and growing market for these procedures.

Ablative skin resurfacing is a method of improving the appearance of the skin by removing the outer layers of the skin. Non-ablative skin resurfacing is a method of improving the appearance of the skin by treating the underlying structure of the skin without damaging the outer layers of the skin. Practitioners use laser and other light-based technologies to selectively target hair follicles, veins or collagen in the dermis, as well as cells responsible for pigmentation in the epidermis, without damaging surrounding tissue. Safe and effective laser and other light-based treatments require an appropriate combination of the following four parameters:

Energy Level: the amount of light emitted to heat a target;

Pulse Duration: the time interval over which the energy is delivered;

Spot Size: the diameter of the energy beam, which affects treatment depth and area; and

Wavelength: the color of light, which impacts the effective depth and absorption of the energy delivered.

For example, in the case of hair removal, by utilizing the correct combination of these parameters, a practitioner can use a laser or other light source to selectively target melanin within the hair follicle to absorb the laser energy and destroy the follicle, without damaging other delicate structures in the surrounding tissue. Wavelength and spot size permit the practitioner to target melanin in the base of the hair follicle, which is found in the dermis. The combination of pulse duration and energy level may vary, depending upon the thickness of the targeted hair follicle. A shorter pulse length with a high energy level is optimal to destroy fine hair, whereas coarse hair is best treated with a longer pulse length with lower energy levels. If treatment parameters are improperly set, non-targeted structures within the skin may absorb the energy thereby eliminating or reducing the therapeutic effect. In addition, improper setting of the treatment parameters or failure to protect the surface of the skin may cause burns, which can result in blistering, scabbing and skin discoloration.

The growth in the demand for aesthetic laser and other light-based procedures has resulted in a significant market for products and technologies that allow practitioners to perform these treatments. However, the most widely-available systems have been, and in many cases remain, single-application devices. Practitioners interested in treating hair, veins and wrinkles have had to incur the expense of purchasing multiple systems and maintaining them in an often confined clinical office space. The need for multiple devices for different applications is primarily a result of technology constraints of most competing systems. Most competing systems cannot combine

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the wide range of energy levels, pulse durations and spot sizes with an effective wavelength to perform a broad variety of aesthetic laser and other light-based applications using a single system.

Our Products

Our unique CoolGlide, Xeo and Solera families of products provide the long-lasting benefits of laser and other light-based aesthetic treatments. Our technology allows for a combination of the widest variety of applications available in a single system. Key features of our solution include:

Multiple Applications Available in a Single System. Our technology platforms enable practitioners to perform multiple aesthetic procedures using a single device. These procedures include hair removal, treatment of unsightly veins, skin rejuvenation treatment of pigmented lesions and tissue tightening. Because practitioners can use our systems for multiple indications, the cost of a unit may be spread across a potentially greater number of patients and procedures, and therefore may be more rapidly recovered.

Technology and Design Leadership. We offer innovative and advanced laser and other light-based solutions for the aesthetic market. Our laser technology combines long wavelength, adjustable energy levels, variable spot sizes and a wide range of pulse durations, allowing our users to customize treatments for each patient and condition. Our proprietary pulsed light handpieces for the treatment of pigmented lesions, hair removal and vascular treatments, optimize the wavelength used for treatments and incorporate a monitoring system to increase safety. Our Titan handpieces utilize a novel light source that had not been previously used for aesthetic treatments.

Upgradeable Platform. We design our products to allow our customers to cost-effectively upgrade to our multi-application products, which provides our customers the option to add additional applications to their existing systems and provides us with a source of recurring revenue. We believe that product upgradeability is a competitive advantage because it allows our users to take advantage of our latest product offerings and provide additional treatment options to their patients, thereby expanding the opportunities for their aesthetic practices.

Treatments for Broad Range of Skin Types and Conditions. Our products remove hair safely and effectively on patients of all skin types, including harder-to-treat patients with dark or tanned skin. In addition, the wide parameter range of our systems allows practitioners to effectively treat patients with both fine and coarse hair. Practitioners may also use our products to treat spider and reticular veins, which are unsightly small veins in the leg, as well as small facial veins. The ability to customize treatment parameters enables our customers to offer safe and effective therapy to a broad base of their patients.

Ease of Use. We design our products to be easy to use. Our proprietary handpieces are lightweight and ergonomic, minimizing user fatigue. Our ClearView handpiece allows practitioners to view an area as it is being treated, reducing the possibility of unintended damage to the skin and increasing the speed of application. Our control console contains a universal graphic user interface with three simple, independently adjustable controls from which to select a wide range of treatment parameters to suit each patient s profile.

Risks involved in the use of our products include risks common to laser and other light-based aesthetic procedures, including the risk of burns, blistering and skin discoloration.

Strategy

Cutera s mission is to maintain and expand its position as a leading, worldwide, provider of light based aesthetic devices by:

Continuing to Develop New Products. We have introduced at least one new product every year since 2000. In 2005, we introduced the Solera Opus platform; and added ProWave 770 and AcuTip 500

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pulsed light handpieces for hair removal and vascular treatments. Our products are currently marketed for hair removal, treatment of veins, skin rejuvenation, treatment of pigmented lesions and tissue tightening, and we are developing our existing technology platforms with the intent of treating additional conditions.

Increasing Sales of Existing Products in the United States. We believe there is significant growth potential for our current products in the United States, and we plan to continue to expand our domestic sales force to capitalize on this opportunity. In 2005, we expanded our United States sales force by assembling a new dedicated sales team that is primarily focused on the price-sensitive medi-spa market, which is comprised of physicians offering aesthetic treatments in a spa environment.

Expanding our International Presence. We believe that the International market will be a significant growth driver for us. As such, we are focused on increasing our market penetration overseas and building global brand-recognition. In July 2005, we opened an office in Zurich, Switzerland. The Zurich office serves as our sales, marketing, and service headquarters for all of our direct sales organizations and distributors in greater Europe. In addition, we have a Pacific Rim hub in Tokyo, Japan. For 2005 and 2004, approximately 28% and 34% of our revenue, respectively, originated outside of the United States. As of December 31, 2005, we had a direct international sales force of 16 employees in Australia, France, Germany, Japan, Spain, Switzerland and the United Kingdom; and distributors in over 25 countries. We intend to add international direct sales employees, distributors and support staff to increase sales and strengthen customer relationships in international markets.

Broadening our Customer Base. We believe we have an opportunity for significant growth targeting non-traditional aesthetic practitioners. Dermatologists and plastic surgeons have generally been regarded as the traditional customers for laser and other light-based aesthetic equipment. In the United States, in 2005, approximately 72% of our business was from non-traditional aesthetic practitioners, including from gynecologists, primary care physicians, physicians offering aesthetic treatments in a spa environment, and other qualified practitioners. We plan to continue to focus sales and marketing efforts on this broader customer base. In the fourth quarter of 2005, we assembled a new subset of our sales organization that is focused on non-traditional aesthetic practitioners, which includes the medi-spa market. Our Solera family of products, which includes a compact, table top console with a lower price point, is targeted towards this market segment.

Leveraging our Installed Base with Sales of Upgrades. Each time we have introduced a new product, we have designed it so existing customers may upgrade their previously purchased systems to offer additional capabilities. For the year ended December 31, 2005, our upgrade revenue was $6.6 million. Providing upgrades to our existing installed base of customers represents a significant opportunity for recurring revenue. We also believe that our upgrade program aligns our interest in generating revenue with our customers interest in improving the return on their investment by expanding the range of applications they can perform.

Generating Revenue from Services and Titan Refills. Our Titan product includes a disposable component, which provides us with a source of recurring revenue from our existing customers. Our extended service contracts are also a source of recurring revenue. We will continue to look for opportunities to leverage our relationships with our existing customers for additional revenue opportunities.

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Products

Our CoolGlide, Xeo and Solera families of products allow for the delivery of multiple laser and other light-based aesthetic applications from a single system. The following table lists our products and the aesthetic applications that can be performed by each.

	Year Introduced	Hair Removal	Vein Treatment	Laser Skin Rejuvenation	Pigmented Lesion	Dermal Heating/ Skin Tightening
CoolGlide CV	2000	X				
CoolGlide Excel	2001	X	X			
CoolGlide Vantage	2002	X	X	X		
CoolGlide Genesis	2002			X		
Xeo	2003	X	X	X	X	
Xeo with Titan	2004	X	X	X	X	X
Solera with Titan	2004					X
Solera Opus	2005	X	X	X	X	

Each of our products consists of a control console and one or more handpieces, depending on the model.

Control Console

Our control console includes a universal graphic user interface, control system software and high voltage electronics. All CoolGlide systems and some models of the Xeo family include our laser module which consists of electronics, a visible aiming beam, a focusing lens and a flashlamp or an Nd:YAG laser that functions at wavelengths that permit penetration over a wide range of depths and is effective across all skin types. The interface allows the practitioner to set the appropriate laser or flashlamp parameters for each procedure through a user-friendly format. The control system software ensures that the operator s instructions are properly communicated from the graphic user interface to the other components within the system. Our high voltage electronics produce over 10,000 watts of peak laser energy, which permits therapeutic effects at short pulse durations. Our Solera console platform comes in two configurations Opus and Titan both of which include a universal graphic user interface, control system software and high voltage electronics. The Solera Opus console is designed specifically to drive our flashlamp handpiece while the Solera Titan console is designed specifically to drive the Titan handpieces. The control system software is designed to ensure that the operator s instructions are properly communicated from the graphical user interface to the other components within the system and includes real-time calibration to control the output energy as the pulse is being delivered during the treatment.

Handpieces

ClearView Handpiece- Our ClearView handpiece delivers laser energy to the treatment area for hair removal, leg and facial vein treatment, and skin rejuvenation procedures. The ClearView handpiece consists of an energy-delivery component, consisting of an optical fiber and lens, and a copper cooling plate with imbedded temperature monitoring. The handpiece weighs approximately 14 ounces, which is light enough to be held with one hand. The lightweight nature and ergonomic design of the handpiece allows the operation of the device without user fatigue. Its design allows the practitioner an unobstructed view of the treatment area, which reduces the possibility of unintended damage to the skin and can increase the speed of treatment. The ClearView handpiece also incorporates our cooling system, providing integrated pre- and post-cooling of the treatment area through a temperature-controlled copper plate to protect the outer layer of the skin. The handpiece is available in either a fixed 10 millimeter spot size, for our CoolGlide CV, or a user-controlled variable 3, 5, 7 and 10 millimeter spot size, for our other models.

Pulsed Light Handpieces- The OPS600, LP560, ProWave 770 and AcuTip 500 handpieces are designed to produce a pulse of light over a wavelength spectrum to treat pigmented lesions, such as age and sun spots, hair

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removal or superficial vessels. The handpieces consist of a custom flashlamp, proprietary wavelength filter, closed-loop power control and embedded temperature monitor, and weigh approximately 13 ounces. The filter in the OPS600 and AcuTip 500 eliminates long and short wavelengths, transmitting only the therapeutic range required for safe and effective treatment. The filter in the LP560 and ProWave 770 eliminates short wavelengths, allowing longer wavelengths to be transmitted to the treatment area. In addition, the wavelength spectrum of the ProWave 770 can be shifted based on the setting of the control console. Our power control includes a monitoring system to ensure that the desired energy level is delivered. The handpieces protect the epidermis by regulating the temperature of the handpiece window through the embedded temperature monitor. These handpieces are available on the Xeo and Solera Opus families of products.

Titan Handpiece- The Titan handpiece is designed to produce a sustained pulse of light over a wavelength spectrum tailored to provide heating in the dermis to treat wrinkles (although it is cleared in the United States only for deep dermal heating). The handpiece consists of a custom light source, proprietary wavelength filter, closed-loop power control, sapphire cooling window and embedded temperature monitor, and weighs approximately three pounds. The temperature of the epidermis is controlled by using a sapphire window to provide cooling before, during and after the delivery of energy to the treatment site. The Titan handpiece is available on the Xeo and Solera families of products. The Titan handpiece requires a periodic refilling process, which includes the replacement of the optical source, after a set number of pulses has been performed.

Cutera Applications and Procedures

Our products are designed to allow the practitioner to select an appropriate combination of energy level, spot size and pulse duration. The ability to manipulate the combinations of these parameters allows our customers to treat the broadest range of conditions available with a single light-based system.

Hair Removal- Our laser technology allows our customers to treat all skin types and hair thicknesses. Our Nd:YAG laser permits energy to safely penetrate through the epidermis of any skin type and into the dermis where the hair follicle is located. Using the universal graphic user interface on our control console, the practitioner sets parameters to deliver therapeutic energy with a large spot size and variable pulse durations, allowing the practitioner to treat fine or coarse hair. Both our ClearView handpiece and our ProWave 770 handpiece, with its pulsed light technology, allow our customers to treat all skin types quickly and effectively. Using the interface, the practitioner selects the appropriate mode and fluence to achieve the desired result.

To remove hair, the treatment site on the skin is first cleaned and shaved. Using the ClearView handpiece, the practitioner applies a thin layer of gel to glide across the skin. The practitioner next applies the ClearView handpiece directly to the skin to cool the area to be treated and then delivers a laser pulse to the pre-cooled area. For the ProWave 770 handpiece, mineral oil is used instead of gel, and cooling is provided by a sapphire window placed directly on the skin, allowing the pulse of light to be applied while the treatment area is being cooled. In the case of both handpieces, delivery of the energy destroys the hair follicles and prevents hair regrowth. This procedure is then repeated at the next treatment site on the body, and can be done in a gliding motion to increase treatment speed. Patients receive on average three to six treatments. Each treatment can take between five minutes and one hour depending on the size of the area and the condition being treated. On average, there are six to eight weeks between treatments.

Leg and Facial Veins- Our laser technology allows our customers to treat the widest range of aesthetic vein conditions, including spider and reticular veins and small facial veins. Our ClearView handpiece s adjustable spot size of 3, 5, 7 or 10 millimeters allows the practitioner to control treatment depth to target different sized veins. Selection of the appropriate energy level and pulse duration ensures effective treatment of the intended target. Our AcuTip 500 handpiece, with its 6 millimeter spot size, is designed for the treatment of facial vessels.

The vein treatment procedure is performed in a substantially similar manner to the hair removal procedure. In addition to pre-cooling the area to be treated using the ClearView handpiece, the handpiece is also used to cool

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the treatment area after the practitioner applies the laser pulse. With the AcuTip 500, the pulse of light is delivered while the treatment area is being cooled with the sapphire tip. The delivered energy damages the vein and, over time, it is absorbed by the body. Patients receive on average between one and six treatments, with six weeks or longer between treatments.

Skin Rejuvenation- Our laser technology allows our customers to perform non-invasive treatments that improve facial skin tone and texture by reducing redness and pore size, and treating other aesthetic conditions. Our products deliver a combination of high laser energy and a very short pulse duration to affect the desired target, minimizing risk of damage to the surrounding tissue.

To perform a skin rejuvenation procedure, cooling is not applied and the handpiece is held directly above the skin. A large number of pulses are directed at the treatment site, repeatedly covering an area, such as the cheek. By delivering many pulses of laser light to a treatment area, a gentle heating of the dermis occurs and collagen growth is stimulated to rejuvenate the skin and reduce wrinkles. Patients typically receive four to six treatments for this procedure. The treatment typically takes less than a half hour and there are typically two to four weeks between treatments.

Pigmented Lesions- Our flashlamp technology allows our customers to safely and effectively treat pigmented lesions, such as age spots and sun spots. The practitioner delivers a narrow spectrum of light to the surface of the skin through our OPS600 or LP560 pulsed-light handpieces. These handpieces include one of our proprietary wavelength filters, which reduce the energy level required for therapeutic effect and minimize the risk of skin injury.

In treating pigmented lesions, the handpiece is placed directly on the skin and then the light pulse is triggered. The cells forming the pigmented lesion absorb the light energy and will darken and then flake off over the course of two to three weeks. Several treatments may be required to completely remove the lesion. The treatment takes a few minutes per area treated and there are typically three to four weeks between treatments.

Tissue Tightening- Our Titan technology allows our customers to use deep dermal heating to tighten lax skin. The practitioner delivers a spectrum of light to the skin through our Titan handpiece. This handpiece includes our proprietary light source and wavelength filter which tailors the delivered spectrum of light to provide heating at the desired depth in the skin.

In treating skin laxity, the handpiece is placed directly on the skin and then the light pulse is triggered. A sustained pulse causes significant heating in the dermis. This heating can cause immediate collagen contraction while also stimulating long-term collagen regrowth. Several treatments may be required to obtain the desired degree of tightening of the skin. The treatment of a full face can take over an hour and there are typically four weeks between treatments.

Our CE Mark allows us to promote the Titan in the European Union, Australia and certain other countries outside the United States for the treatment of wrinkles through skin tightening. However, in the United States we have a 510(k) clearance for only deep dermal heating. We are continuing to gather data in an effort to obtain other clearances from the FDA to market Titan for additional indications.

Product Upgrades

Our products are designed to allow our customers to cost-effectively upgrade to our newest technologies, which provides our customers the option to add applications to their Cutera system and provides us with a source of recurring revenue. When we introduce a new product, we notify our customers of the upgrade opportunity through a sales call or mailing. In most cases, a field service representative can install the upgrade at the customer site in a matter of hours, which results in very little downtime for practitioners. In a few cases, where substantial upgrades are necessary, the customer will receive a fully-refurbished system before sending their prior system back to our headquarters.

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Sales and Marketing

We sell, market and distribute our products in the United States through a direct sales force supported by a team of technical service specialists. Our strategy to increase U.S. market penetration relies on selling directly to our historic customer base of plastic surgeons and dermatologists. In addition, we are targeting a non-traditional aesthetic practice opportunity consisting of gynecologists, primary care physicians, physicians offering aesthetic treatments in a spa environment and other qualified practitioners. As of December 31, 2005, we had a 52-person North American direct sales force, four of whom were regional managers, and one Vice President of North American Sales. We plan to continue hiring additional sales representatives. In addition, in November 2003 we entered into a distribution agreement with Physician Sales and Service, Inc., or PSS, World Medical. PSS operates medical supply distribution service centers with approximately 700 sales representatives serving physician offices in all 50 states of the United States. The agreement with PSS continues indefinitely unless terminated by one of us upon 90 days written notice. PSS sales representatives work in coordination with our sales force to locate additional customers for our products. For the years ended December 31, 2005 and 2004, sales to PSS World Medical accounted for 16% and 12%, respectively, of our net revenue.

As of December 31, 2005, we had a direct sales force of 16 employees in Australia, France, Germany, Japan, Spain, Switzerland and the United Kingdom; and distributors in over 25 additional countries. We generally require our distributors to invest in service training and equipment, to attend certain exhibitions and industry meetings, and in some instances, to commit to minimum sales amounts to gain or retain market exclusivity.

The percentage of our revenue from customers located outside the United States was approximately 28%, 34%, and 23% in fiscal 2005, 2004 and 2003, respectively. Though in 2005 we experienced positive revenue growth in the international market, as a whole, domestic revenue grew at a faster pace. The percentages of our revenue by region are presented in the table below:

	Year Ended December 31,		
	2005	**2004**	**2003**
United States	72%	66%	77%
Japan	6	14	5
Rest of World	22	20	18
Total	100%	100%	100%

Revenue is attributed to regions based on the shipping location of external customers. Our long-lived assets maintained outside the United States are insignificant.

We seek to establish strong ongoing relationships with our customers through the upgradeability of our products; sales of extended service contracts, the refilling of Titan handpieces, and ongoing training and support. We primarily target our marketing efforts to practitioners through office visits, workshops, trade shows, webinars and trade journals. We also market to potential patients through brochures and our website. We offer clinical forums with recognized expert panelists to promote advanced treatment techniques using the CoolGlide, Xeo and Solera families of products to further enhance customer loyalty and uncover new sales opportunities.

Competition

Our industry is subject to intense competition. Our products compete against conventional non-light-based treatments, such as electrolysis, Botox and collagen injections, chemical peels, microdermabrasion and sclerotherapy. Our products also compete against laser and other light-based products offered by public companies, such as Candela, Cynosure, Laserscope, Lumenis, Palomar Medical Technologies and Syneron, as well as private companies, including Thermage and Reliant.

Competition among providers of laser and other light-based devices for the aesthetic market is characterized by extensive research efforts and technology progress. While we attempt to protect our products through patents and

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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. There are many companies, both public and private, that are developing innovative devices that use both light-based and alternative technologies. Many of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as international distribution channels that are more effective than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of performance, brand name, reputation and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to, or prefer the products offered by these competitors. Competitive pressures may result in price reductions and reduced margins over time for our products.

Research and Development

Our research and development group develops new products to address unmet or underserved market needs. The major focus of this group is to leverage our existing technology platforms for new aesthetic applications. As of December 31, 2005, our research and development activities were conducted by a staff of 17 employees with a broad base of experience in lasers and optoelectronics. We have developed relationships with outside contract engineering and design consultants, giving our team additional technical and creative breadth. We work closely with thought leaders and customers, both individually and through our sponsored seminars, to understand unmet needs and emerging applications in aesthetic medicine. Research and development expenses for 2005, 2004 and 2003, were $5.1 million, $4.1 million and $3.1 million, respectively. We expect that we will continue to invest approximately 7-9% of net revenue in research and development activities in order to bring new products to market.

Services and Support

Our products are engineered to enable quick and efficient service and support. There are several separate components of our products, each of which can easily be removed and replaced. We believe that quick and effective delivery of service is important to our customers. We strive to respond to service calls within 48 hours to minimize disruptions for our customers. As of December 31, 2005, we had a 28 person global service department. Internationally, we provide direct service support through our Tokyo and Zurich offices, and also through distributors and third-party service providers. We provide initial warranties on our products to cover parts and service and offer extended warranty packages that vary by the type of product and the level of service desired. Our base warranty on system sales covers parts and service for a period of one to two years. Customers are notified before their initial warranty expires and are able to choose from two different extended service plans covering preventative maintenance and replacement parts and labor. One plan allows the customer to pay only for time and materials at a reduced rate and a second provides yearly preventative maintenance for a fixed fee. In the event one of our customers declines an additional warranty, we will continue to service our products and charge customers for time and materials.

Manufacturing

We manufacture our products with components and subassemblies supplied by vendors. We assemble and test each of our products at our Brisbane, California facility. Quality control, cost reduction and inventory management are top priorities of our manufacturing operations.

We purchase certain components and subassemblies from a limited number of suppliers. We have flexibility with our suppliers to adjust the number of components and subassemblies as well as the delivery schedules. The forecasts we use are based on historical demands and sales projections. Lead times for components and subassemblies may vary significantly depending on the size of the order, time required to fabricate and test the components or subassemblies, specific supplier requirements and current market demand for the components and

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subassemblies. We reduce the potential for disruption of supply by maintaining sufficient inventory and identifying additional suppliers. The time required to qualify new suppliers for some components, or to redesign them, could cause delays in our manufacturing. To date, we have not experienced significant delays in obtaining any of our components or subassemblies.

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.

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. The FDA enforces the QSR through periodic unannounced inspections. We were inspected by the FDA in 2000 and again in 2001 at our former Burlingame facility. Our current facility in Brisbane was inspected by the FDA in 2004 and 2005. There were no significant findings as a result of these audits and our responses have been accepted by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut down of our manufacturing operations and the recall of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to 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. In February 2000, our former facility was awarded the ISO 9001 and EN 46001 certification. In March 2003, we received our ISO 9001 updated certification as well as our certification for ISO 13485 which replaced our EN 46001 certification. We have transferred these certifications to our new facility.

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, 2005, we had five issued U.S. patents primarily covering our ClearView handpiece design and cooling method. Of the five issued patents, three expire in 2019; one expires in 2020; and one expires in 2021. At December 31, 2005, we had sixteen pending U.S. patent applications. We intend to file for additional patents to continue to strengthen our intellectual property rights. CoolGlide is a registered trademark in the United States, Canada, the European Union and Japan. CoolGlide Excel, Coolglide CV and Cutera are registered trademarks in the United States. Our other trademarks include CoolGlide Genesis, CoolGlide Genesis Plus, CoolGlide Vantage, CoolGlide Xeo, CoolGlide Xeo SA, Titan, Solera Opus, Prowave 770, Titan XL, Titan V and AcuTip.

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 in connection with the relationship. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignability 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.

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. Any patents issued to us may be challenged by third parties as invalid or parties may independently develop similar or competing technology or 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 as fully as in the United States.

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Government Regulation

Our products are medical devices subject to extensive and rigorous regulation by the U.S. Food and Drug Administration, as well as other regulatory bodies. FDA regulations govern the following activities that we perform and will continue to perform 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;
- pre-market clearance or approval;
- advertising and promotion;
- production; and
- product sales and distribution.

FDA s Pre-market 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 pre-market 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 pre-market notification requesting permission 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 pre-market 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 pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared 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 pre-market approval applications, or PMA. By regulation, the FDA is required to clear or deny a 510(k), pre-market notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Laser devices used for aesthetic procedures, such as hair removal, have generally qualified for clearance under 510(k) procedures. We received FDA clearance to market our products for the treatment of vascular lesions in June 1999, for hair removal in March 2000, and for permanent hair reduction in January 2001. In addition, in June 2002, we received FDA clearance to market our products for the treatment of benign pigmented lesions, for the treatment of pseudofolliculitis barbae, commonly referred to as razor bumps, and for the reduction of red pigmentation in scars. In October 2002, we received FDA clearance to market our products for the treatment of wrinkles, which we have utilized to market our products for skin rejuvenation. In March 2003, we received FDA clearance to market our pulsed-light handpiece for the treatment of pigmented lesions.

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In February 2004, we received FDA clearance to market our infrared Titan handpiece for deep dermal heating for the temporary relief of minor muscle and joint pain and for the temporary increase in local circulation where applied. In October 2004, we received FDA clearance to market our Titan tabletop console for use with the Titan handpiece. In January 2005, we received FDA clearance to market our Solera tabletop console for use with our pulsed-light handpieces. In March 2005, we received FDA clearance to market our pulsed light handpieces for hair removal and vascular treatments.

In May 2005, the FDA determined that our 510(k) application with respect to marketing our Titan product in the United States for wrinkle reduction was not substantially equivalent to predicate devices for the treatment of wrinkles. We continue to gather additional data to seek a clearance from the FDA to market Titan for additional indications.

Pre-Market Approval (PMA) 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 trials, 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 pre-market approval, nor do we currently expect that any future device or indication will require pre-market approval.

Product Modifications

We have modified aspects of our products since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. After a device receives 510(k) clearance or a PMA, any modification that could significantly 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 such decision and can disagree with a manufacturer s determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require us to seek 510(k) clearance or pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Clinical Trials

When FDA approval of a class I, class II or class III device requires human clinical trials, and if the device presents a significant risk, as defined by the FDA, to human health, the device sponsor is required to file an Investigational Device Exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a non-significant risk, IDE submission to the FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the clinical trial is required. Human clinical studies are generally required in connection with approval of class III devices and may be required for class I and II devices. 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 specified number of patients. Clinical trials for a significant risk device may begin once the application is reviewed and cleared by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our products may require that we submit and obtain clearance of an IDE from the FDA prior to commencing clinical trials. The FDA, and the IRB at each institution at which a clinical trial is being performed, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

We currently do not have any clinical trials underway. We will hold clinical trials in the future if required to do so by the FDA or if we believe additional indications on our products may be obtained by conducting such trials.

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Our clinical department continues to work with physicians and other experts in the medical aesthetic market to gather additional data that may provide the basis for physician-authored white papers, the promotion of our existing products, or seeking the approval for additional indications on our existing and any future products.

Pervasive and Continuing Regulation

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

- quality system regulations, 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 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 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 our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors. In the past, our prior facility has been inspected, and observations were noted. There were no findings that involved a material violation of regulatory requirements. Our responses to these observations have been accepted by the FDA and CDHS, and we believe that we are in substantial compliance with the QSR. Our current manufacturing facility has been inspected by the FDA but not by the CDHS. The FDA noted observations, but there were no findings that involved a material violation of regulatory requirements. Our responses to those observations have been accepted by the FDA.

We are also regulated under the Radiation Control for Health and Safety Act, which requires laser products to comply with performance standards, including design and operation requirements, and manufacturers to certify in product labeling and in reports to the FDA that their products comply with all such standards. The law also requires laser manufacturers to file new product and annual reports, maintain manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- fines, injunctions, consent decrees and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products or new intended uses;

withdrawing 510(k) clearance or pre-market approvals that are already granted; and

criminal prosecution.

The FDA also has the authority to require us to repair, replace or refund the cost of any medical device that we have manufactured or distributed. If any of these events were to occur, they could have a material adverse effect on our business.

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

International

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different.

The primary regulatory environment in Europe is that of the European Union, which consists of twenty-five countries encompassing most of the major countries in Europe. Three member states of the European Free Trade Association have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet European Union requirements. 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 member states of the European Union, the member states of the European Free Trade Association and countries which have entered into a Mutual Recognition Agreement. 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 the conformity assessment. This third-party assessment may consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s device. An assessment by a Notified Body in one member state of the European Union, the European Free Trade Association or one country which has entered into a Mutual Recognition Agreement is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 certification are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. In February 2000, our facility was awarded the ISO 9001 and EN 46001 certification. In March 2003, we received our ISO 9001 updated certification (ISO 9001:2000) as well as our certification for ISO 13485:1996 which replaced our EN 46001 certification. In March 2004, we received our ISO 13485:2003 certification, which is the most current ISO certification for medical device companies.

Employees

As of December 31, 2005, we had 195 employees, with 87 employees in sales and marketing, 38 employees in manufacturing operations, 28 employees in technical service, 11 employees in research and development, 25 employees in general and administrative, and 6 employees in clinical, regulatory and quality control. 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

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission, or SEC, including reports on the following forms: 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. These reports and other information concerning the company may be accessed through the SEC s website at http://www.sec.gov and our website at http://www.cutera.com. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

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Our most recent charter for our Audit and Compensation Committees and our Code of Ethics are available on our website at www.cutera.com. In the event that we grant a waiver under our Code of Ethics to any of our officers and directors we will publish it on our website.

ITEM 1A. RISK FACTORS

Unfavorable results in our intellectual property litigation with Palomar Medical Technologies may result in significant decline to our stock price.

Since February 2002, we have been involved in litigation with one of our public company competitors, Palomar Medical Technologies, which alleges that the manufacture, use and sale of our products for laser hair removal infringe a certain United States patent. Public announcements concerning this litigation that are unfavorable to us have in the past resulted, and may in the future result, in significant declines in our stock price. For example, on December 13, 2005, the date of the public announcement of the denial of our motion for summary judgment, our stock price declined 34.4%. The parties are now preparing for trial, which is expected to start on May 30, 2006. An adverse ruling or judgment in this matter could cause our stock price to decline significantly.

Even if we prevail in this litigation, we do not believe that will end the dispute with Palomar. It is likely that the party who loses at the trial court level will file an appeal. Additionally, in 2005, we became involved in a second litigation against Palomar concerning our products that use pulsed light technology for hair removal, and whether these products infringe two United States patents. Consequently, even following a favorable determination in the litigation set for trial, we expect our stock to be subject to volatility from the Palomar dispute.

Our intellectual property litigation with Palomar is costly and may prevent us from selling many of our products and generating anticipated revenue.

If we do not prevail in our action against Palomar, we may be ordered to pay substantial damages for past sales (including compensatory and treble damages) and an ongoing royalty for future sales of products found to infringe. We could also be ordered to stop selling any products that are found to infringe. Most of our products include an application for laser-based hair removal, the alleged infringing application. If found liable, we do not know whether we could redesign our products to avoid future infringement with respect to this application. Consequently, we could have to remove the infringing application. Alternatively, we could seek a license to the technology from Palomar, but they have indicated publicly that they will not give us a license.

Litigation with Palomar has been and will continue to be expensive and protracted, and our intellectual property position may be weakened as a result of an adverse ruling or judgment. Whether or not we are successful in the pending lawsuits, litigation consumes substantial amounts of or financial resources and diverts management s attention away from our core business. See Item 3 Legal Proceedings. We believe the cost of the Palomar litigation will increase in 2006, and that the increased cost will be substantial as the matter approaches and enters the trial stage.

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

As with Palomar, our competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. In addition, we do not know whether our competitors will apply for and obtain patents that will prevent, limit or interfere with our ability to make, use, sell or import our products. Although we may seek to resolve any potential future claims or actions, we may not be able to do so on reasonable terms, or at all. If, following a successful third-party action for infringement, we cannot obtain a license or redesign our products, we may have to stop manufacturing and marketing our products and our business would suffer as a result.

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We may become involved in litigation not only as a result of alleged infringement of a third party s intellectual property rights but also to protect our own intellectual property. For example, we have been, and may hereafter become, involved in litigation to protect the trademark rights associated with our company name or the names of our products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management s attention from our core business. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our products or processes to avoid infringement. 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 products, any of which would have a material adverse effect on our business, results of operations and financial condition.

Intellectual property rights may not provide adequate protection for some or all of our products, 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 products. At December 31, 2005, we had five issued U.S. patents, some covering our ClearView handpiece design and cooling method. Some of our other components, such as our laser module, electronic control system and high-voltage electronics, are not, and in the future may not be, protected by patents. Additionally, our patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we obtain may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products and use manufacturing processes that are substantially similar to, or superior to, ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

The absence of complete intellectual property protection exposes us to a greater risk of direct competition. Competitors could purchase one of our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, 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 against competitors products and methods, our competitive position could be adversely affected, as could our business.

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

Our products compete against similar products offered by public companies, such as Candela, Laserscope, Lumenis, Palomar, and Syneron as well as private companies such as Reliant Technologies and Thermage. Competition with these companies 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. We also face competition from medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include sclerotherapy, a procedure involving the injection of a solution into the vein to collapse it, electrolysis, a procedure involving the application of electric current to eliminate hair follicles, and chemical peels. We may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products, and includes such factors as:

- intellectual property protection;
- product performance;
- product pricing;

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quality of customer support;

success and timing of new product development and introductions; 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 may decide not to purchase our products, or to delay such purchases. 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 lines. For example, ESC Medical purchased Coherent s medical business in 2001 and the surviving company, Lumenis, incorporated competitive product lines and technologies of the predecessor companies into its current products. 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 laser and other light-based devices for the aesthetic market is characterized by rapid innovation, and we must continuously develop new products or our revenues may decline.

While we attempt to protect our products through patents and other intellectual property, 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 our CoolGlide product was the first long-pulse Nd:YAG, or long wavelength, laser system cleared by the FDA for permanent hair reduction on all skin types, competitors have subsequently introduced systems that utilize Nd:YAG lasers, and received FDA clearances to market these products as treating all skin types. We expect that any competitive advantage we may enjoy from other current and future innovations, such as combining multiple handpieces in a single system to perform a variety of applications, 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 products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue will decline as our customers purchase our competitors products.

Our ability to compete depends upon our ability to innovate, to develop and commercialize new products and product enhancements, and to identify new markets for our technology.

We have created products to apply our technology to hair removal, treatment of veins, skin rejuvenation, treatment of pigmented lesions and treatment of wrinkles. Currently, these applications represent the majority of laser and other light-based aesthetic procedures. To be successful in the future, we must develop new and innovative applications of laser and other light-based technology, identify new markets for our existing technology, and develop new technology that is not light-based. To successfully expand our product offerings, we must:

develop or acquire new products that either add to or significantly improve our current products;

convince our target customers that our new products or product upgrades would be an attractive revenue-generating addition to their practices;

sell our products to non-traditional customers;

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identify new markets and alternative applications for our technology;

protect our existing and future products with defensible intellectual property; and

satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, we have introduced at least one new product and a corresponding upgrade to our existing products. Historically, these introductions have been a significant component of our financial performance. Our business strategy is based, in part, on our expectation that we will continue to make annual product introductions that we can sell to new customers and to existing customers as upgrades. In the future, we plan to invest between 7-9% of net revenue in our research and development department. Even with a significant investment in research and development, we may be unable, however, to continue to develop new products and technologies annually, or at all, which could adversely affect our projected growth rate.

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

We provide guidance to the investing community regarding our anticipated future operating performance, both for the coming quarter and fiscal year end. Our business typically has a short sales cycle, we do not have significant backlog of orders at the start of a quarter, and our ability to sell our products successfully is subject to many uncertainties, as discussed herein. In light of those factors, it is difficult for us to estimate with accuracy our future results. In the past, our actual performance had turned out to be significantly different from our prior guidance. For example, at the beginning of 2005, we indicated that we expected our 2005 revenue to increase by 25% over 2004. Actual 2005 growth was higher, at 44% over 2004. Earlier this year, we stated publicly that we expected our revenue to grow 25% in 2006, compared to 2005. As we stated at the time, such expectations are subject to numerous risks and uncertainties which could make actual results differ materially, either higher or lower. If our actual results do not meet our public guidance, or our results or guidance as to the future were to be below the expectations of third party financial analysts, our stock price could decline significantly.

If we fail to obtain clearance from the U.S. Food and Drug Administration to market our Titan product for additional indications, our revenue from this product may be adversely affected.

Our Titan product, introduced in 2004, is a material component of our growth strategy. We currently have FDA clearance to market Titan in the United States for deep dermal heating. The FDA has denied our initial 510(k) application to market Titan for wrinkle reduction on the basis that Titan is not substantially equivalent to predicate devices for the treatment of wrinkles. We are continuing to seek a clearance from the FDA to market Titan for additional indications, but there are no assurances as to when, or whether, we will ever obtain such a clearance. We cannot promote or advertise our Titan product in the United States for any indications other than deep dermal heating until we receive additional FDA clearances. In the event that we do not obtain additional FDA clearances, our ability to market Titan in the United States and revenue derived therefrom, including revenue from both Titan unit sales and handpiece refills, may be adversely affected.

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

Our products are medical devices that are 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 labeling claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. In the event that we do not obtain additional FDA clearances, our ability to market future products or applications in the United States and revenue derived therefrom may be adversely affected.

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Medical devices may be marketed only for the indications for which they are approved or cleared and if we are found to be marketing our products for off-label, or non-approved, uses we might be subject to FDA enforcement action or have other resulting liability. We have obtained 510(k) clearance for the indications for which we market our products. 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 products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. Our products are 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 products 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 our products. However, a state could change its regulations at any time, thereby 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 products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business.

If we fail to comply with the FDA s Quality System Regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.

We are currently 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 products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. We have been, and anticipate in the future to be, subject to such inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

If we modify one of our FDA-approved devices, we may need to seek re-approval, which, if not granted, would prevent us from selling our modified products or cause us to redesign our products.

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 pre-market approval. We may not be able to obtain additional 510(k) clearance or pre-market approvals for new

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products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearance would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearance 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 devices, which could harm our operating results and require us to redesign our products.

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 products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the United States are regulated by the FDA. 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 may be unable to obtain or maintain regulatory qualifications, clearances or approvals in other countries. We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications. If we experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if we 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, which could have a material adverse effect on our business and growth strategy.

To successfully market and sell our products internationally, we must address many issues with which we have little or no experience.

For the year ended December 31, 2005, approximately 28% of our revenue was derived from international customers, which are a material component of our growth strategy. We depend on third-party distributors and a relatively new direct sales operation to sell our products internationally, and if these distributors or direct sales personnel under-perform, we may be unable to increase or maintain our level of international revenue. We will need to attract additional international distributors to grow our business and expand the territories in which we sell our products. Distributors may not accept our business or commit the necessary resources to market and sell our products to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to engage distributors in particular geographic areas, we may not realize projected international revenue growth. Additionally, we expect to expand our direct sales force in Europe and Asia. If we are unable to hire, retain and obtain satisfactory performance from such additional personnel, our revenue from international operations may be adversely affected.

We believe that an increasing amount of our future revenue will come from international sales as we expand our overseas operations and develop opportunities in additional international territories. International sales are subject to a number of risks, including:

- difficulties in staffing and managing our foreign operations;
- difficulties in penetrating markets in which our competitors products are more established;
- reduced protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification and regulatory requirements;

lengthy payment cycles and difficulty in collecting accounts receivable;

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customs clearance and shipping delays;

political and economic instability;

lack of awareness of our brand in international markets; 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 unsuccessful at finding a solution, our revenue may decline.

The expense and potential unavailability of insurance coverage for our customers and our company could adversely affect our ability to sell our products and our financial condition.

Some of our customers and prospective customers have had difficulty in procuring or maintaining liability insurance to cover their operation and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and, industry-wide, potential customers may opt against purchasing laser and other light-based products due to the cost of or inability to procure insurance coverage.

We have been experiencing steep increases in our product liability insurance premiums. If our premiums continue to rise, we may no longer be able to afford adequate insurance coverage. If we are unable to maintain adequate coverage, potential product liability claims would be paid out of cash reserves, harming our financial condition, operating results and profitability.

Because we do not require training for users of our products, and sell our products to non-physicians, there exists an increased potential for misuse of our products, which could harm our reputation and our business.

Federal regulations allow us to sell our products to or on the order of licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians 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 a defective design, material or workmanship or misuse of our products and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our products or failing to adhere to operating guidelines could cause significant eye and 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 involved, and may in the future be involved, in litigation related to the use of our products. 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

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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, thereby harming our financial condition and reducing our operating results.

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

Many of the components and materials that comprise our products are currently manufactured by a limited number of suppliers. A supply interruption or an increase in demand beyond our current suppliers capabilities could harm our ability to manufacture our products until a new source of supply is 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 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; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

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

Components used in our products are complex in design, and any defects may not be discovered prior to shipment to customers, which could result in warranty obligations, reducing our revenue and increasing our cost.

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to produce. If our suppliers fail to produce components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects that cannot be repaired easily and inexpensively, we may experience:

- loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

increased cost of our warranty program due to product repair or replacement;

inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal action.

The occurrence of any one or more of the foregoing could materially harm our business.

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

We keep limited materials and components 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 nine 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 products to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

If there is not sufficient demand for the procedures performed with our products, practitioner demand for our products could be inhibited, resulting in unfavorable operating results and reduced growth potential.

Continued expansion of the global market for laser- and other light-based aesthetic procedures is a material assumption of our growth strategy. Most procedures performed using our products are elective procedures not reimbursable through government or private health insurance, with the costs borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including:

- the cost of procedures performed using our products;
- the cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser- or other light-based technologies and treatments which use pharmaceutical products;
- the success of our sales and marketing efforts; and
- consumer confidence, which may be impacted by economic and political conditions.

If, as a result of these factors, there is not sufficient demand for the procedures performed with our products, practitioner demand for our products could be reduced, resulting in unfavorable operating results and lower growth potential.

Lack of demand for our products in the medi-spa market would harm our anticipated revenue growth.

An increasing portion of our revenue is derived from sales to customers in the medi-spa market, which is comprised of physicians offering aesthetic treatments in a spa environment. Achieving further penetration into this new market is a material assumption of our growth strategy. Demand for our products in the medi-spa market could be weakened by factors including poor financial performance of medi-spa businesses, reduced patient demand for aesthetic treatments in a spa environment, price sensitivity of medi-spa patients and demand for alternative treatments and services in the medi-spa setting. If we do not achieve anticipated demand for our products in the medi-spa market, our expected revenue growth may not be achieved.

If PSS World Medical fails to perform to our expectations, we may fail to achieve anticipated operating results.

We have a distribution agreement with PSS World Medical, which operates medical supply distribution service centers with approximately 700 sales representatives serving physician offices in all 50 states of the United States. PSS World Medical sales representatives work in coordination with our sales force to locate new potential customers for our products. For the year ended December 31, 2005, approximately 16% of our revenue was from PSS.

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If PSS World Medical does not perform adequately under the arrangement, or terminates our relationship, which it can do at any time upon 90 days notice, it may have a material adverse effect on our business, financial condition, results of operations or future cash flows.

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. In addition, we do not maintain key person life insurance policies covering any of our employees. 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. 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.

Our financial results will be affected by accounting rules governing the recognition of stock-based compensation expense.

Beginning in the first quarter of fiscal 2006, we, like other companies, will be required to measure and record stock-based compensation expense using the fair value method, which will adversely affect our results of operations by increasing our cost by the amount of such stock option charges.

In the year ending December 31, 2006, we estimate that the adoption of FAS 123(R) will increase our cost of goods sold and operating expenses by approximately $3.6 million. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price, employee stock option exercise behaviors, and interest rates.

Failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, operating results and stock price.

Beginning with this annual report for our fiscal year ended on December 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include a report by our management on our internal control over financial reporting. Such report must contain an assessment by management of the effectiveness of our internal control over financial reporting as of the end of our fiscal year and a statement as to whether or not such internal control is effective. Such report must also contain a statement that our independent registered public accounting firm has issued an attestation report on management s assessment of such internal control.

Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, the commitment of time and operational resources and the diversion of management s attention. If our management identifies one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that such internal control is effective. If we are unable to assert that our internal control over financial reporting is effective as of our fiscal year end in future years, our business may be harmed.

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Our effective income tax rate may vary significantly

Unanticipated changes in our tax rates could affect our future results of operations. Our future effective tax rates could be unfavorably affected by changes in tax laws or the interpretation of tax laws, by unanticipated decreases in the amount of revenue or earnings in countries with low statutory tax rates, by changes in the valuation of our deferred tax assets and liabilities, future levels of R&D spending, deductions for employee stock option exercises being different to what we projected, and changes in overall levels of income before taxes.

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 any businesses, products or technologies that we acquire. 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 laser and other light-based products, we may spend time and money on projects that do not increase our revenue.

Any cash acquisition we pursue would diminish our available cash balances to us for other uses, and any stock acquisition would be dilutive to our stockholders. 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.

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

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

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

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

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

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

because a return on your investment will only occur if our stock price appreciates.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters and U.S. operations are located in a 66,000 square foot facility in Brisbane, California. We lease these premises under a non-cancelable operating lease which expires in 2014. In addition, we have leased office facilities of approximately 2,690 square feet and 3,700 square feet, in Switzerland and Japan, respectively. The lease in Switzerland expires in July 2008 and the lease in Japan expires in May 2007. In September 2005, we terminated our 1,400 square foot Germany office lease. We believe that these facilities are adequate for our current and future needs.

ITEM 3. LEGAL PROCEEDINGS

In February 2002, Palomar Medical Technologies filed a lawsuit against us in the United States District Court, District of Massachusetts. A trial date has been set for May 30, 2006. The plaintiff alleges that by making, using, selling or offering for sale our CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, we are willfully and deliberately infringing U.S. Patent No. 5,735,844. This patent concerns a method and apparatus for removing hair with light energy. Massachusetts General Hospital later joined the lawsuit as an additional plaintiff, since Palomar is the exclusive licensee, and MGH is the owner, of the patent at issue in the lawsuit. Palomar and MGH are seeking to enjoin us from selling products found to infringe the patent, and to obtain compensatory and treble damages, reasonable costs and attorney s fees, and other relief as the court deems just and proper. We are defending the action vigorously, asserting that our products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, we have filed a counterclaim alleging that the patent should be declared unenforceable because of inadequate disclosures made to the U.S. Patent and Trademark Office by the plaintiffs during that patent s prosecution with the U.S. Patent and Trademark Office.

In April 2005, the plaintiffs filed a second lawsuit in this same court, alleging that by making, using, selling or offering for sale products that utilize pulsed-light technology for hair removal, we are willfully and deliberately infringing U.S. Patent Nos. 5,735,844 and 5,595,568. The plaintiffs are seeking to enjoin us from selling our products found to infringe those patents, and to obtain compensatory and treble damages, reasonable costs and attorney s fees, and other relief as the court deems just and proper. We have responded by filing a motion to dismiss this second lawsuit on the grounds of lack of jurisdiction, and by filing complaints for declaratory relief against these plaintiffs in California and Delaware. This motion is pending with the court.

We believe that we have meritorious defenses of non-infringement and invalidity in these actions. However, litigation is unpredictable and we may not prevail in successfully defending or asserting our position. If we do not prevail, we may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. We could also be ordered to stop selling any products that perform hair removal. Most of our products include an application for hair removal.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not Applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT S COMMON STOCK AND RELATED SHAREHOLDER MATTERS

Stock Exchange Listing

Cutera s common stock trades on The NASDAQ National Market under the symbol CUTR. At February 28, 2006, the closing sale price of our common stock was $27.09 per share.

Common Stockholders

We had 16 stockholders of record as of February 28, 2006, one of whom was CEDE & CO, a large clearing house that holds shares in its name for banks, brokers and institutions, in order to expedite the sale and transfer of stock. Since many stockholders shares are listed under their brokerage firm s name, we believe the actual number of stockholders is over 8,000.

Stock Prices

The following table sets forth quarterly high and low closing sales prices of our common stock for the indicated fiscal periods. In the first quarter of 2004, we had the initial public offering of our common stock.

	Common Stock			
	2005		2004	
	High	Low	High	Low
4th Quarter	$ 43.50	$ 22.08	$ 13.11	$ 9.51
3rd Quarter	25.94	16.06	14.00	10.89
2nd Quarter	19.56	14.37	16.50	11.11
1st Quarter	19.71	12.47	14.00	14.00

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.

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

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.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 for information regarding securities authorized for issuance under equity compensation plans.

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ITEM 6. SELECTED FINANCIAL DATA

The table set forth below contains certain consolidated financial data for each of the last five fiscal years of Cutera. This data should be read in conjunction with the detailed information, financial statements and related notes, as well as Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere herein.

Consolidated Statements of Operations Data (in thousands, except per share data):

	Year ended December 31,				
	2005	2004	2003	2002	2001
Net revenue (1)	$ 75,620	$ 52,641	$ 39,088	$ 28,327	$ 19,328
Cost of revenue (1)	19,792	14,689	12,317	9,991	6,941
Gross profit	55,828	37,952	26,771	18,336	12,387
Operating expenses:					
Sales and marketing	24,801	19,052	13,410	8,236	5,431
Research and development	5,065	4,136	3,097	2,701	2,108
General and administrative	7,983	8,344	3,916	5,106	1,843
Amortization of stock-based compensation (2)	1,307	1,267	1,184	963	495
Total operating expenses	39,156	32,799	21,607	17,006	9,877
Income from operations	16,672	5,153	5,164	1,330	2,510
Interest and other income, net	2,034	632	30	85	171
Income before income taxes	18,706	5,785	5,194	1,415	2,681
Provision for income taxes	(4,905)	(2,025)	(2,088)	(755)	(342)
Net income	$ 13,801	$ 3,760	$ 3,106	$ 660	$ 2,339
Net income available to common shareholders used in basic earnings per share	13,801	3,284	963	184	561
Net income per share:					
Basic	$ 1.20	$ 0.38	$ 0.46	$ 0.10	$ 0.38
Diluted	$ 1.00	$ 0.31	$ 0.35	$ 0.07	$ 0.27
Weighted-average number of shares used in per share calculations:					
Basic	11,535	8,573	2,106	1,810	1,480
Diluted	13,864	12,222	8,835	8,811	8,731
(1) Includes amortization of stock-based compensation related to:					
Net revenue	$	$	$	$	$ 164
Cost of revenue	135	168	240	234	93
	135	168	240	234	257
(2) Amortization of stock-based compensation is attributable to the following operating expense categories:					
Sales and marketing	220	274	382	366	262
Research and development	288	413	351	287	113

General and administrative	799	580	451	310	120
	1,307	1,267	1,184	963	495
Total amortization of stock-based compensation	$ 1,442	$ 1,435	$ 1,424	$ 1,197	$ 752

	As of December 31,				
	2005	2004	2003	2002	2001
Consolidated Balance Sheet Data (in thousands):					
Cash and cash equivalents	$ 5,260	$ 7,070	$ 10,290	$ 8,276	$ 6,354
Marketable investments	86,736	59,200			
Working capital	98,318	68,519	14,205	8,896	7,854
Total assets	111,958	80,549	24,198	15,426	12,475
Redeemable convertible preferred stock			7,372	7,272	7,272
Retained earnings	21,743	7,942	4,182	1,076	416
Total stockholders equity	97,177	68,456	7,875	3,106	1,226

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the attached financial statements and notes thereto, and with our audited financial statements and notes thereto for the fiscal year ended December 31, 2005. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to our expectations as to future capital expenditures and requirements, growth in our operations, the impact of exchange rate volatility, and the current litigation against Palomar Medical Technologies. These forward-looking statements involve risks and uncertainties. The cautionary statements set forth below and those contained in Item 1A Risk Factors commencing on page 18, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

Introduction

The MD&A is organized as follows:

Executive summary. This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.

Critical accounting policies and estimates. This section describes the key accounting policies that are affected by critical accounting estimates. In addition, it includes a summary of recent accounting pronouncements that may be applicable to us.

Results of operations. This section provides our analysis and outlook for the significant line items on our consolidated statement of operations.

Liquidity and capital resources. This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of December 31, 2005.

Recent accounting pronouncements. This section describes the issuance and effects of new accounting pronouncements that are applicable to our Company.

Executive Summary

Company Description. We are a global medical device company specializing in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetics system to the professional aesthetic market. Our easy-to-use families of products CoolGlide, Xeo and Solera enable dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners to perform safe, effective and non-invasive aesthetic procedures for their patients.

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research, regulatory, sales, marketing and administrative activities. Outside the United States, we have a direct sales presence in Australia, Canada, France, Germany, Japan, Spain, Switzerland and the United Kingdom. As of December 31, 2005, we had 63 direct sales employees worldwide, a global network of distributors located in more than 25 countries, and a distributor relationship in the United States with PSS World Medical. PSS s Physician Sales and Service business operates medical supply distribution service centers with approximately 700 sales representatives serving physician offices in all 50 of the United States.

Products. Our revenue is derived from the sale of products, product upgrades, amortization of pre-paid service contracts, revenue from out-of-warranty services, and Titan handpiece refills. Product revenue represents the sale

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of a system console that incorporates a universal graphic user interface, a laser or other light-based module, control system software, high voltage electronics, and one or more handpieces. We offer our customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications as their practice grows. This enables customers to upgrade their systems whenever they want and provides us with a source of recurring revenue, which we classify as product upgrade revenue. Service revenue relates to amortization of pre-paid maintenance and support contract revenue and receipts for services on out-of-warranty products. Titan handpiece refill revenue is associated with our Titan handpiece, which requires a periodic refilling process, which includes the replacement of the optical source, after a set number of pulses has been performed.

Significant Business Trends. We believe that revenue growth has been and will continue to be primarily attributable to the following:

Investments made in our global sales and marketing infrastructure, including the expansion of our sales force and improved productivity, to increase our market penetration in an expanding aesthetic laser market.

Continuing introduction of new aesthetic products and applications.

Marketing to physicians outside the core dermatologist and plastic surgeon specialties, including the medi-spa market.

During 2005, our business continued to experience significant growth. Net revenue for the year ended December 31, 2005 increased by $23 million, or 44%, compared to 2004, while net revenue for 2004 increased by $13.6 million, or 35%, compared to 2003. On a geographical basis, for 2005, compared to 2004, our U.S. revenue increased by $19.7 million, or 57%, and our international revenue increased by $3.3 million, or 19%. We experienced stronger U.S growth, versus international growth, due primarily to our increased sales and marketing efforts and our higher concentration of direct sales employees in the United States. The slower international growth was partly attributable to reduced revenue to a national chain of clinics in Japan, who purchased systems for all their members beginning in early 2004 and ending in the first quarter of 2005. Our revenue is seasonally strong in the fourth quarter of our fiscal year and accounted for 32% and 31% of our net revenue for 2005 and 2004, respectively.

Due to our patent litigation set for trial on May 30, 2006 see Item 3 Legal Proceedings we expect our general and administrative expenses to increase to $3.5 million in each of the quarters ending March 31, 2006 and June 30, 2006. After the trial is completed, anticipated for June 2006, we expect our general and administrative expenses to be in the range of 8%-10% of revenue for the remainder of 2006.

Starting from January 1, 2006, we will recognize compensation expense for employee stock options using the fair-value based method see the section on Recent Accounting Pronouncements below. As a result, for the year ending December 31, 2006, we expect stock-based compensation expense to increase to approximately $4.5 million. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price, employee stock option exercise behaviors, and interest rates.

Factors that May Impact Future Performance. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances and compliance for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. Our industry is subject to extensive government regulation, including the regulation by the United States Food and Drug Administration. Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other factors that could impact our future performance are provided in Item 1A Risk Factors section above.

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Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires us to make judgments, assumptions, and estimates that affect the amounts reported in the Consolidated Financial Statements and accompanying notes. Note 2 to the Consolidated Financial Statements describes the significant accounting policies and methods used in the preparation of the Consolidated Financial Statements. We consider the accounting policies described below to be affected by critical accounting estimates. Such accounting policies are impacted significantly by judgments, assumptions, and estimates used in the preparation of the Consolidated Financial Statements, and actual results could differ materially from the amounts reported based on these policies.

Revenue Recognition

We recognize distributor and non-distributor revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered, and the collectibility of those fees. In instances where final acceptance of the product is specified by the customer or collectibility has not been reasonably assured, revenue is deferred until all acceptance criteria have been met. Revenue under service contracts is recognized on a straight-line basis over the period of the applicable service contract. Service revenue, not under a service contract, is recognized as the services are provided. Total deferred revenue for service contracts was $3.1 million and $1.9 million as of December 31, 2005 and December 31, 2004, respectively. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Allowance for Doubtful Accounts

Our accounts receivable balance, net of allowance for doubtful accounts, was $6.5 million as of December 31, 2005, compared with $6.6 million as of December 31, 2004. The allowance for doubtful accounts as of December 31, 2005, was $177,000, compared with $487,000 as of December 31, 2004. We perform periodic credit evaluations of our customers and adjust credit limits based upon payment history and the customer s current creditworthiness, as determined by our review of current credit information. We monitor collections and payments from our customers and maintain an allowance for doubtful accounts based upon our historical experience and any specific customer collection issues that have been identified. While our credit losses have historically been within our expectations and the allowance established, we may not continue to experience the same credit loss rates that we have in the past.

Allowance for Inventory

We state our inventory at the lower of cost or market, computed 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. Standard costs are monitored on a monthly basis and updated annually and as necessary to reflect changes in raw material costs and labor and overhead rates. Our inventory balance was $5.2 million as of December 31, 2005, compared with $3.0 million as of December 31, 2004. Our inventory allowances as of December 31, 2005 were $992,000, compared with $378,000 as of December 31, 2004. We provide inventory allowances 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 allowances are measured as the difference between the cost of inventory and estimated market value. 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

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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 when product is sold.

Warranty Reserve

The liability for product warranties, included in other accrued liabilities, was $2.0 million as of December 31, 2005, compared with $1.9 million as of December 31, 2004. Our products sold are generally covered by a warranty for periods ranging from one to two years. We accrue for warranty costs as part of our cost of sales at the time revenue is recognized. Product warranty cost is based on associated material costs, technical support labor costs, and associated overhead. We provide for the estimated cost of product warranties by considering historical material, labor and overhead expenses and applying the experience rates to the outstanding warranty period for products sold. As we sell new products to our customers, we must exercise considerable judgment in estimating the expected failure rates and warranty costs. Should actual product failure rates, material usage, service delivery costs or overhead costs differ from our estimates, revisions to the estimated warranty liability would be required. For more information on warranty reserves, see Note 4 to the Notes To Consolidated Financial Statements.

Stock based compensation

We have stock option plans to reward our employees. We account for these plans under the recognition and measurement principles of Accounting Principles Board, or APB, Opinion No. 25 and related interpretations and apply the disclosure provisions of SFAS No. 123, as amended by SFAS No. 148. We have recorded stock-based compensation expense for the fair market value of restricted stock granted to employees in 2005; and the difference between the deemed fair value of our common stock on the date of grant and the option exercise price with respect to stock options granted to employees prior to our initial public offering in 2004. We amortize employee stock-based compensation on a straight-line basis over the vesting terms of the underlying options.

We issue stock options to non-employees, generally for services, which we account for under the provisions of SFAS No. 123 and Emerging Issues Task Force, or EITF, No. 96-18. These options are valued using the Black-Scholes option valuation model and are subject to periodic adjustment as the underlying options vest. Changes in fair value are amortized over the vesting period on a straight-line basis.

Provision for Income Taxes

We are subject to income taxes in both the U.S. and other foreign jurisdictions, where we have a presence. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. We establish reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes and interest will be due. These reserves are established when, despite our belief that our tax return positions are fully supportable, we believe that certain positions are likely to be challenged and may not be sustained on review by tax authorities. We adjust these reserves in light of changing facts and circumstances, such as the closing of a tax audit. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate, as well as any related net interest.

Our effective tax rates differ from the statutory rate primarily due to research and development tax credits, state taxes, benefits from disqualifying dispositions of incentive stock option exercises, tax exempt interest income, and the tax impact of foreign operations. Our effective tax rate was 26%, 35% and 40% for the year ended December 31, 2005, 2004 and 2003, respectively. Our future effective tax rates could be adversely affected by earnings being lower than anticipated in countries where we have lower statutory rates and higher than anticipated in countries where we have higher statutory rates, or by changes in tax laws or interpretations thereof. In addition, we are subject to the continuous examination of our income tax returns by the Internal Revenue

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Service and other tax authorities. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes.

Undistributed earnings of the Company s foreign subsidiaries of approximately $515,000 at December 31, 2005, are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes have been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to various foreign countries.

Contingencies

We record charges for the costs we anticipate incurring in connection with litigation and claims against us when we can reasonably estimate these costs. As disclosed in Part I, Item 3 Legal Proceedings, we are involved in patent litigation with Palomar Medical Technologies, Inc. Since the outcome of this litigation is unpredictable, no expense has been recorded with respect to the contingent liability associated with this matter. Legal fees in connection with loss contingencies are recognized as the fees are incurred.

Recent Accounting Pronouncements

In December 2004, the FASB originally issued SFAS No. 123(R). SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R), as amended, is effective for public companies for the first annual period beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 123(R) will be effective January 1, 2006 for us. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) No. 107, TOPIC 14: Share-based payment. SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately.

We plan to adopt SFAS No. 123(R) using the modified prospective method, under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123(R) for all share-based payments granted after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date. The amounts disclosed within our consolidated financial statement footnotes are not necessarily indicative of the amounts that will be expensed upon the adoption of SFAS No. 123(R). Compensation expense calculated under SFAS No. 123(R) may differ from amounts currently disclosed within our consolidated financial statement footnotes based on changes in the fair value of our common stock, changes in the number of options granted or the terms of such options, the treatment of tax benefits and changes in interest rates or other factors. The adoption of SFAS No. 123(R) is expected to increase our cost of goods sold and operating expenses by approximately $3.6 million in 2006 based upon employee stock options outstanding as of December 31, 2005 and estimated 2006 option grants to employees. We expect the adoption of SFAS 123(R) to have a significant impact on our consolidated income statements and the presentation of the consolidated statements of cash flows. SFAS 123(R) also requires excess tax benefits from the exercise of stock options to be presented in the consolidated statement of cash flows as a financing activity rather than an operating activity, as currently presented.

In May 2005, the FASB issued SFAS 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. SFAS 154 requires retrospective application to prior period financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 also requires that retrospective application of a change

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in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle should be recognized in the period of the accounting change. SFAS 154 further requires a change in depreciation, amortization, or depletion method for long-lived, non-financial assets to be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS 154 to have a material impact on its financial condition or results of operations.

Results of Operations

The following table sets forth selected consolidated financial data for the periods indicated, expressed as a percentage of net total revenue.

	Year ended December 31,		
	2005	**2004**	**2003**
Revenue mix by geography:			
Revenue from United States customers	72%	66%	77%
Revenue from International customers	28%	34%	23%
	100%	100%	100%
Revenue mix by product category:			
Products	84%	83%	84%
Product upgrades	9%	12%	12%
Service	5%	5%	4%
Titan refills	2%	%	%
	100%	100%	100%
Net revenue growth	44%	35%	38%
Net revenue	100%	100%	100%
Cost of revenue	26%	28%	32%
Gross profit	74%	72%	68%
Operating expenses:			
Sales and marketing	33%	36%	34%
Research and development	7%	8%	8%
General and administrative	10%	16%	10%
Amortization of stock-based compensation	2%	2%	3%
Total operating expenses	52%	62%	55%
Income from operations	22%	10%	13%
Interest and other income, net	3%	1%	0%
Income before income taxes	25%	11%	13%
Provision for income taxes	7%	4%	5%
Net income	18%	7%	8%

Net Revenue

Revenue is derived primarily from the sale of products, product upgrades, service related to our products, and Titan handpiece refills. For the year ended December 31, 2005, compared to the year ended December 31, 2004, net revenue increased $23.0 million, or 44%. The $23.0 million increase was the result of a $19.8 million, or 45%, increase of product revenue; $1.5 million, or 61%, increase in service revenue; and $1.7 million increase in revenue from Titan handpiece refills. Upgrade revenue for the year ended December 31, 2005, when compared to

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the same period in 2004, remained unchanged at $6.6 million due primarily to an increasing number of existing customers choosing to purchase a second system, primarily from our Solera family of products, instead of upgrading their existing systems.

Of the $23.0 million increase in net revenue, $19.7 million was attributable to higher U.S. revenue and $3.3 million was attributable to higher international revenue. The primary contributors to our revenue growth were the continued expansion of our direct sales force, higher revenue from our multi-application CoolGlide Xeo product, the introduction of our new Solera family of products, the strong market acceptance of our products in the medi-spa market, increased service revenue due to the increased number of units installed at customer sites and the increase of Titan handpiece refill revenue resulting from the periodic need for refilling the handpiece and an increased number of units sold.

For the year ended December 31, 2004, compared to the year ended December 31, 2003, net revenue increased $13.6 million, or 35%. Product revenue increased $10.3 million, due primarily to sales of our multi application Xeo product; upgrade revenue increased by $2.1 million, due primarily to the release of the Titan upgrade product in 2004; and service and other revenue increased by $1.2 million due partly to a higher installed base of customers. The geographical source of the $13.6 million revenue increase was, $8.9 million from international sales and $4.7 million from U.S. sales. The large growth internationally occurred primarily in the Pacific Rim countries resulting from our sales force expansion and new product introductions.

Cost of Revenue

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the year ended December 31, 2005, compared to the year ended December 31, 2004, cost of revenue increased $5.1 million, or 35%. Cost of revenue as a percentage of net revenue, decreased to 26% for the year ended December 31, 2005, from 28% for the year ended December 31, 2004. This improvement in margins was primarily attributable to lower overhead expenses resulting from the leveraging of our manufacturing operations, a favorable product mix towards our multi-application Xeo products, and reduced warranty and service costs associated with improved product reliability.

For the year ended December 31, 2004, compared to the year ended December 31, 2003, cost of revenue increased $2.4 million, or 19%. Key contributors to this increase include; $1.4 million of increased labor and overhead costs and $1.0 million of higher material costs associated with increased unit shipments.

Sales and Marketing

Sales and marketing expenses consist primarily of personnel costs and expenses associated with customer-attended workshops, trade shows and advertising. For the year ended December 31, 2005, compared to the year ended December 31, 2004, sales and marketing expenses increased by $5.7 million, or 30%. This increase was primarily attributable to approximately $4.7 million of higher personnel expenses associated primarily with the increased expenses relating to higher headcount, higher commission expense due to increased revenue and higher recruiting expenses and $354,000 of higher travel expenses attributable with the higher headcount. As a percentage of net revenue, for the year ended December 31, 2005 sales and marketing expenses decreased by three percentage points from 36% in the year ended December 31, 2004 to 33% in the same period in 2005. This decrease was primarily attributable to improved leveraging and productivity that resulted from the higher revenue growth, compared to the expense growth.

For the year ended December 31, 2004, compared to the year ended December 31, 2003, sales and marketing expenses increased $5.6 million, or 42%. This increase was primarily attributable to an increase of $2.2 million in promotional expenses, $2.5 million of personnel costs and $734,000 in travel costs. Promotional expenses result primarily from customer workshops and industry trade shows.

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Research and Development

Research and development expenses consist primarily of personnel, clinical, regulatory and material costs. For the year ended December 31, 2005, compared to the year ended December 31, 2004, research and development expenses increased $929,000 or 22%. This increase was primarily attributable to $888,000 of higher personnel expense due primarily to increased headcount. As a percentage of net revenue, research and development expenses for the year ended December 31, 2005, compared to the same period in 2004, decreased by one percentage point from 8% to 7% due to the higher net revenue in 2005.

For the year ended December 31, 2004, compared to the year ended December 31, 2003, research and development expenses increased $1.0 million or 34%. This increase was primarily attributable to higher facility related expenses of $353,000 associated with the move to our new Brisbane, California location in 2004, $272,000 of higher third party expenses associated with clinical projects and $243,000 of higher material and personnel related costs for new product development.

General and Administrative

General and administrative expenses consist primarily of personnel costs, legal and accounting fees and other general administrative expenses. For the year ended December 31, 2005, compared to the same period in 2004, general and administrative expenses decreased by $361,000, or 4%. This decrease was primarily attributable to lower legal expenses of $1.4 million, partly due to the timing of our litigation with Palomar, and expenses incurred in 2004 but not in 2005, including costs of $291,000 associated with moving our facilities from Burlingame, California to Brisbane, California and a litigation settlement of $175,000. This was offset by $1.7 million of higher personnel expenses, due to higher headcount and a net increase of $340,000 in accounting, tax and audit consulting fees, due primarily to our Sarbanes Oxley implementation in 2005. As a percentage of net revenue, general and administrative expenses decreased from 16% in 2004 to 10% in 2005.

For the year ended December 31, 2004, compared to the same period in 2003, general and administrative expenses increased by $4.4 million, or 113%. This increase was primarily attributable to $1.2 million in increased outside service costs, primarily associated with our initial public offering and being a public company, $1.1 million of higher legal expenses, $611,000 of higher facilities costs primarily associated with the move to our new Brisbane, California location and $444,000 in increased personnel costs.

Interest and Other Income, Net

For the year ended December 31, 2005, compared to the same period in 2004, interest and other income increased $1.4 million. This increase was primarily attributable to higher tax-exempt interest income, resulting from higher investment balances and rising yields in 2005, compared to 2004.

For the year ended December 31, 2004, compared to the same period in 2003, interest and other income, net, increased by $602,000. This increase in interest income was primarily a result of higher cash and investment balances resulting from the proceeds of our initial public offering in April 2004.

Provision for Income Taxes

For the year ended December 31, 2005, 2004 and 2003, our effective tax rate was 26%, 35% and 40%, respectively. The decrease in the effective tax rate in 2005, compared to 2004, was primarily attributable to higher incentive stock option exercises that became tax deductible due to a disqualifying disposition by the option holders, and higher benefit from research and development credits resulting from increased research and development expenses. For the year ended December 31, 2004, compared with the same period in 2003, this decrease in effective tax rates resulted primarily from higher tax-exempt interest income and lower stock-based compensation charges on incentive stock options that are not tax deductible.

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Amortization of Stock-Based Compensation

Stock-based compensation consists of amortization of deferred stock-based compensation related to restricted stock units, stock options to purchase common stock issued to employees below their deemed fair market value and the value of options to purchase common stock issued to non-employees. Deferred stock-based compensation is amortized on a straight-line basis to the respective departments that benefit from the services of the individuals who were granted the equity instruments.

In 2005, instead of granting employees stock option, we granted them a mix of stock options and restricted stock units. During the year ended December 31, 2005, we granted 71,500 shares of restricted stock units that vest in four equal, annual installments on the anniversaries of the date of grant. We recorded $1,448,000 of deferred stock-based compensation for these restricted stock unit grants, which is being amortized over a four year expected service period of the employees.

As of December 31, 2005, we had $2.2 million of deferred stock-based compensation cost related to non-vested stock options and restricted stock awards, that will be expensed over the next three and a half years.

During each of the years ended December 31, 2005, 2004 and 2003, we recorded $1.4 million of deferred stock-based compensation.

Liquidity and Capital Resources

Net Cash Provided by Operating Activities

For the year ended December 31, 2005, net cash provided by operations was $20.4 million. This was primarily attributable to net income of $13.8 million; cash provided from tax benefits related to employee stock option exercises of $7.4 million; add back for non-cash amortization of deferred stock-based compensation of $1.4 million; and an increase in deferred revenue resulting primarily from an increase in customer service contracts sold in 2005. This was offset by cash used to increase inventory by $3.1 million to support anticipated shipments and a broader product offering; and an increase in other assets of $2.9 million that resulted from income taxes paid prior to the fourth quarter of 2005 becoming refundable due to an increase in employee stock option deductions in the fourth quarter of 2005.

For the year ended December 31, 2004, net cash provided by operating activities was $9.2 million, which primarily resulted from net income of $3.8 million; adjusted for $2.5 million from an increase in accrued liabilities, primarily due to higher employee related accruals; and $1.4 million of non-cash stock-based compensation expense. This was partly offset by $1.1 million cash used to increase inventory for anticipated revenue shipments and a reduction in accounts payable of $720,000.

Net Cash Used in Investing Activities

For the year ended December 31, 2005, net cash used in investing activities was $28.3 million. Of this amount, $27.6 million, net, was used to purchase additional marketable investments from the cash generated by operations, the exercises of stock options and employee stock purchases. In addition, $539,000 was primarily used to purchase research and development and manufacturing equipment; and $165,000 was used to purchase intangibles associated with the set up of a new office in Zurich, Switzerland through the acquisition of a distributor.

For the year ended December 31, 2004, net cash used in investing activities was $59.8 million. Of this amount, $59.2 million net was used to purchase marketable investments and $854,000 was used for purchasing property and equipment primarily for our manufacturing, research and development in our new Brisbane, California location. This was partly offset by $250,000 from the removal of restrictions on cash deposits with our bank.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2005, was $6.1 million, which was attributable to proceeds from the issuance of stock through our stock option and employee stock purchase plans.

Net cash provided by financing activities for the year ended December 31, 2004 was $47.3 million. Of this amount, $46.3 million, net, was from the sale of common stock associated with our initial public offering and $1.0 million was attributable to the proceeds from the purchase of stock through our stock option and employee stock purchase plans.

As of December 31, 2005, we had cash, cash equivalents and marketable investments of $92.0 million, which we believe are sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

As disclosed in Note 5 to the Notes to Consolidated Financial Statements Contingencies, we are involved in patent litigation with Palomar Medical Technologies, Inc. Since the outcome of this litigation is unpredictable, and since management believes that a significant adverse result for the Company is not probable, no expense has been recorded with respect to the contingent liability associated with this matter. If we do not prevail in this litigation, we could be ordered to pay substantial damages, which could adversely impact the working capital available for use in future operations. See Item 1A Risk Factors relating to this litigation. Our 2006 expense projections include significant spending on this litigation.

Contractual Cash Obligations

The following table discloses aggregate information about the Company s contractual obligations for minimum lease payments related to facility leases, net of sub lease income in 2006, and the periods in which these payments are due as of December 31, 2005.

		Payments Due by Period ($ 000 s)			
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
Operating leases	$ 8,778	$ 686	$ 1,677	$ 2,138	$ 4,277

Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest 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. As of December 31, 2005, we were not involved in any unconsolidated transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies, municipal bonds and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity (interest reset date for auction-rate securities and variable

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rate demand notes) of generally less than eighteen months. For maturities of our marketable investments, see Note 3 to the Notes to Consolidated Financial Statements. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of December 31, 2005 would have potentially declined by $313,000.

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. To date, our exposure to exchange rate volatility has not been significant. We cannot assure that there will not be a material impact in the future. Although the majority 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.

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CUTERA, INC. AND SUBSIDIARY COMPANIES

ANNUAL REPORT ON FORM 10-K

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

The following Consolidated Financial Statements of the Registrant and its subsidiaries are required to be included in Item 8:

The following Consolidated Financial Statement Schedule of the Registrant and its subsidiaries for the years ended December 31, 2005, 2004 and 2003 is filed as a part of this Report as required to be included in Item 15(a) and should be read in conjunction with the Consolidated Financial Statements of the Registrant and its subsidiaries:

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 Consolidated Financial Statements or the Notes thereto.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Cutera, Inc.:

We have completed an integrated audit of Cutera, Inc. s 2005 consolidated financial statements and of its internal control over financial reporting as of December 31, 2005 and audits of its 2004 and 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Cutera, Inc. and its subsidiaries at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated 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 of financial statements 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.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in the Report of management on internal control over financial reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting

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includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 15, 2006

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CUTERA, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2005	2004
Assets		
Current assets:		
Cash and cash equivalents	$ 5,260	$ 7,070
Marketable investments	86,736	59,200
Accounts receivable, net of allowance for doubtful accounts in 2005 and 2004 of $177 and $487, respectively	6,478	6,643
Inventory	5,245	3,004
Deferred tax asset	3,027	2,284
Other current assets	3,728	878
Total current assets	110,474	79,079
Property and equipment, net	1,015	1,071
Intangibles, net	469	399
Total assets	$ 111,958	$ 80,549
Liabilities and Stockholders Equity		
Liabilities:		
Accounts payable	$ 1,352	$ 1,195
Accrued liabilities	9,131	8,194
Deferred revenue	1,673	1,171
Total current liabilities	12,156	10,560
Deferred rent	1,096	648
Deferred revenue, net of current portion	1,469	833
Deferred tax liability	60	52
Total liabilities	14,781	12,093
Commitments and contingencies (Note 5)		
Stockholders equity:		
Redeemable convertible preferred stock, $0.001 par value		
Authorized: 5,000,000 shares; none issued and outstanding		
Common stock, $0.001 par value:		
Authorized: 50,000,000 shares in both 2005 and 2004;		
Issued and outstanding: 12,213,474 and 10,957,202 shares in 2005 and 2004, respectively	12	11
Additional paid-in capital	77,705	62,738
Deferred stock-based compensation	(2,171)	(2,226)
Retained earnings	21,743	7,942
Accumulated other comprehensive loss	(112)	(9)
Total stockholders equity	97,177	68,456
Total liabilities and stockholders equity	$ 111,958	$ 80,549

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

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CUTERA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2005	2004	2003
Net revenue	$ 75,620	$ 52,641	$ 39,088
Cost of revenue (1)	19,792	14,689	12,317
Gross profit	55,828	37,952	26,771
Operating expenses:			
Sales and marketing	24,801	19,052	13,410
Research and development	5,065	4,136	3,097
General and administrative	7,983	8,344	3,916
Amortization of stock-based compensation (2)	1,307	1,267	1,184
Total operating expenses	39,156	32,799	21,607
Income from operations	16,672	5,153	5,164
Interest and other income, net	2,034	632	30
Income before income taxes	18,706	5,785	5,194
Provision for income taxes	(4,905)	(2,025)	(2,088)
Net income	$ 13,801	$ 3,760	$ 3,106
Net income available to common stock holders used in basic earnings per share	$ 13,801	$ 3,284	$ 963
Net income per share:			
Basic	$ 1.20	$ 0.38	$ 0.46
Diluted	$ 1.00	$ 0.31	$ 0.35
Weighted-average number of shares used in per share calculations:			
Basic	11,535	8,573	2,106
Diluted	13,864	12,222	8,835
(1) Cost of revenue includes amortization of stock-based compensation of:	$ 135	$ 168	$ 240
(2) Amortization of stock-based compensation is attributable to the following operating expense categories:			
Sales and marketing	220	274	382
Research and development	288	413	351
General and administrative	799	580	451
	1,307	1,267	1,184

Total amortization of stock-based compensation	$ 1,442	$ 1,435	$ 1,424

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

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CUTERA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Deferred Stock-Based Compensation	Retained Earnings	Other Comprehensive Loss	Total Stockholders Equity
	Shares	Amount					
Balance at December 31, 2002	1,963,384	$ 2	$ 4,643	$ (2,615)	$ 1,076	$	$ 3,106
Exercise of stock options	266,130		108				108
Deferred stock-based compensation			2,591	(2,591)			
Amortization of stock-based compensation				1,318			1,318
Tax benefit related to employee stock options			131				131
Non-employee stock-based compensation			106				106
Net income					3,106		3106
Balance at December 31, 2003	2,229,514	2	7,579	(3,888)	4,182		7,875
Issuance of common stock from initial public offering, net of issuance costs	3,629,800	4	46,308				46,312
Conversion of redeemable convertible preferred stock to common stock at initial public offering	4,725,000	5	7,367				7,372
Issuance of common stock upon net exercise of warrant	18,010						
Issuance of common stock for employee purchase plan	35,235		323				323
Exercise of stock options	319,643		714				714
Deferred stock-based compensation			(227)	227			
Amortization of stock-based compensation							