

**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, 2004

Commission file number: 000-50644

CUTERA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0492262
(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 whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

The aggregate market value of the registrant's voting and non-voting stock, held by non-affiliates of the registrant as of June 30, 2004 based upon the closing price of such stock on the NASDAQ Stock Market on that date, was \$76,812,107. 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, 2005 was 11,091,148.

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 design, develop, manufacture and market our CoolGlide, Xeo and Solera families of products for aesthetic treatments. Our easy-to-use families of laser and other light-based products 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 is 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 dermal heating to treat wrinkles, which was introduced initially as an upgrade option on the Xeo platform. 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 yet using broadband infrared light; for the treatment of benign pigmented lesions; and for 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. As of December 31, 2004 we had sold over 1700 systems and over 400 upgrades, including, in some instances, multiple upgrades to the same customer. We have been profitable since 2000.

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 2.8 million people in 2003, representing a 200% increase over 1998 and a 41% increase over 2002. 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, currently ages 39 to 57, represents over 27% of the U.S. population. The size of this aging segment, and its desire to retain a youthful appearance, have 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 payor reimbursement restrictions in the United States, and similar payment related constraints outside the United States, are motivating practitioners to establish or expand their elective aesthetic practices with procedures that are paid for directly by patients. 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. Despite the time-consuming and painful nature of electrolysis, approximately 1.0 million procedures were performed in the United States in 2001, according to the Millenium Research Group's 2002 Aesthetic Lasers Report.

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 480,000 sclerotherapy procedures in 2003.

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

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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 2003 its members performed over 2.8 million Botox and over 500,000 collagen injection procedures, over 900,000 chemical peels and over 900,000 microdermabrasion procedures.

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 76,000 facelifts and over 134,000 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. The 2002 Epilation Market Report, published by Michael Moretti, Medical Insight, estimates a \$2.4 billion worldwide market for laser and other light-based hair removal procedures in 2002, and projects this market will grow to over \$3.3 billion by 2005. Millennium Research Group estimates that over 2.6 million aesthetic laser procedures were performed in the United States in 2002, and estimates that this number will increase to over 4.4 million in 2005, as follows:

Laser and Other Light-Based Aesthetic Procedures	Estimated Procedures	
	2002	2005
Hair Removal	1,100,000	1,520,000
Non-Ablative Skin Resurfacing	708,000	1,267,000
Pigmented Lesion or Tattoo Removal	327,500	386,500
Vascular Lesion Removal	270,000	300,000
Ablative Skin Resurfacing	125,500	134,500
Acne Treatment	92,400	795,600

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 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 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, 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

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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

Our goal is to become the worldwide leading provider of laser and other light-based medical devices to the aesthetic market by:

- *Continuing to Develop New Products.* We have introduced at least one new product every year since 2000. In 2004, we introduced the Titan application for the Solera and Xeo platforms. 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 North America.* We believe there is significant growth potential for our current products in North America, and we plan to continue to expand our domestic sales force to capitalize on this opportunity.
- *Expanding our International Presence.* We believe the size of the international market is comparable to the United States market, and we are focused on increasing our market penetration overseas and building global brand-recognition. For 2004 and 2003, approximately 34% and 23% of our revenue, respectively, originated outside of the United States. As of December 31, 2004, we had a direct sales force of 14 employees in Australia, France, Germany, Japan, Spain and the United Kingdom, and distributors in over 25 additional 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, for 2004 and 2003 we received 69% and 70%, respectively, of orders from gynecologists, primary care physicians and other qualified practitioners. We plan to continue to focus sales and marketing efforts on this broader customer base.
- *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. As of December 31, 2004, we had sold over 400 upgrades, including in some instances, multiple upgrades to the same customer. We believe the ability to provide 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.
- *Acquiring Complementary Products, Technologies or Businesses.* We intend to pursue opportunities to expand our core business, offering a broad range of laser and other light-based products for the aesthetic market, by acquiring complementary products, technologies or businesses.

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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.

	<u>Year Introduced</u>	<u>Hair Removal</u>	<u>Vein Treatment</u>	<u>Laser Skin Rejuvenation</u>	<u>Pigmented Lesion</u>	<u>Dermal Heating/Skin Tightening</u>
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

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.

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.

OPS 600 and LP 560 Handpieces- The OPS 600 and LP 560 handpieces are designed to produce a pulse of light over a wavelength spectrum to treat pigmented lesions, such as age and sun spots. 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 OPS 600 eliminates long and short wavelengths, transmitting only the therapeutic range required for safe and effective treatment, while the filter in the LP 560 eliminates short wavelengths, allowing longer wavelengths to be transmitted to the treatment area. Our power control includes a monitoring system to ensure that the desired energy level is delivered. Since cooling of the dermis is not necessary for treating pigmented lesions, the handpieces do not contain the same cooling features as

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the ClearView handpiece, but protect the epidermis by regulating the temperature of the handpiece window through the embedded temperature monitor. These handpieces are available on the Xeo family 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. 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.

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.

To remove hair, the treatment site on the skin is first cleaned and shaved. The practitioner applies a thin layer of gel to allow the ClearView handpiece 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. 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.

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, the handpiece is also used to cool the treatment area after the practitioner applies the laser pulse. 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.

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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 OPS 600 or LP 560 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 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 deep dermal heating and a pending 510(k) submission for the treatment of wrinkles and will not be allowed to promote our products for this latter use in the United States unless FDA clearance is obtained.

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.

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 newer aesthetic practice opportunity consisting of gynecologists, primary care physicians and other qualified practitioners. As of December 31, 2004, we had a 37-person North American direct sales force, four of whom were regional managers, and one North American Sales Director. We plan to continue hiring additional sales representatives. In addition, in November 2003 we entered into a distribution arrangement with PSS World Medical, an organization of over 750 U.S. medical product sales consultants covering a wide range of medical specialties. The arrangement is scheduled to continue until December 2005, but will automatically be renewed for successive one-year terms, unless earlier terminated. PSS sales representatives work in coordination with our sales force to locate additional customers for our products. For the years ended December 31, 2004, 2003 and 2002, sales to PSS World Medical accounted for 12%, 2% and 0% respectively, of our net revenue.

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As of December 31, 2004, we had a direct sales force of 15 employees in Australia, France, Germany, Japan, Spain and the United Kingdom, and distributors in over 25 additional countries. We 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 34%, 23%, and 19% in fiscal 2004, 2003 and 2002, respectively. The percentages of our revenue by region are presented in the table below:

	Years Ended December 31,		
	2004	2003	2002
United States	66%	77%	81%
Japan	14	5	2
Rest of World	20	18	17
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 and through ongoing training and support. We primarily target our marketing efforts to practitioners through office visits, workshops, trade shows 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, Laserscope, Lumenis, Palomar Medical Technologies and Syneron, as well as several smaller specialized private companies, including Thermage.

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 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 worldwide 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. We expect that 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

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December 31, 2004, our research and development activities were conducted by a staff of 14 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 2004, 2003 and 2002, were \$4.1 million, \$3.1 million and \$2.7 million, respectively. We expect that we will continue to invest approximately 8-10% 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, 2004, we had ten domestic service engineers, each of whom covers various regions of the United States and Canada. Internationally, we provide direct service support in combination with 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 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 warranty 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. 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 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. 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

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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, 2004, we had four issued U.S. patents primarily covering our ClearView handpiece design and cooling method, three of which expire in 2019 and one of which expires in 2020, and eleven pending U.S. patent applications. We intend to file for additional patents to strengthen our intellectual property rights. CoolGlide is a registered trademark in the United States, Canada, the European Union and Japan. CoolGlide Excel is a registered trademark in the United States. Our other trademarks include CoolGlide Genesis, CoolGlide Genesis Plus, CoolGlide Vantage, CoolGlide Xeo, CoolGlide Xeo SA and Cutera.

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.

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;

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- 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.

In February 2004, we received FDA clearance to market our infrared Titan handpiece for 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.

Pre-market Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical 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

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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 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 Institutional Review Board 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 have conducted a clinical trial to support regulatory submissions to the FDA. We evaluated the performance of our products in a hair removal clinical trial involving the treatment of 25 subjects. We followed the subjects for 15 months. Short-term adverse effects were observed, which included infrequent blistering and change in pigmentation of the skin. There were no long-term adverse effects observed.

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

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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.

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 fifteen 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

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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.

Employees

As of December 31, 2004, we had 140 employees, with 62 employees in sales and marketing, 26 employees in manufacturing operations, 19 employees in technical service, 10 employees in research and development, 19 employees in general and administrative, and 4 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>.

You may also find on our website at <http://www.cutera.com> electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

Our most recent charter for our Audit- and Compensation Committees and our Code of Ethics are available on our website 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 2. PROPERTIES

In January 2004, we moved to a 66,000 square foot facility in Brisbane, California, under a ten-year lease. In addition, we have offices located in Germany and Japan where we lease facilities of approximately 1,400 square feet and 3,700 square feet that expire in March 2007 and May 2006, respectively. We believe that these facilities are adequate for our current and future needs.

ITEM 3. LEGAL PROCEEDINGS

In February 2002, Palomar Medical Technologies ("Palomar") filed a lawsuit against the Company in the United States District Court, District of Massachusetts. The plaintiff alleges that by making, using, selling or offering for sale the Company's CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, the Company is 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 ("MGH") 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 the Company 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. The Company is defending the action vigorously, claiming that its products do

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not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, the Company has 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. The litigation is active and the parties are moving toward trial, although a trial date has not yet been set by the court. The court recently held a hearing on the Company's summary judgment motion but has not yet issued a ruling. The outcome of this motion could accelerate the litigation's determination. The Company believes that it has meritorious defenses of non-infringement and invalidity in this action. However, litigation is unpredictable and the Company may not prevail in successfully defending or asserting its position. If the Company does not prevail, it may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. The Company could also be ordered to stop selling any products that perform laser-based hair removal. Most of our products include an application for laser-based hair removal.

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

Not Applicable.

PART II**ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS**

Cutera's common stock trades on The NASDAQ National Market under the symbol "CUTR." At February 28, 2005, the closing sale price of our common stock was \$16.52 per share.

As of March 22, 2005, there were approximately 1,824 stockholders of record of our common stock.

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

	<u>High</u>	<u>Low</u>
Fiscal 2004		
First Quarter	\$ 14.00	\$ 14.00
Second Quarter	16.50	11.11
Third Quarter	14.00	10.89
Fourth Quarter	13.11	9.51

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.

In April 2004, upon the closing of our initial public offering, we converted 4,725,000 shares of preferred stock to common stock. A total of 3,629,800 shares of common stock were sold in the offering including the underwriters over-allotment exercise at a price of \$14.00 per share, resulting in net proceeds of \$46.3 million.

Use of Proceeds

Of the \$46.3 million in net offering proceeds, through December 31, 2004, we have spent approximately \$14.8 million for sales and marketing initiatives, \$3.2 million for product research and development, and \$6.3 million for legal and general corporate purposes. In addition, the Company invested the proceeds from the offering in short-term, investment-grade, interest-bearing instruments.

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 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 CONSOLIDATED 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):

	Years ended December 31,				
	2004	2003	2002	2001	2000
Net revenue (1)	\$52,641	\$39,088	\$28,327	\$19,328	\$ 9,531
Cost of revenue (1)	14,689	12,317	9,991	6,941	3,365
Gross profit	37,952	26,771	18,336	12,387	6,166
Operating expenses:					
Sales and marketing	19,052	13,410	8,236	5,431	2,794
Research and development	4,136	3,097	2,701	2,108	1,539
General and administrative	8,344	3,916	5,106	1,843	989
Amortization of stock-based compensation (2)	1,267	1,184	963	495	—
Total operating expenses	32,799	21,607	17,006	9,877	5,322
Income from operations	5,153	5,164	1,330	2,510	844
Interest and other income, net	632	30	85	171	193
Income before income taxes	5,785	5,194	1,415	2,681	1,037
Provision for income taxes	(2,025)	(2,088)	(755)	(342)	—
Net income	\$ 3,760	\$ 3,106	\$ 660	\$ 2,339	\$ 1,037
Net income available to common shareholders used in basic earnings per share	3,284	963	184	561	192
Net income per share:					
Basic	\$ 0.38	\$ 0.46	\$ 0.10	\$ 0.38	\$ 0.18
Diluted	\$ 0.31	\$ 0.35	\$ 0.07	\$ 0.27	\$ 0.13
Weighted-average number of shares used in per share calculations:					
Basic	8,573	2,106	1,810	1,480	1,064
Diluted	12,222	8,835	8,811	8,731	8,008

(1) Includes amortization of stock-based compensation related to:

Net revenue	\$ —	\$ —	\$ —	\$ 164	—
Cost of revenue	168	240	234	93	—
	168	240	234	257	—

(2) Amortization of stock-based compensation is attributable to the following operating expense categories:

Sales and marketing	274	382	366	262	—
Research and development	413	351	287	113	—
General and administrative	580	451	310	120	—
	1,267	1,184	963	495	—
Total amortization of stock-based compensation	\$ 1,435	\$ 1,424	\$ 1,197	\$ 752	\$ —

	As of December 31,				
	2004	2003	2002	2001	2000
Consolidated Balance Sheet Data (in thousands):					
Cash and cash equivalents	\$ 7,070	\$10,290	\$ 8,276	\$ 6,354	\$ 3,562
Marketable investments	59,200	—	—	—	—
Working capital	68,519	14,205	8,896	7,854	4,768
Total assets	80,549	24,198	15,426	12,475	7,038

Redeemable convertible preferred stock	—	7,372	7,272	7,272	7,272
Retained earnings (deficit)	7,942	4,182	1,076	416	(1,923)
Total stockholders' equity (deficit)	68,456	7,875	3,106	1,226	(1,918)

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, 2004. 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 "Factors That May Affect Future Results," commencing on page 31, 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.

Overview

We design, develop, manufacture, market and service the CoolGlide, Xeo and Solera families of laser and other light-based products for aesthetic treatments. Our products enable our customers to remove hair, treat leg and facial veins, rejuvenate skin, treat pigmented lesions and treat wrinkles using laser technology or through skin tightening. 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 deep dermal heating, and a pending 510(k) submission for the treatment of wrinkles and will not be allowed to promote our products for this latter use in the United States unless FDA-clearance is obtained. Our customers consist generally of dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners. Since 2000, we have continued to develop new products and have introduced at least one new product each year. Our products are designed to allow our customers to cost-effectively upgrade to our newest products. We have been profitable since 2000 and, as of December 31, 2004, had retained earnings of \$7.9 million.

We derive revenue primarily from the sale of our aesthetic laser and other light-based products and upgrades. For 2004, 2003 and 2002, we derived 82%, 84% and 91%, respectively, of our revenue from product sales, and 13% and 11% and 5%, respectively, from product upgrades. As our installed base continues to increase, we expect a greater percentage of our revenue to be derived from product upgrades. The balance of our revenue is derived from product service and other revenue, which we expect to increase over time as our installed base grows and related warranties expire. As we introduce new products with greater functionality, our revenue tends to shift towards these newer products. Due to the high dollar revenue per system sold, variations in unit sales may significantly impact revenue in a given quarter.

Based in Brisbane, California, we sell our products directly in the United States, Canada, Australia, Japan and major European markets, and use distributors to sell our products in countries where we do not have a direct presence, or to complement our direct sales force in selected countries. As of December 31, 2004, we had approximately 52 direct sales and sales support employees worldwide and a global network of distributors located in more than 25 countries. As our international sales increase, currency fluctuations may affect our international revenue.

We have a limited history of operations. We anticipate that our results of operations may fluctuate for the foreseeable future due to several factors, including delays in introduction and acceptance of future products, delays in our manufacturing operations, introduction of new and improved products by competitors, and the performance of our direct sales force and distributors. We expect our operating expenses to increase in the future as a result of: increased sales and marketing expenses to promote revenue growth and geographic expansion;

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continued research and development of new products and technologies; and increased general and administrative expenses to keep pace with our overall growth, expenses associated with being a public company and higher legal expenses associated with the ongoing patent litigation. Our limited history makes accurate predictions of future operating results difficult.

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. Service revenue is generally deferred and recognized as the services are provided and, for service contracts, is recognized ratably over the period of the applicable contract. Total deferred revenue for service contracts was \$1.9 million and \$1.3 million as of December 31, 2004 and December 31, 2003, 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 \$6.6 million as of December 31, 2004, compared with \$7.6 million as of December 31, 2003. The allowance for doubtful accounts as of December 31, 2004, was \$487,000, compared with \$307,000 as of December 31, 2003. 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 inventories 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.

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Our inventory balance was \$3.0 million as of December 31, 2004, compared with \$2.2 million as of December 31, 2003. Our inventory allowances as of December 31, 2004 were \$378,000, compared with \$178,000 as of December 31, 2003. 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 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 \$1.9 million as of December 31, 2004, compared with \$1.7 million as of December 31, 2003. 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 employee stock-based compensation based upon the difference between the estimated fair value of common stock on the date of grant and the option exercise price. 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.

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Our effective tax rates differ from the statutory rate primarily due to research and development tax credits, state taxes, tax exempt interest income, and the tax impact of foreign operations. The effective tax rate was 35%, 40%, and 53% for fiscal 2004, 2003, and 2002, 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, by changes in the valuation of our deferred tax assets or liabilities, 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 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 \$227,000 at December 31, 2004, 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.

The American Jobs Creation Act of 2004 (the "Jobs Act"), enacted on October 22, 2004, provides for a temporary 85% dividends received deduction on certain foreign earnings repatriated during a one-year period. The deduction would result in an approximate 5.25% federal tax rate on the repatriated earnings. To qualify for the deduction, the earnings must be reinvested in the United States pursuant to a domestic reinvestment plan established by a company's chief executive officer and approved by the Company's board of directors. Certain other criteria in the Jobs Act must be satisfied as well.

The Company does not anticipate it will apply the above provision to qualifying earnings repatriations in fiscal year 2005; however, as additional clarifying language on key elements of the provision becomes available, the Company will continue to analyze and assess whether such repatriation would be practical.

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 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 issued FASB Statement No. 123 (Revised 2004), "*Share-Based Payment*." Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, "*Accounting for Stock Issued to Employees*", which was permitted under Statement 123, as originally issued.

The revised Statement also requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements.

The Company is currently evaluating the impact of the adoption of this Statement, which must be adopted in the third quarter of the fiscal year ending on December 31, 2005.

[Table of Contents](#)**Results of Operations**

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

	For the Years ended December 31,		
	2004	2003	2002
Consolidated Statement of Operations:			
Revenue Mix By Geography:			
Revenue From United States Customers	66%	77%	81%
Revenue From International Customers	34%	23%	19%
	<u>100%</u>	<u>100%</u>	<u>100%</u>
Revenue Mix By Product:			
Product revenue	82%	84%	91%
Product upgrade revenue	13%	11%	5%
Service and other revenue	5%	5%	4%
	<u>100%</u>	<u>100%</u>	<u>100%</u>
Operating Ratios:			
Total gross profit	72%	68%	65%
Operating expenses:			
Sales and Marketing	36%	34%	29%
Research and development	8%	8%	10%
General and administrative	16%	10%	18%
Amortization of stock-based compensation	2%	3%	3%
	<u>62%</u>	<u>55%</u>	<u>60%</u>
Total operating expenses	62%	55%	60%
Income from operations	10%	13%	5%
Interest and other income, net	1%	0%	0%
	<u>11%</u>	<u>13%</u>	<u>5%</u>
Income before income taxes	11%	13%	5%
Provision for income taxes	4%	5%	3%
	<u>7%</u>	<u>8%</u>	<u>2%</u>
Net income	7%	8%	2%

Years Ended December 31, 2004 and December 31, 2003***Net Revenue***

Revenue is derived from the sale of products, upgrades, and product service. For the year ended December 31, 2004, compared to the year ended December 31, 2003, net revenue increased \$13.6 million, or 35%, from \$39.1 million to \$52.6 million. Product revenue increased \$10.3 million, due primarily to sales of 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 products. 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. Our revenue is seasonally strong in the fourth quarter of our fiscal year and accounted for 31% and 32% of our net revenue for the years ended December 31, 2004 and 2003, respectively. For the year ending December 31, 2005, we expect revenue to increase by approximately 25%, compared to the year ended December 31, 2004.

Cost of Revenue

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the year ended December 31, 2004, compared to the year ended December 31, 2003, cost of revenue increased \$2.4 million, or 19%, from \$12.3 million to \$14.7 million. 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. Cost of revenue as a percentage of net revenue, decreased from 32% for the year ended December 31, 2003 to 28% for the year ended December 31, 2004. This improvement in margins was primarily attributable to a favorable product mix and reduced overhead expenses associated with improved product reliability. We expect cost of revenue to be between 28% to 30% of net revenue for 2005.

Sales and Marketing

Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops, trade shows and advertising. 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%, from \$13.4 million to \$19.1 million. This increase was primarily attributable to an increase of \$2.2 million in promotional expenses, \$2.5 million of personnel costs and \$0.7 million in travel costs. Promotional expenses result primarily from customer workshops and industry trade shows. As a percentage of net revenue, sales and marketing expenses increased from 34% for the year ended December 31, 2003 to 36% in 2004. We expect our sales and marketing expenses to be in the range of 36% to 38% of net revenue for 2005 as we continue to build our distribution network and invest in domestic and international expansion.

Research and Development

Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, and material costs. 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%, from \$3.1 million to \$4.1 million. 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. As a percentage of net revenue, research and development expenses for the year ended December 31, 2004, compared to the same period in 2003, remained the same at 8%. We expect research and development expenses to be between 8% to 10% of net revenue for 2005.

General and Administrative

General and administrative expenses consist primarily of personnel costs, legal and accounting fees, and other general operating expenses. 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%, from \$3.9 million to \$8.3 million. 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. As a percentage of net revenue, general and administrative expenses increased from 10% in 2003 to 16% in 2004. We expect general and administrative expenses to be between 12% to 15% of net revenue for 2005, assuming continuing legal expenses associated with our patent litigation throughout 2005.

Amortization of Stock-Based Compensation

We record deferred stock-based compensation for financial reporting purposes as the difference between the exercise price of options granted to employees and the estimated fair value of our common stock at the time of grant. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and a

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compensation charge booked over the period that the options are expected to be earned by the non-employee. Deferred stock-based compensation is amortized on a straight-line basis to cost of revenue, sales and marketing expenses, research and development expenses, and general and administrative expenses. For the years ended December 31, 2004, and 2003, amortization of stock-based compensation was \$1.4 million for both years.

Interest and Other Income, Net

For the year ended December 31, 2004, compared to the same period in 2003, interest and other income, net, increased by \$602,000 from \$30,000 to \$632,000. 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

The provision for income taxes results from a combination of activities of both the domestic and foreign subsidiaries of the Company. Provision for income taxes decreased by \$63,000, from \$2.0 million for the year ended December 31, 2004, compared to \$2.1 million for the year ended December 31, 2003 due primarily to a lower effective tax rate. The Company recorded a 35% effective tax rate for the year ended December 31, 2004, compared to a 40% effective tax rate for the year ended December 31, 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, in the year ended December 31, 2004, compared to the year ended December 31, 2003.

Results of Operations

Years Ended December 31, 2003 and December 31, 2002

Net Revenue

Revenue is derived from the sale of products, upgrades, and product service. For the year ended December 31, 2003, compared to the year ended December 31, 2002, net revenue increased \$10.8 million, or 38%, from \$28.3 million to \$39.1 million. The geographical source of the \$10.8 million revenue increase was, \$7.2 million from U.S. sales and \$3.6 million was from international sales. The increase was primarily attributable to sales resulting from the introduction of our Xeo product in March 2003, including sales of upgrades to our installed base, which together accounted for \$17.1 million in net revenue, partially offset by a decrease of \$7.2 million in sales of our other products. Revenue shifted from other older products to the new Xeo product that offers our customers maximum functionality. Service revenue increased \$858,000 between these two years. The increase in service revenue resulted from sales of annual service contracts to our customers with expired warranties.

Cost of Revenue

Our cost of revenue consists primarily of material, labor and manufacturing overhead expenses. For the year ended December 31, 2003, compared to the year ended December 31, 2002, cost of revenue increased \$2.3 million, or 23%, from \$10.0 million to \$12.3 million. The increase was primarily attributable to increases of \$1.4 million in labor and overhead costs associated with greater sales of our products and \$787,000 in higher material costs. As a percentage of net revenue, cost of revenue decreased from 35% in 2002 to 32% in 2003. The improved margin is the result of higher average selling prices of our new products.

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Sales and Marketing

Sales and marketing expenses consist primarily of personnel costs and costs related to customer-attended workshops, trade shows and advertising. For the year ended December 31, 2003, compared to the year ended December 31, 2002, Sales and marketing expenses increased \$5.2 million, or 63%, from \$8.2 million to \$13.4 million. The increase was primarily attributable to an increase of \$2.4 million in personnel related expense and \$922,000 in related travel expenses associated with the expansion of our sales force. Promotional costs increased \$1.5 million primarily due to our increased number of customer workshops, trade shows and international promotional efforts. The impact of the increased workshops, trade shows and international promotional efforts was \$350,000, \$200,000 and \$600,000, respectively. As a percentage of net revenue, sales and marketing expenses increased from 29% in 2002 to 34% in 2003.

Research and Development

Research and development expenses consist primarily of personnel costs, clinical and regulatory costs, and material costs. For the year ended December 31, 2003, compared to the year ended December 31, 2002, research and development expenses increased \$396,000 or 15%, from \$2.7 million to \$3.1 million. The increase was primarily attributable to an increase of \$278,000 in personnel costs related to hiring additional engineers and \$166,000 of higher material costs related to the launch of the Xeo product. As a percentage of net revenue, research and development expenses for the year ended December 31, 2003, compared to the year ended December 31, 2002, decreased from 10% to 8% due to higher revenue in 2003.

General and Administrative

General and administrative expenses consist primarily of personnel costs, legal and accounting fees, and other general operating expenses. For the year ended December 31, 2003, compared to the year ended December 31, 2002, general and administrative expenses decreased \$1.2 million or 23%, from \$5.1 million to \$3.9 million. This decrease was primarily attributable to a \$1.2 million write-off of costs associated with our withdrawn initial public offering in June 2002, partially offset by \$227,000 in higher accounting expenses associated with our planned 2003 initial public offering. As a percentage of net revenue, general and administrative expenses for the year ended December 31, 2003, compared to the year ended December 31, 2002, decreased from 18% to 10%.

Amortization of Stock-Based Compensation

We record deferred stock-based compensation for financial reporting purposes as the difference between the exercise price of options granted to employees and the estimated fair value of our common stock at the time of grant. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and a compensation charge booked over the period that the options are expected to be earned by the non-employee. Deferred stock-based compensation is amortized on a straight-line basis to cost of revenue, sales and marketing expenses, research and development expenses, and general and administrative expenses. For the years ended December 31, 2003, and 2002, amortization of stock-based compensation was \$1.2 million and \$1.0 million, respectively.

Interest and Other Income, Net

For the year ended December 31, 2003, compared to the year ended December 31, 2002, interest and other income, net, decreased by \$55,000 from \$85,000 to \$30,000. This decrease was attributable to lower interest rates, partially offset by higher average cash and cash equivalents balances.

Provision for Income Taxes

The provision for income taxes results from a combination of activities of both the domestic and foreign subsidiaries of the Company. For the year ended December 31, 2003, compared to the year ended December 31,

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2002, provision for income taxes increased by \$1.3 million, from \$755,000 to \$2.1 million. The Company recorded a 40% effective tax rate for the year ended December 31, 2003, compared to a 53% effective tax rate for the year ended December 31, 2002. This decrease in effective tax rates resulted primarily from a reduction in stock-based compensation charges of incentive stock options, that are not tax deductible.

Liquidity and Capital Resources

Net Cash Provided by Operating Activities

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 \$0.7 million.

For the year ended December 31, 2003, net cash provided by operating activities was \$2.6 million, which primarily resulted from \$3.1 million of net income; \$1.9 million of increased accrued liabilities, due to an increase in payroll, income tax and professional fee accruals; \$1.4 million of non-cash stock-based compensation expenses; \$1.0 million of deferred revenue, primarily due to the sale of additional service contracts; and \$1.0 million from an increase in accounts payable. This was partly offset by \$4.8 million increase in accounts receivable and \$1.0 million increase in inventories.

For the year ended December 31, 2002, net cash provided by operating activities was \$2.7 million, which primarily resulted from \$0.7 million of net income; adjusted for \$1.2 million of non-cash stock-based compensation expenses; \$1.0 million of increased accrued liabilities, due to an increase in warranty reserves; partly offset by an increase in inventories of \$1.1 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$59.8 million for the year ended December 31, 2004. Of the \$59.8 million, \$82.7 million was used to purchase marketable investments and \$854,000 was used for purchasing property and equipment for manufacturing, research and development in our new Brisbane, California location. This was partly offset by \$9.1 million of cash proceeds from the sale of marketable investments; \$14.3 million from the maturities of marketable investments and \$250,000 from the removal of restrictions on cash deposits with our bank.

Net cash used in investing activities for the year ended December 31, 2003 was \$779,000. Of this amount, \$589,000 was used for purchasing property and equipment for manufacturing, research and development and \$190,000 was put on deposit as collateral against merchant accounts and a facility lease.

Net cash used in investing activities for the year ended December 31, 2002 was \$778,000. Of this amount, \$538,000 was used for purchasing a licensing agreement for our products, \$280,000 was used for purchasing property and equipment for manufacturing, research and development, which was offset by \$40,000 of cash generated due to the removal of restrictions on cash deposits.

Net Cash Provided by Financing Activities

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 options and employee stock purchase plans.

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Net cash provided by financing activities for the year ended December 31, 2003 was \$208,000, which was attributable to \$108,000 proceeds from the exercise of stock options and \$100,000 proceeds from the exercise of warrants.

Net cash provided by financing activities for the year ended December 31, 2002 was \$23,000, which was attributable to proceeds from the exercise of stock options.

Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, and continued progress of our research and development of new products. We expect to increase capital expenditures consistent with our anticipated growth in manufacturing, infrastructure and personnel. We also may increase our capital expenditures as we expand our product lines or invest to address new markets.

As of December 31, 2004, the Company had \$7.1 million in cash and cash equivalents and \$59.2 million in marketable investments. The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Investments held for use in current operations are classified in current assets as "Marketable Investments."

We believe that our current cash and investment balances and cash generated from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

As disclosed in 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. 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.

The Company leases its office and manufacturing facility under a non-cancelable operating lease, which expires in 2014. In addition, the Company has leased office facilities of approximately 1,400 square feet and 3,700 square feet, in Germany and Japan, respectively. The lease in Germany expires in March 2007 and the lease in Japan expires in May 2006. The following table discloses aggregate information about the Company's contractual obligations for minimum lease payments related to facility leases and the periods in which these payments are due as of December 31, 2004 (in thousands).

<u>Contractual Obligations</u>	<u>Payments Due by Period (\$'000's)</u>				
	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More Than 5 Years</u>
Operating leases	\$9,290	\$ 685	\$1,398	\$1,782	\$ 5,425

Factors That May Affect Future Results

We have a limited history of operations, which could impair our ability to grow significantly

We were incorporated in 1998 and commercially launched our first product in 2000. Consequently, we have a limited history of operations. The future success of our business will depend on our ability to increase product sales, successfully introduce new products, expand our sales force and distribution network, and control costs, which we may be unable to do. As a result, we may not be able to continue our revenue growth and maintain profitability.

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. It may be difficult for us to control costs if we significantly expand our manufacturing capacity. Our success in growing our business also will depend upon the ability of our management team to implement improvements in our operational systems, realize economies of scale, manage multiple development projects, and continue to expand, train and manage our personnel worldwide. If we cannot scale and manage our business appropriately, or manage the introduction of new products, we will not experience our projected growth and our financial results will suffer.

It is difficult to predict future performance, and our success is dependent on a number of factors over which we have limited control. As a result, our financial results may fluctuate unpredictably

Our limited operating history makes it difficult for us to predict future performance. Historically, the demand for our products has varied from quarter to quarter. Due to the high dollar revenue per system sold, variations in unit sales may cause revenue to vary significantly from quarter to quarter. As a result, it is difficult for us to accurately predict sales for subsequent periods. In addition, we base our production, inventory and operating expenditure levels on anticipated orders. If orders are not received when expected in any given quarter, expenditure levels could be disproportionately high in relation to revenue for that quarter. A number of additional factors, over which we have limited control, may contribute to fluctuations in our financial results, such as:

- delays in introductions and acceptance of our future products;
- delays in, or failure of, delivery of components by our suppliers;
- introductions of new and improved products by competitors;
- performance of our independent distributors;
- increases in the length of our sales cycle;
- fluctuations in foreign currency;
- changes in our ability to obtain and maintain regulatory approvals; and
- reductions in the efficiency of our manufacturing processes.

In the event our actual revenue and operating results do not meet our forecasts for a particular period, the market price of our common stock may decline substantially.

If we fail to obtain and maintain necessary U.S. Food and Drug Administration 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 Food and Drug Administration, or FDA, for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it

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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. For example, with regard to our recently introduced Titan product, we currently have FDA clearance to market the product in the United States for only dermal heating and we are currently seeking the ability to market it in the United States for treating wrinkles. We have not received clearance from the FDA to market the Titan product for treating wrinkles and we can provide no assurance that we will obtain such clearance. We cannot promote or advertise for this indication in the United States until we receive clearance. The FDA may require us to perform one or more clinical trials in support of a clearance for treating wrinkles and such a trial may be costly, time-consuming, and a distraction to management. In the event that we do not obtain FDA clearance for treating wrinkles, our ability to market the Titan in the U.S. for that indication and revenue derived therefrom may be adversely affected. The FDA's 510(k) clearance process usually takes from three to twelve months, but it can last longer.

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 may be subject to FDA enforcement action or have other resulting liability. We have obtained 510(k) clearance for treatments for which we offer 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 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.

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 using laser technology or through skin tightening. 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 deep dermal heating, and a pending 510(k) submission for the treatment of wrinkles and will not be allowed to promote our products for this latter use in the United States unless FDA clearance is obtained. 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

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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;
- protect our 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 8-10% of net revenues to 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 expected growth rate.

Our success depends on market acceptance of our products, many of which have been recently introduced

All of our products have been introduced within the last five years. It is difficult for us to predict how successful recently introduced products will be over the long term. Our failure to significantly penetrate current or new markets with our products could negatively impact our business, financial condition and results of operations. The market for aesthetic devices is highly competitive and dynamic, and marked by rapid and substantial technology development and product innovations. Demand for our products could be diminished by equivalent or superior products and technologies offered by competitors. Decreases in forecasted demand could leave us with excess inventory, which could become obsolete and have to be written off.

We are involved in costly intellectual property litigation with Palomar Medical Technologies that may hurt our competitive position and may prevent us from selling many of our products and generating revenue.

We are currently involved in a lawsuit brought by one of our public company competitors, Palomar Medical Technologies, which alleges that the manufacture, use and sale of our products for hair removal infringes a patent it has licensed. In the lawsuit, Palomar is attempting to stop us from selling our products for hair removal and to obtain compensatory and treble damages. We are defending ourselves by claiming that we do not infringe the patent and that the patent is invalid and unenforceable. Although we believe that these defenses are meritorious, litigation is unpredictable and we may not prevail. 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. The Company could also be ordered to stop selling any products that perform laser-based hair removal. Most of our products include an application for laser-based hair removal. If found liable, we do not know whether we could redesign our products to avoid future infringement. Any public announcement concerning the litigation that is unfavorable to us may result in a decline in our stock price.

The litigation is active and the parties are moving toward trial, although a trial date has not yet been set by the court. The court recently held a hearing on the Company's summary judgment motion but has not yet issued a ruling. The outcome of this motion could accelerate the litigation's determination. This litigation 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. Whether or not we are successful in this lawsuit, this litigation consumes substantial amounts of our financial resources and diverts management's attention away from our core business.

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Palomar may file additional claims against us, or we may file additional claims against Palomar, which could increase the risk, expense and duration of the litigation. For more information regarding this litigation, see Item 3 Legal Proceedings.

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.

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. We have and may hereafter become involved in litigation to protect the trademark rights associated with our company name or the names of our products. We have only recently adopted the name "Cutera," and do not know whether others will assert that our company name infringes their trademark rights. In addition, names we choose for our products, such as CoolGlide, may be claimed to infringe names held by others. If we have to change the name of our company or products, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

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. We have four issued U.S. patents, mostly 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 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:

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

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

In the future, we expect our revenue from international operations to comprise a growing percentage of overall revenue. In 2004, 34% of our revenue was derived from international sales as compared to 23% of our revenue in 2003. We currently 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 underperform we may be unable to increase or maintain our level of international revenue. We will need to attract additional distributors to grow our business and expand the territories in which we sell our products. Distributors may not 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 locate distributors in particular geographic areas, we may not realize expected international revenue growth. Additionally, we expect to expand our direct sales force in Europe and Asia. If we are unable to do so successfully, our revenue from international operations will be adversely affected.

We believe that an increasing percentage 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;
- customs clearance and shipping delays;
- political and economic instability; and
- preference for locally-produced products.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and if we are 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 and 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.

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

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approval. We may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and 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 clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

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.

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.

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, offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our

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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 increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and reducing our operating results.

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.

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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.

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

Most procedures performed using our products are not reimbursable through government or private health insurance and are therefore elective procedures, the cost of which must be 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;
- 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.

Reliance on Key Distributor

In November 2003, the Company entered into a distribution arrangement with PSS World Medical, an organization of over 750 U.S. medical product sales consultants covering a wide range of medical specialties. The arrangement is scheduled to continue until December 2005, but will automatically be renewed for successive one-year terms, unless earlier terminated by either party. PSS World Medical sales representatives work in coordination with our sales force to locate additional customers for our products. For the year ended December 31, 2004, 2003 and 2002, PSS World Medical accounted for 12%, 2% and 0%, respectively, of the Company's net revenue. If PSS World Medical does not continue performing under the arrangement or seeks to terminate the

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arrangement or if PSS World Medical encounters financial difficulties, it may have a material adverse effect on our business, financial condition, results of operations, and 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, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use and benefits of our products. 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 could be affected by the changed accounting rules governing the recognition of stock-based compensation expense

We measure compensation expense for our employee stock compensation plans under the intrinsic value method of accounting prescribed by APB Opinion No. 25, “Accounting for Stock Issued to Employees.” Under this method, we recognized compensation charges related to stock compensation plans, net of related tax effect, of \$1.2 million, \$1.1 million and \$1.0 million in fiscal years 2004, 2003 and 2002, respectively. In accordance with SFAS No. 123, “Accounting for Stock-Based Compensation,” we provide disclosures of our operating results as if we had applied the fair value method of accounting (pro-forma basis). Included in our Quarterly Reports on Form 10-Q we have provided such disclosures in accordance with SFAS No. 148, “Accounting for Stock-Based Compensation -Transition and Disclosure.” Had we accounted for our compensation expense under the fair value method of accounting prescribed by SFAS No. 123, the charges, net of tax, would have been significantly higher than the intrinsic value method used by us, totaling \$1.8 million, \$1.4 million and \$2.0 million in fiscal 2004, 2003 and 2002, respectively. The Financial Accounting Standards Board has announced changes to accounting rules concerning the recognition of stock option compensation expense. Beginning in the third quarter of fiscal 2005 when these changes are expected to be implemented, we and other companies will be required to measure compensation expense using the fair value method, which will adversely affect our results of operations by increasing our losses by the additional amount of such stock option charges.

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

Beginning with our annual report for our fiscal year ending on December 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 will require us to include a report by our management on our internal controls over financial reporting. Such report must contain an assessment by management of the effectiveness of our internal controls over financial reporting as of the end of our fiscal year and a statement as to whether or not such internal controls are effective. Such report must also contain a statement that our independent auditors have issued an attestation report on management’s assessment of such internal controls.

In order to achieve timely compliance with Section 404, in fiscal 2004 we began a process to document and evaluate our internal controls over financial reporting. 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

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internal controls over financial reporting, we will be unable to assert such internal controls are effective. If we are unable to assert that our internal controls over financial reporting are effective as of December 31, 2005 or if our independent registered public accounting firm is unable to attest that our management's report is fairly stated or they are unable to express an opinion on our management's evaluation or on the effectiveness of our internal controls- our business may be harmed. Market perception of our financial condition and the trading price of our stock may be adversely affected and customer perception of our business may suffer.

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.

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 expectations 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 maximize 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 an average maturity (interest reset date for auction-rate securities) 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, 2004 would have potentially declined by \$41,000.

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 you 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.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Consolidated financial statements of Cutera at December 31, 2004 and 2003, and for each of the three years ended December 31, 2004, the Report of Independent Registered Public Accounting Firm thereon and Supplementary Data are included as separate sections in this Annual Report on Form 10-K in Item 6 "Selected Financial Data" and Item 16, "Exhibits, Financial Statement Schedules and reports on Form 8-K."

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act.

There were no changes in our internal control over financial reporting during the fourth fiscal quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of Cutera's fiscal year ended December 31, 2004.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information regarding the Company's directors and executive officers as required by this Item 10 is incorporated by reference to the Definitive Proxy Statement for our 2005 Annual Meeting of Shareholders under the headings "Election of Directors," "Management," and "Section 16(a) Beneficial Ownership Reporting Compliance," respectively.

ITEM 11. EXECUTIVE COMPENSATION

Certain information concerning executive compensation is incorporated herein by reference from the information contained in the section entitled "Compensation and Other Information Concerning Directors and Officers" in the Definitive Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Certain information concerning security ownership of certain beneficial owners and management is incorporated herein by reference from the information contained in the section entitled "Security Ownership of Certain Beneficial Owners and Management" in the Definitive Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Certain information concerning certain relationships and related transactions is incorporated herein by reference from the information contained in the section entitled "Certain Relationships and Related Transactions" in the Definitive Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Certain information concerning principal accountant fees and services is incorporated herein by reference from the information contained in the section entitled "Principal Accountant Fees and Services" in the Definitive Proxy Statement.

PART IV**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.****1. Financial Statements:**

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3. Exhibits

(a) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
3.2 ⁽¹⁾	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 ⁽¹⁾	Bylaws of the Registrant.
4.1	Specimen Common Stock certificate of the Registrant.
10.1 ⁽¹⁾	Form of Indemnification Agreement for directors and executive officers.
10.2 ⁽¹⁾	1998 Stock Plan.
10.3 ⁽¹⁾	2004 Equity Incentive Plan.
10.4 ⁽¹⁾	2004 Employee Stock Purchase Plan.
10.5 ⁽¹⁾	Amended and Restated Investor Rights Agreement dated November 12, 1999 by and among the Registrant and certain stockholders.
10.6 ⁽¹⁾	Brisbane Technology Park Lease dated August 5, 2003 by and between the Registrant and Gal-Brisbane, L.P. for office space located at 3240 Bayshore Boulevard, Brisbane, California.
10.7 ^{(1)†}	Sales Agent Agreement dated February 14, 2003 by and between the Registrant and PSS World Medical, Inc. and the Amendments thereto.
10.8 ^{(2)†}	Third, Fourth and Fifth Amendments to the Sales Agent Agreement dated February 14, 2003 by and between Registrant and PSS World Medical, Inc.
10.9 [†]	Sixth Amendment to the Sales Agent Agreement dated November 10, 2004 by and between Registrant and PSS World Medical, Inc.
14.1 ⁽³⁾	Amended and Restated Code of Ethics for Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page 46).

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<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.

(2) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 12, 2004.

(3) Incorporated by reference from our Current Report on Form 8-K filed on April 29, 2004.

† Portions of the Exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the Securities and Exchange Commission.

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CUTERA, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Cutera, Inc.:

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, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 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 Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP
San Jose, California
March 21, 2005

CUTERA, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,070	\$10,290
Restricted cash	—	250
Marketable investments	59,200	—
Accounts receivable, net of allowance for doubtful accounts in 2004 and 2003 of \$487 and \$307, respectively	6,643	7,597
Inventory	3,004	2,239
Current portion of deferred tax asset	2,284	1,699
Other current assets	878	879
Total current assets	79,079	22,954
Property and equipment, net	1,071	734
Intangibles, net	399	453
Deferred tax asset, net of current portion	—	57
Total assets	\$80,549	\$24,198
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Liabilities:		
Accounts payable	\$ 1,195	\$ 1,915
Accrued liabilities	8,194	5,709
Deferred revenue	1,171	1,125
Total current liabilities	10,560	8,749
Deferred rent	648	—
Deferred revenue, net of current portion	833	202
Non-current portion of deferred tax liability	52	—
Total liabilities	12,093	8,951
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock, \$0.001 par value:		
Authorized: 5,000,000 and 4,784,000 shares in 2004 and 2003, respectively;		
Issued and outstanding: none and 4,725,000 shares in 2004 and 2003, respectively		
(Liquidation and redemption value: \$7,450 in 2003)	—	7,372
Stockholders' equity:		
Common stock, \$0.001 par value:		
Authorized: 50,000,000 and 20,000,000 shares in 2004 and 2003, respectively;		
Issued and outstanding: 10,957,202 and 2,229,514 shares in 2004 and 2003, respectively	11	2
Additional paid-in capital	62,738	7,579
Deferred stock-based compensation	(2,226)	(3,888)
Retained earnings	7,942	4,182
Other comprehensive loss	(9)	—
Total stockholders' equity	68,456	7,875
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$80,549	\$24,198

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

CUTERA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years Ended December 31,		
	2004	2003	2002
Net revenue	\$52,641	\$39,088	\$28,327
Cost of revenue(1)	14,689	12,317	9,991
Gross profit	37,952	26,771	18,336
Operating expenses:			
Sales and marketing	19,052	13,410	8,236
Research and development	4,136	3,097	2,701
General and administrative	8,344	3,916	5,106
Amortization of stock-based compensation(2)	1,267	1,184	963
Total operating expenses	32,799	21,607	17,006
Income from operations	5,153	5,164	1,330
Interest and other income, net	632	30	85
Income before income taxes	5,785	5,194	1,415
Provision for income taxes	(2,025)	(2,088)	(755)
Net income	\$ 3,760	\$ 3,106	\$ 660
Net income available to common shareholders used in basic earnings per share	\$ 3,284	\$ 963	\$ 184
Net income per share:			
Basic	\$ 0.38	\$ 0.46	\$ 0.10
Diluted	\$ 0.31	\$ 0.35	\$ 0.07
Weighted-average number of shares used in per share calculations:			
Basic	8,573	2,106	1,810
Diluted	12,222	8,835	8,811
(1) Includes amortization of stock-based compensation of:	\$ 168	\$ 240	\$ 234
(2) Amortization of stock-based compensation is attributable to the following operating expense categories:			
Sales and marketing	274	382	366
Research and development	413	351	287
General and administrative	580	451	310
	1,267	1,184	963
Total amortization of stock-based compensation	\$ 1,435	\$ 1,424	\$ 1,197

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

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, 2001	1,840,154	\$ 2	\$ 4,527	\$ (3,719)	\$ 416	\$ —	\$ 1,226
Exercise of stock options	123,230	—	23	—	—	—	23
Deferred stock-based compensation	—	—	(78)	78	—	—	—
Amortization of stock-based compensation	—	—	—	1,026	—	—	1,026
Non-employee stock-based compensation	—	—	171	—	—	—	171
Net income	—	—	—	—	660	—	660
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	—	3,106
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	—	—	—	1,435	—	—	1,435
Tax benefit related to employee stock options	—	—	674	—	—	—	674
Components of other comprehensive income:	—	—	—	—	—	—	—
Net income	—	—	—	—	3,760	—	3,760
Other comprehensive loss	—	—	—	—	—	(9)	(9)
Comprehensive income	—	—	—	—	—	—	3,751
Balance at December 31, 2004	10,957,202	\$ 11	\$ 62,738	\$ (2,226)	\$ 7,942	\$ (9)	\$ 68,456

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

CUTERA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended		
	2004	2003	2002
Cash flows from operating activities:			
Net income	\$ 3,760	\$ 3,106	\$ 660
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	524	443	382
Loss on disposal of fixed assets	47	35	4
Allowance for doubtful accounts	293	333	141
Reserve for excess and obsolete inventory	300	139	993
Amortization of stock-based compensation	1,435	1,424	1,197
Change in deferred tax asset	(476)	(587)	(310)
Tax benefit related to employee stock options	674	131	—
Change in assets and liabilities:			
Accounts receivable	661	(4,752)	(952)
Inventory	(1,065)	(1,012)	(1,132)
Deferred cost of revenue	—	—	30
Other current assets	1	(578)	593
Accounts payable	(720)	990	116
Accrued liabilities	2,485	1,914	955
Deferred rent	648	—	—
Deferred revenue	677	999	—
Net cash provided by operating activities	<u>9,244</u>	<u>2,585</u>	<u>2,677</u>
Cash flows from investing activities:			
Acquisition of property and equipment	(854)	(589)	(280)
Proceeds from sales of marketable investments	9,133	—	—
Proceeds from maturities of marketable investments	14,310	—	—
Purchase of marketable investments, net	(82,652)	—	—
Change in restricted cash	250	(190)	40
Acquisition of intangibles	—	—	(538)
Net cash used in investing activities	<u>(59,813)</u>	<u>(779)</u>	<u>(778)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options and employee stock purchase plan	1,037	108	23
Proceeds from exercise of warrant	—	100	—
Proceeds from issuance of common stock in connection with initial public offering, net	46,312	—	—
Net cash provided by financing activities	<u>47,349</u>	<u>208</u>	<u>23</u>
Net increase in cash and cash equivalents	(3,220)	2,014	1,922
Cash and cash equivalents at beginning of year	10,290	8,276	6,354
Cash and cash equivalents at end of year	<u>\$ 7,070</u>	<u>\$ 10,290</u>	<u>\$ 8,276</u>
Supplemental disclosure of cash flow information:			
Conversion of preferred to common stock	\$ 7,372	\$ —	\$ —
Deferred stock-based compensation, net of terminations	(227)	2,591	(78)
Cash paid for taxes	\$ 2,526	\$ 2,295	\$ 997

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

CUTERA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—ORGANIZATION:

Formation and business of the Company

Cutera, Inc. (the “Company”) designs, develops, manufactures, and markets the CoolGlide, Xeo and Solera families of products for use in laser and other light-based aesthetic applications. The Company’s products enable dermatologists, plastic surgeons, gynecologists, primary care physicians, and other qualified practitioners to offer non-invasive aesthetic treatments to their patients.

Initial public offering

On April 5, 2004, the Company completed an initial public offering in which it sold 3,100,000 shares of common stock at \$14.00 per share. On April 28, 2004, the underwriters exercised the over-allotment option to purchase an additional 529,800 shares at \$14.00 per share. The Company’s initial public offering raised approximately \$46.3 million, net of underwriting discounts, commissions and other offering costs of \$4.5 million. Upon the closing of the offering, all the Company’s outstanding shares of redeemable, convertible, preferred stock converted on a one-to-one basis into 4,725,000 shares of common stock.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Basis of presentation

As of December 31, 2004, the Company has seven wholly-owned subsidiaries in France, Germany, United Kingdom, Japan, Canada, Australia and Spain. The purpose of these subsidiaries is to market and sell the Company’s products outside of the United States. The consolidated financial statements include the accounts of the subsidiaries, and all inter-company transactions and balances have been eliminated.

Use of estimates

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

Cash, cash equivalents and investments

Cash equivalents or short-term financial investments that are readily convertible to cash are stated at cost, which approximates market value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Management determines the appropriate classification of its short-term and long-term marketable investment securities at the time of purchase and reevaluates such determination as of each balance sheet date. Management has classified the Company’s marketable investments as “available-for-sale” securities in the accompanying financial statements. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in other comprehensive income. Investments held for use in current operations are classified in current assets.

Restricted cash

At December 31, 2003 cash balances of \$250,000 were restricted from withdrawal and held by a bank in the form of certificates of deposit. These certificates of deposit served as collateral against merchant accounts and a facility lease. In 2004, these restrictions were removed.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Fair value of financial instruments

Carrying amounts of the Company's financial instruments including cash and cash equivalents, marketable investments, accounts receivable, accounts payable and accrued liabilities, approximate their fair values due to their short maturities.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents, marketable investments and accounts receivable. The Company's cash and cash equivalents are primarily invested in deposits and money market accounts with one major bank in the United States. Deposits in this bank may exceed the amount of insurance provided on such deposits, if any. Management believes that this financial institution is financially sound and, accordingly, minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents. Accounts receivable are typically unsecured and are derived from revenues earned from customers primarily located in the United States. The Company performs ongoing credit evaluations of its customers and maintains reserves for potential credit losses. Historically, such losses have been within management's expectations. Concentrations of accounts receivable balances are presented in Note 3. Segment, geographic and major customer information is presented in Note 11.

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 an average maturity (interest reset date for auction-rate securities and variable rate demand notes) of generally less than eighteen months.

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

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

Inventory

Inventory is stated at the lower of cost or market, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis) and market being determined as the lower of replacement cost or net realizable value.

The Company includes demonstration units within inventory. Demonstration units are carried at cost and amortized over their estimated economic life of two years. Amortization expense related to demonstration units is recorded in cost of revenue and the operating departmental expenses of the specific function where the equipment is used. Proceeds from the sale of demonstration units are recorded as revenue.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Property and equipment

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

Intangible assets

Intangible assets are amortized using the straight-line method over their expected useful lives. Intangible assets at December 31, 2004 and 2003 principally comprised a technology license obtained as a result of the settlement of a patent litigation case. The license was acquired during the year ended December 31, 2002 at a cost of \$538,000 and with an expected useful life of ten years from the date of purchase. Amortization expense during the years ended December 31, 2004, 2003 and 2002 was \$54,000, \$54,000 and \$31,000, respectively. The license had a net carrying amount of \$399,000 and \$453,000 at December 31, 2004 and 2003, respectively. Estimated future amortization expense for each of the years ended December 31, 2005 through December 31, 2009 is \$54,000 per year.

Impairment of long-lived assets

In accordance with the provisions of Statement of Financial Accounting Standards Board (“SFAS”) No. 144, “Accounting for the Impairment or Disposal of Long-lived Assets,” the Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under SFAS No. 144, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. Through December 31, 2004, there have been no such impairments.

Revenue recognition

Product revenue, including upgrade revenue, is recognized when title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable, remaining obligations are insignificant and collectibility is reasonably assured. Transfer of title and risk of ownership generally occurs when the product is shipped to the customer or when the customer receives the product, depending on the nature of the arrangement. Revenue is recorded net of customer and distributor discounts.

The Company generally offers a warranty with its products. The Company provides for the estimated cost to repair or replace products under warranty at the time of sale. Service revenue is recognized as the services are provided and, for service contracts, on a straight-line basis over the period of the applicable service contract. Service revenue for the years ended December 31, 2004, 2003 and 2002, was \$2,414,000, \$1,617,000 and \$758,000, respectively.

Research and development expenditures

Costs related to research, design and development of products are charged to research and development expense as incurred. They primarily include employee related expenses; clinical and regulatory expenses; third party contractor fees; facilities expenses; and expensed material costs associated with research, development and testing.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Advertising costs

Advertising expenses are included in sales and marketing expenses and are expensed as incurred. Advertising expense for the years ended December 31, 2004, 2003 and 2002, were \$1,314,000, \$886,000 and 496,000, respectively.

Stock-based compensation

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

The following table illustrates the effect on net income if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation arrangements (in thousands, except per share data):

	Years Ended December 31,		
	2004	2003	2002
Net income, as reported	\$ 3,760	\$ 3,106	\$ 660
Add: Stock-based employee compensation expense included in reported net earnings, net of related tax effects	1,184	1,137	1,026
Deduct: Total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(1,823)	(1,424)	(1,998)
Pro forma net income (loss)	\$ 3,121	\$ 2,819	\$ (312)
Net income (loss) per share:			
Basic—as reported	\$ 0.38	\$ 0.46	\$ 0.10
Basic—pro forma	\$ 0.32	\$ 0.42	\$ (0.05)
Diluted—as reported	\$ 0.31	\$ 0.35	\$ 0.07
Diluted—pro forma	\$ 0.26	\$ 0.31	\$ (0.05)

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In computing these pro forma amounts, the Company has used the minimum value method for options granted prior to January 15, 2004 (the date of the first filing of the Company's Form S-1 in connection with its initial public offering) and the fair value method for options granted after this date. The following weighted average assumptions were used to measure the value of for stock options and employee stock purchase plan (ESPP) shares granted in the periods presented:

	Years Ended December 31,		
	2004	2003	2002
Risk-free interest rate for stock options	3.12%	2.10%	2.97%
Risk-free interest rate for ESPP	1.14%	— %	— %
Expected life for stock options (in years)	3.63	4.00	4.00
Expected life for ESPP option (in years)	0.57	—	—
Expected stock price volatility for stock options	69%	— %	— %
Expected stock price volatility for ESPP	55%	— %	— %
Dividend yield	—	—	—

Based on the above assumptions, the weighted-average estimated fair values of options granted for the years ended December 31, 2004, 2003 and 2002, were \$6.98, \$3.94 and \$0.48 per share, respectively, and the weighted average fair value of ESPP shares granted for the year end December 31, 2004 was \$3.34.

Income taxes

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

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity from transactions and other events and circumstances other than those resulting from investments by owners and distributions to owners. For the years ended December 31, 2004, 2003 and 2002, the Company had \$9,000, \$0, and \$0, respectively, of unrealized losses from its marketable investments.

Foreign currency

The U.S. dollar is the functional currency of the Company's subsidiaries. Monetary and non-monetary assets and liabilities are remeasured into U.S. dollars at period end and historical exchange rates, respectively. Sales and expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to non-monetary assets which are remeasured at historical exchange rates. Gains or losses resulting from foreign currency transactions are included in net income and are insignificant. The effect of exchange rate changes on cash and cash equivalents was insignificant for each of the three years presented in the period ended December 31, 2004.

Recent accounting pronouncements

In December 2004, the FASB issued FASB Statement No. 123 (Revised 2004), "*Share-Based Payment*." Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, “Accounting for Stock Issued to Employees”, which was permitted under Statement 123, as originally issued.

The revised Statement also requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements.

The Company is currently evaluating the impact of the adoption of this Statement, which must be adopted in the third quarter of the fiscal year ending on December 31, 2005.

NOTE 3—BALANCE SHEET DETAIL:

Cash, Cash Equivalents and Marketable Investments

The Company considers all highly liquid investments, with an original maturity of three months or less at the time of purchase, to be cash equivalents. Investments in debt securities are accounted for as “available-for-sale” securities, carried at fair value with unrealized gains and losses reported in other comprehensive income, held for use in current operations and classified in current assets as “Marketable Investments.” The following is a summary of cash, cash equivalents and marketable investments at December 31, 2004 (in thousands).

	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Market Value
Checking and money market funds	\$ 7,070	\$ —	\$ —	\$ 7,070
Variable rate demand notes	19,439	—	—	19,439
Auction rate securities and municipal bonds	39,770	—	(9)	39,761
	<u>\$ 66,279</u>	<u>\$ —</u>	<u>\$ (9)</u>	<u>\$66,270</u>
Reported as:				
Cash and cash equivalents	\$ 7,070	\$ —	\$ —	\$ 7,070
Marketable investments	59,209	—	(9)	59,200
	<u>\$ 66,279</u>	<u>\$ —</u>	<u>\$ (9)</u>	<u>\$66,270</u>

The maturities of our cash, cash equivalents and our marketable-investments as of December 31, 2004 are as follows (in thousands):

December 31, 2004	Amount
Due in less than one year	\$17,547
Due in 1 to 3 years	13,477
Due in 3 to 5 years	2,008
Due in 5 to 10 years	5,522
Due in greater than 10 years	27,716
Total	<u>\$66,270</u>

Securities with contractual maturities of greater than one year include one municipal bond for \$2.0 million and the remaining balance relates to either auction rate securities or variable rate demand notes. While the contractual maturities are long-term, we believe the securities are highly liquid and that the Company can take advantage of interest rate re-set periods of between one and thirty-five days to liquidate the securities. Management has the

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

ability and intent, if necessary, to liquidate these investments to fund operations within the next twelve months and accordingly has classified all investments as short-term “Marketable Investments” in the Consolidated Balance Sheets.

As of December 31, 2003, the Company did not have any marketable investments.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We determine the allowance based on historical write-off experience and any specific customer issues that we have identified. We review our allowance for doubtful accounts monthly. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers. As of December 31, 2004 and 2003, one customer accounted for 37% and 8% of the Company’s total accounts receivable balance, respectively.

Receivables consist of the following at December 31, 2004 and 2003 (amounts in thousands):

	2004	2003
Gross Trade receivables	\$7,130	\$7,904
Less: Allowance for doubtful accounts	(487)	(307)
Net Trade receivables	\$6,643	\$7,597

Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2004	2003
Raw materials	\$ 1,510	\$ 1,110
Finished goods	1,494	1,129
	\$ 3,004	\$ 2,239

Other current assets

Other current assets consist of the following (in thousands):

	December 31,	
	2004	2003
Prepaid expenses	\$292	\$361
Deferred public offering costs	—	225
Tax receivable	199	140
Deposits	194	126
Prepaid commissions	193	—
Other	—	27
	\$878	\$879

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Property and equipment, net

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2004	2003
Leasehold improvements	\$ 67	\$ 132
Office equipment and furniture	1,340	822
Machinery and equipment	1,141	676
Construction in progress	—	220
	<u>2,548</u>	<u>1,850</u>
Less: Accumulated depreciation and amortization	(1,477)	(1,116)
	<u>\$ 1,071</u>	<u>\$ 734</u>

Depreciation and amortization expense related to property and equipment was \$470,000, \$389,000 and \$351,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2004	2003
Payroll and related expenses	\$ 3,200	\$ 2,424
Warranty	1,850	1,700
Professional fees	818	158
Income tax payable	783	808
Sales & marketing accruals	723	128
Sales tax	329	211
Other	492	280
	<u>\$ 8,194</u>	<u>\$ 5,709</u>

NOTE 4—WARRANTY AND SERVICE CONTRACTS:**Warranty**

The Company has a direct field service organization in North America that provides service for its products. The Company generally provides a warranty with its products, depending on the type of product. After the warranty period, maintenance and support is provided on a service contract basis or on an individual call basis. On distributor sales, the Company provides a warranty on parts only. The Company currently provides for the estimated cost to repair or replace products under warranty at the time of sale.

Warranty reserve (in thousands):	
Balance, December 31, 2002	\$1,500
Add: Accruals for warranties issued in 2003	1,444
Less: Settlements made during the period	1,244
	<u>1,700</u>
Balance, December 31, 2003	\$1,700
Add: Accruals for warranties issued in 2004	2,112
Less: Settlements made during the period	1,962
	<u>1,850</u>
Balance, December 31, 2004	<u>\$1,850</u>

CUTERA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Service contracts

Service contract revenue is recognized on a straight-line basis over the period of the applicable service contract.

Deferred service contract revenue (in thousands):	
Balance, December 31, 2002	\$ 328
Add: Payments received	2,095
Less: Revenue recognized	1,096
	<hr/>
Balance, December 31, 2003	1,327
Add: Payments received	2,164
Less: Revenue recognized	1,585
	<hr/>
Balance, December 31, 2004	\$1,906
	<hr/>

Costs incurred under service contracts during the years ended December 31, 2004, 2003 and 2002 amounted to \$702,000, \$780,000, and \$408,000, respectively, and are recognized as incurred.

NOTE 5—COMMITMENTS AND CONTINGENCIES:**Facility lease**

The Company leases its office and manufacturing facility under a non-cancelable operating lease, which expires in 2014. In addition, the Company has leased office facilities of approximately 1,400 square feet and 3,700 square feet, in Germany and Japan, respectively. The lease in Germany expires in March 2007 and the lease in Japan expires in May 2006. The following table discloses aggregate information about the Company's contractual obligations for minimum lease payments related to facility leases and the periods in which these payments are due as of December 31, 2004 (in thousands).

<u>Years Ending December 31,</u>	
2005	\$ 685
2006	679
2007	719
2008	792
2009	990
2010 and thereafter	5,425
	<hr/>
Future minimum rental payments	\$9,290
	<hr/>

For the years ended December 31, 2004, 2003 and 2002, rent expense was \$1.2 million, \$193,000 and \$189,000, respectively.

In February 2004, we terminated our Burlingame, California facility lease and incurred a termination charge of \$250,000, which was expensed to general and administrative expense.

Sublease Agreement

On January 11, 2005, the Company entered into a sublease rental agreement to lease a portion of its facility to an unaffiliated third-party. The term of the lease is for a period of three years with monthly rental income approximating \$32,000. This sublease rental income has been excluded from the above table.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Contingencies

In February 2002, Palomar Medical Technologies (“Palomar”) filed a lawsuit against the Company in the United States District Court, District of Massachusetts. The plaintiff alleges that by making, using, selling or offering for sale the Company’s CoolGlide CV, CoolGlide Excel, CoolGlide Vantage and CoolGlide Xeo products, the Company is 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 (“MGH”) 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 the Company 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. The Company is defending the action vigorously, claiming that its products do not infringe applicable claims of the patent, and that these claims are invalid and unenforceable. Additionally, the Company has 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. The litigation is active and the parties are moving toward trial, although a trial date has not yet been set by the court. The court recently held a hearing on the Company’s summary judgment motion but has not yet issued a ruling. The outcome of this motion could accelerate the litigation’s determination. The Company believes that it has meritorious defenses of non-infringement and invalidity in this action. However, litigation is unpredictable and the Company may not prevail in successfully defending or asserting its position. If the Company does not prevail, it may be ordered to pay substantial damages for past sales and an ongoing royalty for future sales of products found to infringe. The Company could also be ordered to stop selling any products that perform laser-based hair removal. Most of our products include an application for laser-based hair removal.

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Management does not believe the final disposition of these matters will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

Legal fees in connection with loss contingencies are recognized as the fees are incurred.

NOTE 6—REDEEMABLE CONVERTIBLE PREFERRED STOCK:

On April 5, 2004, upon the closing of the initial public offering, all the Company’s outstanding shares of redeemable convertible preferred stock converted on a one-to-one basis into 4,725,000 shares of common stock.

NOTE 7—STOCKHOLDERS’ EQUITY:

Preferred Stock

On January 12, 2004, the Board of Directors approved an amendment to the Company’s amended and restated certificate of incorporation increasing the number of authorized preferred stock to 5,000,000 shares. The Company’s Board of Directors is authorized to determine the designation, powers, preferences and rights of preferred stock.

Common stock

On January 12, 2004, the Board of Directors approved an amendment to the Company’s amended and restated certificate of incorporation increasing the number of authorized common stock to 50,000,000 shares.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of the preferred stockholders.

2004 Employee Stock Purchase Plan

On January 12, 2004, the Board of Directors adopted the 2004 Employee Stock Purchase Plan. A total of 200,000 shares of common stock were reserved for issuance pursuant to the 2004 Employee Stock Purchase Plan. Under the 2004 Employee Stock Purchase Plan (“2004 ESPP”), eligible employees are permitted to purchase common stock at a discount through payroll deductions. Shares of common stock will be increased on the first day of each fiscal year, commencing in 2005, by an amount equal to the lesser of (i) 600,000 shares, (ii) 2.0% of the outstanding shares of common stock on such date or (iii) an amount as determined by the Board of Directors. Each offering period includes two six-month purchase periods. The Company added 219,144 reserved shares to the 2004 ESPP on January 1, 2005. The price of the common stock purchased shall be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The initial offering period commenced on March 31, 2004, the effective date of the Company’s initial public offering. The Company issued approximately 35,235 shares of common stock in fiscal 2004 under the ESPP. At December 31, 2004, approximately 164,765 shares remained available for future issuance.

2004 Equity Incentive Plan and 1998 Stock Plan

In 1998, the Company adopted the 1998 Stock Plan (the “1998 Plan”) under which 4,650,000 shares of the Company’s common stock have been reserved for issuance to employees, directors and consultants.

On January 12, 2004, the Board of Directors adopted the 2004 Equity Incentive Plan. A total of 1,750,000 shares of common stock were reserved for issuance pursuant to the 2004 Equity Incentive Plan. In addition, the shares reserved for issuance under the 2004 Equity Incentive Plan included shares reserved but unissued under the 1998 Plan and shares returned to the 1998 Plan as the result of termination of options or the repurchase of shares.

Shares of common stock approved under the 2004 Equity Incentive Plan will be increased on the first day of each fiscal year, commencing in 2005, by an amount equal to the lesser of: (i) 5% of the outstanding shares of the first day of such year; (b) 2 million shares; or, (c) an amount determined by our board. On January 1, 2005, the Company added 547,860 shares to the 2004 Equity Incentive Plan.

Options granted under the 1998 Plan and 2004 Equity Incentive Plan may be incentive stock options or non-statutory stock options. Stock purchase rights may also be granted under the Plan. Incentive stock options may only be granted to employees. The Board of Directors determines the period over which options become exercisable, however, except in the case of options granted to officers, directors and consultants, options shall become exercisable at a rate of no less than 20% per year over five years from the date the options are granted. Options are to be granted at an exercise price not less than the fair market value per share on the grant date for incentive options or 85% of fair market value for nonqualified stock options. For employees holding more than 10% of the voting rights of all classes of stock, the exercise price shall not be less than 110% of the fair market value per share on the grant date. Options granted under the Plan generally become exercisable 25% on the first anniversary of the vesting commencement date and an additional 1/48th of the total number of shares subject to the option shares shall become exercisable on the last day of each calendar month thereafter until all of the shares have become exercisable. Unvested options that have been exercised are subject to repurchase upon termination of the holder’s status as an employee, director or consultant. The term of the options is ten years.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Activity under the 1998 and 2004 Plans is summarized as follows:

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted-Average Exercise Price
Balances, December 31, 2001	434,552	3,170,271	\$ 1.33
Additional shares reserved	800,000	—	
Options granted	(809,732)	809,732	\$ 4.25
Options exercised	—	(123,230)	\$ 0.19
Options cancelled	200,107	(200,107)	\$ 4.33
Balances, December 31, 2002	624,927	3,656,666	\$ 1.85
Options granted	(944,500)	944,500	\$ 6.67
Options exercised	—	(266,130)	\$ 0.41
Options cancelled	543,123	(543,123)	\$ 4.02
Balances, December 31, 2003	223,550	3,791,913	\$ 2.83
Additional shares reserved	1,750,000	—	
Options granted	(699,375)	699,375	\$ 13.34
Options exercised	—	(319,643)	\$ 2.20
Options cancelled	223,217	(223,217)	\$ 9.96
Balances, December 31, 2004	1,497,392	3,948,428	\$ 4.39

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2004.

Exercise Price	Options Outstanding		Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Number Outstanding	Weighted-Average Exercise Price
\$0.10	1,451,700	4.70	1,451,700	\$ 0.10
\$0.20	11,417	5.12	11,417	\$ 0.20
\$0.50	140,896	5.55	140,896	\$ 0.50
\$0.75	27,250	6.26	26,229	\$ 0.75
\$2.50	149,506	6.44	128,650	\$ 2.50
\$3.00	55,500	6.59	48,271	\$ 3.00
\$4.25	997,117	8.06	503,143	\$ 4.25
\$4.50	101,813	6.64	83,230	\$ 4.50
\$5.50	140,000	6.73	113,750	\$ 5.50
\$6.00	63,500	8.68	20,386	\$ 6.00
\$6.50	17,750	6.78	15,042	\$ 6.50
\$7.25	3,000	6.90	1,854	\$ 7.25
\$10.00	72,500	9.81	2,188	\$ 10.00
\$13.30	236,125	9.55	0	\$ 13.30
\$13.80	277,354	9.00	86,458	\$ 13.80
\$14.00	53,000	9.29	16,000	\$ 14.00
\$14.14	150,000	9.36	0	\$ 14.14
	3,948,428	6.81	2,649,214	\$ 2.08

As of December 31, 2003, there were 2,380,428 outstanding options that were exercisable.

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock-based compensation

During the years ended December 31, 2003, and 2001, the Company issued options to certain employees and directors under the 1998 Plan with exercise prices below the estimated fair value, determined with hindsight, of the Company's common stock on the date of grant. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options and the estimated fair value of the Company's stock on the date of grant. This deferred stock-based compensation is being amortized to expense on a straight-line-basis over the period during which the Company's right to repurchase the stock lapses or the options become vested, generally four years. During the years ended December 31, 2004, 2003 and 2002, the Company recorded deferred stock-based compensation in the amount of \$0, \$3,803,000 and \$0, respectively. During the years ended December 31, 2004, 2003 and 2002, the Company reversed deferred stock-based compensation of \$227,000, \$1,212,000 and \$78,000, respectively, for unvested options cancelled in connection with employee terminations. During the years ended December 31, 2004, 2003 and 2002, the Company recorded employee stock-based compensation expense of \$1,435,000, \$1,318,000 and \$1,026,000, respectively.

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line-basis as the stock options are earned in accordance with SFAS No. 123. The Company believes that the fair values of the stock options are more reliably measurable than the fair values of the services received. The estimated fair values of the stock options granted are calculated at each reporting date using the Black-Scholes option pricing model, as prescribed by SFAS No. 123, using the following weighted-average assumptions:

	Years Ended December 31,		
	2004	2003	2002
Risk-free interest rate	—%	4.19%	4.59%
Contractual life (in years)	—	10	10
Dividend yield	—	—	—
Expected volatility	—%	80%	80%

The stock-based compensation expense related to non-employees will fluctuate as the deemed fair market value of the common stock fluctuates as the options are earned. In connection with the grants of stock options to non-employees during the years ended December 31, 2004, 2003 and 2002, the Company recorded stock-based compensation expense of \$0, \$106,000 and \$171,000, respectively.

NOTE 8—INCOME TAXES:

The U.S. and international components of the provision for income taxes are as follows (in thousands):

	December 31,		
	2004	2003	2002
Current:			
Federal	\$2,123	\$2,413	\$ 990
State	309	214	69
Foreign	69	48	6
	<u>2,501</u>	<u>2,675</u>	<u>1,065</u>
Deferred:			
Federal	(410)	(606)	(210)
State	(34)	19	(100)
Foreign	(32)	—	—
	<u>(476)</u>	<u>(587)</u>	<u>(310)</u>
Total provision for income taxes	<u>\$2,025</u>	<u>\$2,088</u>	<u>\$ 755</u>

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company's deferred tax asset consists of the following (in thousands):

	December 31,	
	2004	2003
Capitalized start-up costs	\$ 3	\$ 13
Accrued warranty	704	656
Other Accruals and reserves	926	659
Stock-based compensation	619	384
Depreciation and amortization	—	44
Foreign	32	—
Deferred tax asset	2,284	1,756
Depreciation and amortization	(52)	—
Net deferred tax asset	\$2,232	\$1,756

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

	Years Ended December 31,		
	2004	2003	2002
Tax at federal statutory rate	34.00%	34.00%	34.00%
State, net of federal benefit	4.07	4.58	4.34
Meals and entertainment	0.89	0.67	2.45
Benefit for research and development credit	(3.71)	(4.62)	(25.62)
Stock-based compensation	1.67	5.92	41.03
Tax-exempt interest	(3.37)	—	—
Other	1.45	(0.35)	(2.85)
Provision for taxes	35.00%	40.20%	53.35%

Management evaluates on a periodic basis the recoverability of deferred tax assets and the need for a valuation allowance.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$227,000 at December 31, 2004, 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.

NOTE 9—NET INCOME PER SHARE:

The Company adopted Emerging Issues Task Force Statement No. 03-06 "Participating Securities and the Two Class Method Under FASB Statement No. 128, Earnings Per Share" during the period ended June 30, 2004 and has retroactively adjusted reported earnings per share for the two years ended December 31, 2003.

Basic net income per share is computed by dividing net income available to the common stockholders by the weighted-average number of common shares outstanding during the period.

Diluted net income per share is computed by giving effect to all dilutive potential common shares, including options, common stock subject to repurchase, warrants and redeemable convertible preferred stock. A

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

reconciliation of the numerator and denominator used in the calculation of basic and diluted net income per share follows (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Numerator:			
Net income	\$ 3,760	\$ 3,106	\$ 660
Less Amount allocated to participating preferred stockholders:	(476)	(2,143)	(476)
Net income available to common stockholders—Basic	3,284	963	184
Net income available to common stockholders—Diluted	3,760	3,106	660
Denominator:			
Weighted-average number of common shares outstanding used in computing basic net income per share	8,573	2,106	1,810
Dilutive potential common shares used in computing diluted net income per share	3,649	6,729	7,001
Total weighted-average number of shares used in computing diluted net income per share	12,222	8,835	8,811

Anti-dilutive securities

The following outstanding options (prior to the application to the treasury stock method) were excluded from the computation of diluted net income per common share for the periods presented because including them would have had an antidilutive effect (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Options to purchase common stock	566	210	—

NOTE 10—EMPLOYEE BENEFIT PLAN:

In April 1999, the Company adopted a defined contribution retirement plan (the “plan”), which qualifies under Section 401(k) of the Internal Revenue Code. The plan covers all employees. Eligible employees may make voluntary contributions to the plan up to 100% of their annual compensation, subject to statutory annual limitations. In addition, the Company is allowed to make discretionary contributions. During the years ended December 31, 2004 and 2003, and 2002, the Company made contributions of \$227,000, \$174,000, and \$160,000, respectively, under the plan.

NOTE 11—SEGMENT, GEOGRAPHIC AND MAJOR CUSTOMER INFORMATION:

The Company operates in one business segment, which encompasses the designing, developing, manufacturing, marketing and servicing of aesthetic laser systems for dermatologists, plastic surgeons, gynecologists, primary care physicians and other practitioners worldwide. Management uses one measurement of profitability and does not segregate its business for internal reporting.

The Company’s long-lived assets maintained outside the United States are insignificant.

Revenue is attributed to geographical regions based on the shipping location of the external customers.

CUTERA, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

For the years ended December 31, 2004, 2003 and 2002, the Company had one customer that represented 12%, 2% and 0%, respectively, of net revenue.

The following table summarizes revenue by geographic region (in thousands):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Revenue:			
United States	34,826	30,102	22,944
Japan	7,460	1,779	594
Rest of the world	10,355	7,207	4,789
	<u> </u>	<u> </u>	<u> </u>
Consolidated total	52,641	39,088	28,327
	<u> </u>	<u> </u>	<u> </u>

SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)
(In thousands, except per-share amounts)

Quarters ended	Dec 31, 2004	Sept 30, 2004	June 30, 2004	March 31, 2004	Dec 31, 2003	Sept 30, 2003	June 30, 2003	March 31, 2003
Net revenue	\$ 16,094	\$ 12,703	\$ 12,265	\$ 11,580	\$ 12,449	\$ 11,025	\$ 9,018	\$ 6,596
Cost of revenue (1)	4,235	3,408	3,400	3,647	3,711	3,613	2,760	2,233
Gross profit	\$ 11,859	\$ 9,295	\$ 8,865	\$ 7,933	\$ 8,738	\$ 7,412	\$ 6,258	\$ 4,363
Operating expenses								
Sales and marketing	5,473	4,677	4,623	4,279	4,300	3,573	3,049	2,489
Research and development	1,150	979	1,047	959	922	740	683	751
General and administrative	2,195	2,171	1,909	2,069	846	809	1,179	1,082
Amortization of stock-based compensation (2)	313	317	316	321	374	437	196	178
Total operating expense	\$ 9,131	\$ 8,144	\$ 7,895	\$ 7,628	\$ 6,442	\$ 5,559	\$ 5,107	\$ 4,500
Income from operations	\$ 2,728	\$ 1,151	\$ 970	\$ 305	\$ 2,296	\$ 1,853	\$ 1,151	\$ (137)
Interest and other income, net	\$ 378	\$ 198	\$ (2)	\$ 58	\$ 2	\$ (2)	\$ 12	\$ 18
Income before income taxes	3,106	1,349	968	363	2,298	1,851	1,163	(119)
Provision for income taxes	\$ (1,034)	\$ (472)	\$ (377)	\$ (142)	\$ (913)	\$ (754)	\$ (468)	\$ 47
Net income	\$ 2,072	\$ 877	\$ 591	\$ 221	\$ 1,385	\$ 1,097	\$ 695	\$ (72)
Net income available to common stockholders used in basic earnings per share:	\$ 2,072	\$ 877	\$ 576	\$ 72	\$ 441	\$ 345	\$ 213	\$ (22)
Net income per share—basic	\$ 0.19	\$ 0.08	\$ 0.06	\$ 0.03	\$ 0.20	\$ 0.16	\$ 0.10	\$ (0.01)
Net income per share—diluted	\$ 0.16	\$ 0.07	\$ 0.05	\$ 0.02	\$ 0.15	\$ 0.12	\$ 0.08	\$ (0.01)
Weight-average number of shares used in per share calculations:								
Basic	10,867	10,729	10,289	2,292	2,204	2,145	2,071	2,000
Diluted	13,167	13,085	12,960	9,411	9,025	8,862	8,799	2,000
Cash, cash equivalents and marketable investments	\$ 66,270	\$ 61,962	\$ 58,992	\$ 11,228	\$ 10,540	\$ 9,102	\$ 8,546	\$ 6,810
(1) Includes amortization of stock-based compensation of:	39	39	39	51	51	101	46	42
(2) Amortization of stock-based compensation is attributable to the following operating expense categories:								
Sales and marketing	63	63	64	83	149	159	45	28
Research and development	104	105	105	99	94	112	73	72
General and administrative	146	149	147	139	131	166	78	78
	313	317	316	321	374	437	196	178
Total amortization of stock-based compensation	352	356	355	372	425	538	242	220

SCHEDULE II
CUTERA, INC.
VALUATION AND QUALIFYING ACCOUNTS
(in thousands)
For the years ended December 31, 2004, 2003 and 2002

	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
Allowance for doubtful accounts receivable				
Year ended December 31, 2002	\$ 81	\$ 141	\$ 82	\$ 140
Year ended December 31, 2003	\$ 140	\$ 333	\$ 166	\$ 307
Year ended December 31, 2004	\$ 307	\$ 293	\$ 113	\$ 487
Reserve for excess and obsolete inventory				
Year ended December 31, 2002	\$ 54	\$ 993	\$ 923	\$ 124
Year ended December 31, 2003	\$ 124	\$ 139	\$ 85	\$ 178
Year ended December 31, 2004	\$ 178	\$ 300	\$ 100	\$ 378



CUTERA

NUMBER
ZQ

SHARES

CUSIP 232109 10 8

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SEE REVERSE FOR CERTAIN DEFINITIONS

SPECIMEN

IS THE OWNER OF

FULLY PAID AND NONASSESSABLE SHARES OF COMMON STOCK, \$.001 PAR VALUE PER SHARE, OF
CUTERA, INC.

transferable only on the books of the Corporation by the holder hereof in person or by duly authorized Attorney upon surrender of this certificate properly endorsed. This certificate is not valid until countersigned by the Transfer Agent and Registrar.
WITNESS the facsimile signatures of its duly authorized officers.

Dated:

Paul J. Smith
CHIEF FINANCIAL OFFICER AND TREASURER



Kevin P. Long
PRESIDENT AND CHIEF EXECUTIVE OFFICER

COUNTERSIGNED:
COMFRESHARE TRUST COMPANY, INC.
P.O. BOX 1596, DENVER, COLORADO 80201

By _____
Transfer Agent and Registrar - Authorized Signature

1154

SECURITY NUMBER 0017 08

CUTERA, INC.

THE CORPORATION WILL FURNISH WITHOUT CHARGE TO EACH STOCKHOLDER WHO SO REQUESTS THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OR SERIES THEREOF AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND/OR RIGHTS. SUCH REQUEST MUST BE MADE TO THE CORPORATION'S SECRETARY AT THE PRINCIPAL EXECUTIVE OFFICE OF THE CORPORATION.

Keep this Certificate in a safe place. If it is lost, stolen or destroyed, the Corporation will require a bond of indemnity as a condition to the issuance of a replacement certificate.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common
TEN ENT - as tenants by the entireties
JT TEN - as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT-

_____ Custodian _____
(Cust) (Minor)

under Uniform Gifts to Minors

Act _____
- (State)

UNIF TRF MIN ACT-

_____ Custodian (until age _____)
(Cust)

_____ under Uniform Transfers
(Minor)

to Minors Act _____
(State)

Additional abbreviations may also be used though not in the above list.

For Value Received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY NUMBER OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE OF ASSIGNEE(S))

Shares represented by the within Certificate, and do hereby irrevocably constitute and

appoint _____ Attorney
to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

In presence of _____
NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____
THE SIGNATURES MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM) PURSUANT TO S.E.C. RULE 17Ad-15.

AMENDMENT NO. 6 TO SALES AGENT AGREEMENT

This Amendment No. 6 To Sales Agent Agreement (“Amendment No. 6”) is made this 10th day of November, 2004, between Cutera Inc. (formerly Altus Medical, Inc.) (“Cutera”) and PSS World Medical, Inc. (“PSS”).

WHEREAS, Cutera and PSS entered into that February 14, 2003 Sales Agent Agreement, that March 17, 2003 Amendment No. 1 To Sales Agent Agreement, that November 6, 2003 Amendment No. 2 To Sales Agent Agreement, that May 3, 2004 Amendment No. 3 To Sales Agent Agreement, that June 18, 2004 Amendment No. 4 to Sales Agent Agreement and that September 21, 2004 Amendment No. 5 to Sales Agent Agreement (collectively, “Agreement”), and are hereby amending the Agreement as follows:

1. The first sentence of Section 1.4 is hereby deleted and replaced with the following:

“1.4 **Products** means Cutera’s CoolGlide CV-, CoolGlide Excel-, CoolGlide Vantage-, CoolGlide Genesis Plus- (a/k/a CoolGlide Xeo Rejuvenation-), CoolGlide Xeo-, CoolGlide Xeo Limited-, Xeo SA-, Omnilux- and Titan Tabletop systems, and related Product Upgrades.”

2. Exhibit A is hereby deleted and replaced with the following:

“Product Pricing”

For Products sold to PSS through March 31, 2005, the unit pricing will be as set forth below. The pricing for Products sold after March 31, 2005 will be negotiated by the parties in good faith at least two months before that date. All Product pricing information will be deemed Cutera’s Confidential Information.

<u>Products</u>	<u>Unit Price</u>
CoolGlide CV	\$ [****]
Xeo SA – w/ LP560 or OPS600	\$ [****]
Xeo SA – w/ Titan	\$ [****]
Xeo SA – w/ Titan, plus LP560 or OPS600	\$ [****]
CoolGlide Excel	\$ [****]
CoolGlide Genesis Plus (CoolGlide Xeo Rejuv.)	\$ [****]
CoolGlide Vantage	\$ [****]
CoolGlide Xeo Limited	\$ [****]
CoolGlide Xeo – w/ LP560 or OPS600	\$ [****]
CoolGlide Xeo – w/ Titan, plus LP560 or OPS600	\$ [****]
Omnilux (double-headed unit)	\$ [****]
Titan Tabletop	\$ [****]
 <u>Upgrades</u>	 <u>Unit Price</u>
CV -> Excel	\$ [****]
CV -> Vantage	\$ [****]
Excel -> Vantage	\$ [****]
Genesis -> Vantage	\$ [****]
CV -> Xeo	\$ [****]
Excel -> Xeo	\$ [****]
Genesis Plus -> Xeo	\$ [****]
Vantage to Xeo	\$ [****]
Xeo add LP-560 or OPS-600	\$ [****]
Xeo add Titan	\$ [****]

2. The capitalized terms that are used, but not defined, in this Amendment No. 6 shall have the same definitions provided in the Agreement. Except as expressly stated in this Amendment No. 6, the Agreement shall remain unmodified and in full force and effect.

Cutera, Inc.

PSS World Medical, Inc.

By: /s/ Ronald J. Santilli

By: /s/ Robert P. Gibson

Printed: Ronald J. Santilli

Printed: Robert P. Gibson II

Its: V.P. and CFO

Its: V.P. Marketing

**** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-114149 and No. 333-123495) of Cutera, Inc. of our report dated March 21, 2005 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 21, 2005

**Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Kevin P. Connors, certify that:

1. I have reviewed this annual report on Form 10-K of Cutera, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's Registered Public Accounting Firm and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2005

/s/ KEVIN P. CONNORS

Kevin P. Connors
President, Chief Executive Officer and Director
(Principal Executive Officer)

**Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Ronald J. Santilli, certify that:

1. I have reviewed this annual report on Form 10-K of Cutera, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's Registered Public Accounting Firm and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2005

/s/ RONALD J. SANTILLI

Ronald J. Santilli
Chief Financial Officer and Vice President of Finance and Administration
(Principal Financial and Accounting Officer)

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kevin P. Connors, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Cutera Inc. on Form 10-K for the fiscal year ended December 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Cutera Inc.

Date: March 25, 2005

By: /s/ Kevin P. Connors
Kevin P. Connors
President, Chief Executive Officer and Director
(Principal Executive Officer)

I, Ronald J. Santilli, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Cutera Inc. on Form 10-K for the fiscal year ended December 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Cutera Inc.

Date: March 25, 2005

By: /s/ Ronald J. Santilli
Ronald J. Santilli
Chief Financial Officer and Vice President of Finance and
Administration
(Principal Accounting and Financial Officer)